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Clinical evaluation of lithium disilicate versus indirect resin composite partial posterior restorations – A 7.8-year retrospective study

Edina Lempel[a,*,1], Sarolta Gyulai[a,b], Bálint Viktor Lovász[c], Sára Jeges[d], József Szalma[b]

[a] Department of Restorative Dentistry and Periodontology, University of Pécs Medical School, Tüzér Street 1, Pécs 7623, Hungary
[b] Department of Oral and Maxillofacial Surgery, University of Pécs Medical School, Tüzér Street 1, Pécs 7623, Hungary
[c] Oral and Maxillofacial Department, Manchester University Foundation Trust, Manchester Royal Infirmary Hospital, Oxford Rd, Manchester M13 9WL, United Kingdom
[d] Faculty of Health Sciences, University of Pécs, Vörösmarty M. Street 4, Pécs 7621, Hungary

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ABSTRACT

Objective: To evaluate retrospectively the longevity of lithium disilicate ceramic (LidiSi) vs. laboratory-processed resin-based composite (RBC) inlay/onlay/overlay restorations and risk factors associated with restoration deficiencies and failures.

Methods: Patients (n = 91) receiving LidiSi (73.1%) and RBC (36.9%) inlays/onlays/overlays between 2007 and 2017 were selected. The restorations were evaluated using the modified U.S. Public Health Service criteria. The survival of the restorations was analyzed using the Kaplan-Meier method and log rank test. Factors affecting the occurrence of deficiencies were examined by logistic regression analysis. This was performed with the use of the Generalized Estimating Equation model including Repeated measurements (GEER), with the consideration that the same patient had several teeth in the sample. Risk estimation was conducted for each evaluated criterion ($p < 0.05$).

Results: The survival of LidiSi and RBC restorations were 96.8% and 84.9%, respectively after a mean observation period of 7.8 ± 3.3 years. The annual failure rate was 0.2% for LidiSi and 1.0% for RBC. The probability of survival was above 98% for both restorations in the first 6 years, however, it dropped to 60% for RBC by the end of the 15th year. For both materials the reasons for failure included secondary caries, restoration fracture, and endodontic complication. In addition, LidiSi also failed due to tooth fracture, while RBC due to marginal gap formation and loss of retention. Among the evaluated risk factors, material of restoration (OR = 6.8, $CI_{95\%}$:3.1–14.9), oral hygiene (OR = 8.0, $CI_{95\%}$: 2.9–22.1], and bruxism (OR = 1.9, $CI_{95\%}$: 1.1–3.3) showed a significant impact on the evaluated criteria.

Significance: LidiSi and RBC restorations showed similarly excellent 6-year survival, however, in the long term significantly more failures should be expected for RBCs.

1. Introduction

Direct resin-based composite (RBC) fillings are used successfully as restorative methods in the posterior region with a high survival rate [1–4]. Restoration survival or longevity is influenced by a variety of factors including the condition of the supporting tooth, patient habits or clinical protocols, and the properties of the restorative material used [5]. As an alternative to direct fillings, partial indirect restorations may provide more control over anatomical form and reinforcement of a tooth compromised by fracture or caries, especially in the case of larger defects in posterior teeth [6]. Due to the increasing aesthetic demands, these indirect restorations are mostly made of ceramics and RBCs. Since these two materials differ in composition, their properties result in distinctive biomechanical behaviors. The ceramics for single partial restorations are mainly composed of glass reinforced by crystals to increase the strength, while RBC restorations are made of a resin matrix reinforced by filler particles [7,8].

Glass matrix ceramics with refined crystal size and a leucite content of approximately 70 vol% were developed to improve flexural strength, wear, thermal shock and corrosion resistance [9]. Enhanced crack bridging in these lithium disilicate ceramics (LidiSi) were evidenced by several tortuous crack paths at the microstructural scale, resulting in

* Corresponding author.
E-mail address: lempel.edina@pte.hu (E. Lempel).
1 orcid.org/0000-0002-9839-0515

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large deflections [10]. Furthermore, improved esthetics of LidiSi is a result of the high translucency even with the high crystalline content due to the relatively low refractive index of the lithium disilicate crystals [7]. In addition to the equally good aesthetic appearance, indirect RBCs have been proven to increase the fracture resistance of teeth [11]. In contrary, based on the results of a 3-D finite element analysis, LidiSi inlay and onlay material tested transferred less stress to the tooth structures than the RBC [12]. While the wear resistance of ceramics proved to be better than that of the RBC [13], Regarding fatigue strength, it was found that RBC restorations may be used as an equivalent alternative to glass-rich-ceramic inlays [14].

Although there are a few in vitro tests that seem to have limited correlation with the short-term clinical performance of ceramics and RBC indirect restorations [15,16], there are no methods which can reliably predict the long-term clinical performance [17] despite the invested energy into laboratory studies. Clinical studies, which have evaluated LidiSi or RBC indirect partial restorations separately, found good clinical short- and long-term performance with slightly different success rate in favor to ceramics [18–26]. Only a few, short-term comparative clinical reports are available in the literature and most of them for CAD/CAM fabricated ceramics and RBC inlays [25,26]. The success rate of RBC and ceramics restorations ranged from 85.7% to 100% and 93.3–100%, respectively [27]. The results showed caries to be the main biological complication, followed by a root and/or tooth fracture incidence and endodontic failure. Restoration fracture represented the most common technical complication, followed by loss of retention and chipping [28]. There are also systematic reviews and meta-analyses available to provide more information regarding the performance of RBC indirect restorations compared to ceramics inlays/onlays, as well as to identify the types of complications associated with the main clinical outcomes [29–31]. However, due to incomplete data in the literature, most of the systematic reviews on the clinical survival of ceramics and RBC indirect partial restorations were inconclusive as it was not feasible to conduct a meta-analysis based on the selected samples [29,30]. A number of these studies stated that ceramics partial coverage restorations outperformed RBC partial coverage restorations both at 5-year and 10-year follow-ups [29], while medium-quality data of a meta-analysis indicated that LidiSi and indirect composite materials demonstrate comparable survival rates in short-term follow-up [32]. The survival rate decreases over time with the use of RBC as restorative material [31]. Others concluded, that the survival rate of indirect restorations remained high, irrespective of the follow-up time and regardless of the material, study design, and study setting [30].

Although inlays/onlays/overlays are often used as less invasive restoration methods compared to crowns, systematic reviews agreed that the literature is incomplete regarding the long-term survival and clinical evidence for the justification of RBC compared to ceramics partial restorations [30]. More clinical information is necessary regarding the most optimal material to be use for onlays on endodontically treated teeth [33,34]. Moreover, the prognostic factors that influence the choice of material have never been confirmed.

Thus, the purpose of this retrospective clinical trial was to compare the long-term survival and clinical performance of heat-pressed lithium disilicate ceramic and inhomogen microfilled laboratory-processed RBC indirect partial restorations of posterior teeth up to 15 years. Further aim was to investigate the reasons for failures or deteriorations and to clarify the patient, tooth and restoration related risk factors thought to be associated with failure. The null-hypothesis was two-fold; (1) there is no difference in long-term survival of ceramic and RBC indirect restorations, and that (2) there is no significant influence of the risk factors on the restoration's survival.

2. Materials and methods

This retrospective longitudinal study was designed as a comparative evaluation of LidiSi and RBC indirect partial restorations performed in posterior teeth. The study protocol was approved by the Regional Research Ethics Committee of University of Pécs (3410.1/PTE/2009). The study has been carried out in accordance with the Declaration of Helsinki principled.

2.1. Patients' selection

For this retrospective study, 145 adult patients with indirect LidiSi or RBC Class II inlays/onlays/overlays were selected from the registers of a Hungarian clinical practice (University of Pécs). The involved restorations were placed between August of 2007 and August of 2017, ensuring a minimum of 5 and a maximum of 15 years observation period. The selected patients were contacted by mail or telephone. Follow-up was scheduled (August-November 2022) for 118 patients who were available and agreed to participate in the clinical trial. The patients gave their written informed consent before starting the clinical evaluation. A data collection form was used to record all information which was obtained from the written patients' records along with the findings of the clinical and radiographic examinations.

Patients evaluated in the study had at least one LidiSi or indirect RBC Class II inlay, onlay or overlay. The following inclusion criteria had to be met in order for a patient to be included in the clinical trial: patients who can consent for themselves (over the age of 18) are in good general and dental health; the selected teeth need to be in occlusal function with a natural tooth and in interproximal contact with two adjacent teeth, the cavo-surface margin of the dental preparation is in enamel; the restorations are made by the same operator. These patients had remained in continuous clinical follow-up for the last 5–15 years, attending regular check-ups at least every two years without visiting other dentists. Indirect restorations placed for cracked teeth, table top overlays without intracoronal defect, and restorations with deep margin elevation were excluded from the study.

2.2. Restorative procedure

2.2.1. Indications of indirect restorations

Decision making was strongly influenced by cavity factors, including residual cusp wall thickness (interaxial dentin), the presence and thicknesses of proximal ridges, the depth of the cavity together with the presence or absence of the roof of the pulp chamber according to the following:

Class II, two- or three-surface inlays were indicated: as replacement for amalgam or old RBC fillings where buccal and lingual walls remained intact with more than 2.5 mm thickness; after removal of caries where buccal and lingual walls remained intact with more than 2.5 mm thickness but with excessive isthmus width; for multiple medium-sized cavities in the same quadrant; or as an alternative of medium-sized direct resin composite restorations to overcome their limitations. Onlays were indicated: when the cusp's thickness was less than 2.0 mm with less than 4.0 mm cusp's height or less than 2.5 mm with more than 4 mm cusp's height; when there was presence of signs (cracks, wide attrition facets) indicating traumatic overload on the relatively thick cusp delimiting the cavity; for root canal treated teeth with one missing marginal ridge where the other ridge was intact with a minimum 2 cusps of more than 2.5 mm thickness each. Overlays were indicated: in root canal treated teeth with MOD cavities or less than 2 mm thick axial walls; if intracoronal restoration was indicated with the need of an additional increase in vertical occlusal dimension (VDO). The assessment of cusp thicknesses was performed by measuring the base of cusp with a double-sided caliper (Keystone, Singen, Germany).

2.2.2. Material selection

Heat-pressed lithium disilicate glass-ceramic (IPS e-max Press, Ivoclar Vivadent, Schaan, Liechtenstein) and inhomogen microfilled light-curing laboratory RBC (SR Nexco Paste, Ivoclar Vivadent, Schaan, Liechtenstein; matrix composition: aromatic and aliphatic urethane dimethacrylate, aliphatic dimethacrylates; fillers: 19.8% highly dispersed microfilled silicon dioxide and 62.9% microfilled prepolymer) were used as alternatives to each other in decision-making. Usually, the first choice wasLidiSi, but in case of financial limitations RBC restoration were fabricated instead. Furthermore, LidiSi was the choice of restoration to restore upper teeth in case of complex oral rehabilitations to improve the esthetic appearance homogenously in harmony with the frontal ceramic veneers. RBC was used in such cases for the lower teeth to decrease discomfort, which may arise from ceramic-to-ceramic articulation. Oral rehabilitation was necessary in those complex cases of bruxism where erosion/attrition induced loss of tooth structure.

2.2.3. Cavity preparation and cementation

Primary caries or existing/failed restorations were removed. Decision was made regarding cusp reduction as described above. Generally, a minimum of 1.5–2 mm of pulpal floor depth, 1.5–2 mm of isthmus width, and 1.5–2 mm of axial cusp reduction (if it was necessary) was defined as minimally adequate preparation dimensions. Occlusally tapered cavity design was achieved by a 10° of axial wall convergence. Internal line and point angles were rounded. Butt-joint cavosurface angles of 90° were prepared. The entire preparation had smooth-flowing margins to facilitate the fabrication of the restoration. There was at a least 1 mm distance between the proximal cavity margins and adjacent tooth in order to allow good flow of the impression material to facilitate accurate gypsum cast fabrication. A ceramic bulk thickness of min. 1.5–2 mm was applied in areas of potential contact from opposing teeth. In some cases, to provide internal tapered design with the preservation of remaining sound tooth structure a block-out was maintained or the pulp chamber in endodontically treated teeth was closed by the application of an RBC base (Filtek Z250, shade UD or Filtek Supreme/Ultimate Flow shade A2 or A3, 3 M ESPE, St. Paul, MN, USA). No basing or lining with conventional cement was applied. The prepared surfaces were finished and polished with red diamond bur (60 and 40 μm grit), followed by rubber points (Shofu composite polishing kit, Shofu, Kyoto, Japan). Gingival retraction cord (UltraPak, Ultradent, South Jordan, UT, USA) was placed in the sulcus when it was necessary to retract gum tissues for the purpose of impression taking. Upper two-stage and lower one-stage sandwich vinyl polysiloxane impressions (Variotime Easy Putty and Light Flow, Kulzer, Hanau, Germany) were taken. This was followed by wax bite registration recorded in maximum intercuspation. Tooth shade was chosen using the Vita Classic guide (VITA, Bad Säckingen, Germany). Bis-acryl provisional restorations (Protemp 3 and 4, shade A2 or A3, 3 M ESPE, St. Paul, MN, USA) were made with the help of pre-operative impressions and luted with a eugenol-free temporary cement (RelyX Temp NE, 3 M ESPE, St. Paul, MN, USA).

LidiSi and RBC indirect restorations were manufactured by the same dental technician following the manufacturer’s instructions.

The definitive cementation of all restorations was carried out within a maximum of 2 weeks following impression taking. The operative field was isolated with a rubber dam and the prepared teeth were cleaned with prophylaxis brush and fluoride-free prophy paste (Depural Neo, Pentron, Orange, CA, USA). Before cementation the restoration was checked on the gypsum cast and tried in the mouth to examine the fit. To achieve durable bond strength, the internal surfaces of the cleaned LidiSi restorations were etched with 9.5% hydrofluoric acid (Porcelain Etch, Ultradent, South Jordan, UT, USA) for 20 s, followed by a one-minute washing, drying, and silane (Silane, Ultradent, South Jordan, UT, USA) application which was left to dry at least for one minute [35]. The surface treatment of indirect RBC restorations was performed in the laboratory by sandblasting with 50 μm aluminium-oxide for 10 s

Total-etch adhesive procedure was undertaken on the isolated teeth by conditioning the margins and cavity walls with 37% phosphoric acid (3 M ESPE, St. Paul, MN, USA) for 20 s. After 20 s rinsing the cavity was carefully dried with air (wet bonding technique) and a two-step etch-and-rinse enamel-dentin adhesive system (Adper Single Bond, 3 M ESPE, St. Paul, MN, USA) was applied for 15–20 s. This was followed by air-drying (10–15 s) to evaporate the solvent. Excessive material was removed by the vacuum of the high-volume evacuator’s tip. A clean microbrush was used to remove the collected excess at the line angles if the air-stream and the evacuator’s effect had to be completed. The adhesive was cured with a LED curing unit (1100–1200 mW/cm^2 light intensity, 400–500 nm wavelength) (Elipar Freelight, 3 M ESPE, St. Paul, MN, USA or Woodpecker LED C, Guilin, China) for 20 s

A dual-curable adhesive resin cement (NX3 Nexus Third Generation, Kerr, Bioggio, Switzerland) was applied in the cavities, and the indirect restoration was then gently seated with finger pressure and a blunt-ended hand instrument. Excess cement was removed with a micro- and a thin modelling brush. The above-mentioned LED curing unit was used to polymerize the cement for 4 × 20 s from labial, mesial, distal and incisal aspects with 5 s break to avoid heat damage of the pulp in cases of vital teeth. After removal of excess, already set cement with a No.12 surgical scalpel, marginal areas were then polished with rubber points (Shofu composite polishing kit, Shofu, Kyoto, Japan). Proximal overhangs were removed with polishing strips (Metal Strips, GC Europe, Leuven, Belgium and Sof-Lex, 3 M ESPE, St. Paul, MN, USA). Restorations were checked and corrected for any occlusal interference.

2.3. Evaluation of restorations

The indirect partial restorations were evaluated by two examiners in accordance with the modified United States Public Health Service (USPHS) criteria. The examiners were trained and calibrated before the evaluation. Observer agreement was calculated using Cohen’s kappa test. Dental mirror and probe was used to examine the restorations. The tightness of proximal contacts was checked with the help of a dental floss and proximal margins were examined with a Gottlieb probe. Sensibility of vital teeth was tested 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 taken in cases of root canal treated teeth and when the clinical examination or complaints justified the radiographic evaluation [36]. The data to be evaluated were obtained from the dental history of the restorations involving annual periapical/interproximal radiographic images and from the information collected during the clinical assessment. The dental records were used to obtain the date and the reason for placement and failure. Re-interventions such as replacement or repair were considered as failures.

The evaluation was performed according to the modified USPHS guideline [37,38], which included the following characteristics: marginal integrity, marginal stain, color mismatch, surface roughness, anatomical form, proximal contact, restoration fracture, tooth fracture, secondary caries, loss of retention, endodontic failure.

The characteristics were assessed according to the following criteria: Alpha (A) – restoration without changes or clinical remarks; Bravo (B) – restoration with small changes that are clinically acceptable without need for replacement; Charlie (C) – restoration with major changes that are clinically unacceptable and require the replacement of the restoration. All restorations given a Charlie rating during the evaluation were regarded as failed.

Independent variables which were either patient, tooth or restoration related were recorded as risk factors influencing the survival of the restoration. The recorded patient-related factors included oral hygiene (based on the amount of plaque: satisfactory vs. unsatisfactory) and signs of bruxism related occlusal stress (‘probable’ sleep or awake bruxism was established from the pre-assessment questionnaire and clinical examination findings such as tooth wear with remarkable attrition facets, chipping or abfraction, teeth mobility, hypersensitivity, masticatory muscle hypertrophy or discomfort, clicking of the temporomandibular joint and tongue or cheek indentation). Recorded tooth-related risk factors included tooth type (premolar vs. molar), tooth location (upper vs. lower), and status (vital vs. endodontically treated teeth); examined restoration-related factors were material of restoration

(LidiSi vs. RBC), extension of restoration (inlay vs. onlay/overlay), and age of filling (< 10 years vs. ≥10 years).

2.4. Statistical analysis

The data collection and the statistical analyses were performed with SPSS (Version 28.0; IBM, Armonk, NY, USA).

Binary logistic regression analysis was used to compare the characteristics of the restorations against the material type of the restoration. Given that the sample included several teeth of the same patient this was performed with the Generalized Estimating Equations including Repeated measurements module (GEER). Because of the cluster-effect due to multiple restorations in some individuals it was necessary to include the potential "dependency" by assuming that it is the result of a latent patient level random effect or shared frailty. Similarly, a binary logistic regression model (GEER) was also used to assess the influence of risk factors on the incidence of failures and deficiencies. A multivariate analysis performed using GEER was used to compare the occurrence of failures and acceptable defects between groups, and estimate the influence of the restoration's material on the evaluated criteria. The effect of material type on the presence of deficiencies and failures was controlled against other factors that may also influence the outcome. The survival function of LidiSi and RBC restorations was plotted against the calculated date of failure over a maximum of 15 years of service using Kaplan–Meier analysis. This was followed by a log-rank test to determine whether significant differences existed for the survival outcomes of the investigated groups.

P values less than 5% were considered to be statistically significant in all applied tests.

3. Results

Both intra- (kappa value 0.77 and 0.79) and inter-observer's (kappa value, 0.82) agreement was found to be excellent during the clinical evaluation.

According to the inclusion and exclusion criteria 91 adult patients' inlays/onlays/overlays (125 LidiSi, and 73 RBC) were finally evaluated after a mean observation period of 7.8 ± 3.3 years. After the application of the inclusion and exclusion criteria the recall rate was 81.0% (118 patients out of 145) and the drop-out rate was 33.0%. In total 18 (19.8%) males with 63 (31.8%) teeth and 73 (80.2%) females with 135 (68.2%) teeth were included in the sample. The characteristics of the evaluated teeth according to the restoration types (LidiSi restorations vs. RBC restorations) and the statistical significance of the differences are presented in Table 1, taking into account the possible correlation between the properties of the teeth belonging to the same patient.

The overall survival during the registration period was 92.4% (96.8% in case of LidiSi and 84.9% in case of RBCs). 15 restorations out of 198 were determined to be unacceptable, thus the total failure rate was 7.6%. The failure rate of LidiSi restorations was 3.2%, while that of RBC restorations was 15.1%. The total annual failure rate (AFR) was 0.5%. The annual failure rate for LidiSi and RBC were 0.2% and 1.0%, respectively. The reasons for failure in both restoration types included secondary caries (2/198 = 1.0%), bulk (cusp of onlay) fracture of the restoration (4/198 = 2.0%), and endodontic complication (3/198 = 1.5%), while severe marginal gap formation (4/198 = 2.0%) and loss of retention (1/198 = 0.5%) were observed only in RBCs; tooth fracture (1/198 = 0.5%) was a failure mode only in LidiSi restoration. Failed LidiSi and RBC indirect partial restorations according to the investigated criteria during the 15-year monitoring period are presented in Table 2. The survival function of the LidiSi and RBC restorations was plotted against the calculated date of failure over the maximum 15 years of service using the Kaplan–Meier method with the log-rank test (Fig. 1).

Binary logistic regression analysis of patient-, tooth- and restoration-related risk factors influencing the occurrence of deteriorations is presented in Table 3.

Among the examined factors which influenced the incidence of defects patient-related factors included unsatisfactory oral hygiene and the presence of occlusal stress, while restoration-related factors included material (RBC) and restoration age. Therefore, when the differences between occurrence of deteriorations of LidiSi and RBC restorations were analyzed, these significant risk factors were used to control the multivariate models.

In case of LidiSi restorations, the most frequent defect (including B scores without intervention and C scores in the need of intervention) was marginal staining (38.8%), followed by marginal gap formation (7.2%), and restoration fracture (bulk fracture and minor chipping) (2.4%). Regarding the remaining criteria, no defects were found in the case of LidiSi restorations. However, in the case of RBC restorations, significantly worse outcomes were detected in several of the tested parameters. The most common defect (including B scores without intervention and C scores in the need of intervention) was degradation in the anatomical form (increased wear) (61.3%), followed by surface roughness (or loss of gloss) (58.1%), marginal staining (54.8%), marginal gap formation (28.8%), color mismatch (22.6%), loss of proximal contact (9.7%), and restoration fracture (bulk fracture and minor chipping) (6.8%). Table 4. presents the comparison of the detected failures, acceptable deficiencies and risk estimation for the evaluated criteria between LidiSi and RBC indirect partial restorations.

The material type (specifically the RBC), as a risk factor had the most significant effect on surface roughness, loss of anatomical form, marginal gap, color mismatch, and loss of proximal contact. While the material of the restoration had a significant influence on the changes of several examined criteria, a stronger correlation was found between

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

Variables			*LidiSi restorations (n = 125)*	*RBC restorations (n = 73)*	*P-value**
Patient related variables	Patient gender	Male	33 (26.4)	30 (41.1)	**0.039**
		Female	92 (73.6)	43 (58.9)	
	Patient's mean age ± S.D.		42.5 ± 7.4	41.6 ± 12.8	0.279
	Unsatisfactory oral hygiene		29 (23.2)	26 (35.6)	0.397
	Patients with bruxism		40 (26.4)	41 (56.9)	< **0.001**
Tooth related variables	Tooth location	Upper teeth	53 (42.4)	22 (30.1)	0.088
		Lower teeth	72 (57.6)	51 (69.9)	
	Tooth type	Molar teeth	98 (78.4)	52 (71.2)	0.258
		Premolar teeth	27 (21.6)	21 (28.8)	
	Tooth status	Vital	104 (83.2)	57 (78.1)	0.374
		Root canal treated	21 (16.8)	16 (21.9)	
Restoration related variables	Extension of restoration	Inlay	15 (12.0)	6 (8.2)	0.105
		Onlay/Overlay	110 (88.0)	67 (91.8)	
	Restoration age category	< 10 years	89 (71.2)	54 (74.0)	0.674
		≥ 10 years	36 (28.8)	19 (26.0)	

* Wald Chi-Square test. P ≤ 0.05 was considered significant.

Table 2
Failed LidiSi or resin-based composite restorations during the 15-year monitoring period.

Failed parameter	Time of failure (years) of LidiSi/resin-based composite restorations															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Total
Marginal integrity	0/0	0/0	0/0	0/0	0/0	0/0	**0/4**	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	**0/4**
Restoration fracture	0/0	0/0	0/0	**0/1**	0/0	0/0	0/0	**0/1**	0/0	0/0	**1/0**	0/0	**0/1**	0/0	0/0	**1/3**
Tooth fracture	0/0	**1/0**	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	**1/0**
Secondary caries	0/0	0/0	0/0	0/0	0/0	**0/1**	0/0	0/0	0/0	0/0	0/0	**1/0**	0/0	0/0	0/0	**1/1**
Loss of retention	0/0	0/0	0/0	0/0	0/0	0/0	0/0	**0/1**	0/0	0/0	0/0	0/0	0/0	0/0	0/0	**0/1**
Endodontic failure	0/0	0/0	0/0	**0/1**	0/0	**1/0**	0/0	0/0	0/0	**0/1**	0/0	0/0	0/0	0/0	0/0	**1/2**
Total	0/0	**1/0**	0/0	**0/2**	0/0	**1/1**	**0/4**	**0/2**	0/0	**0/1**	**1/0**	**1/0**	**0/1**	0/0	0/0	**4/11**

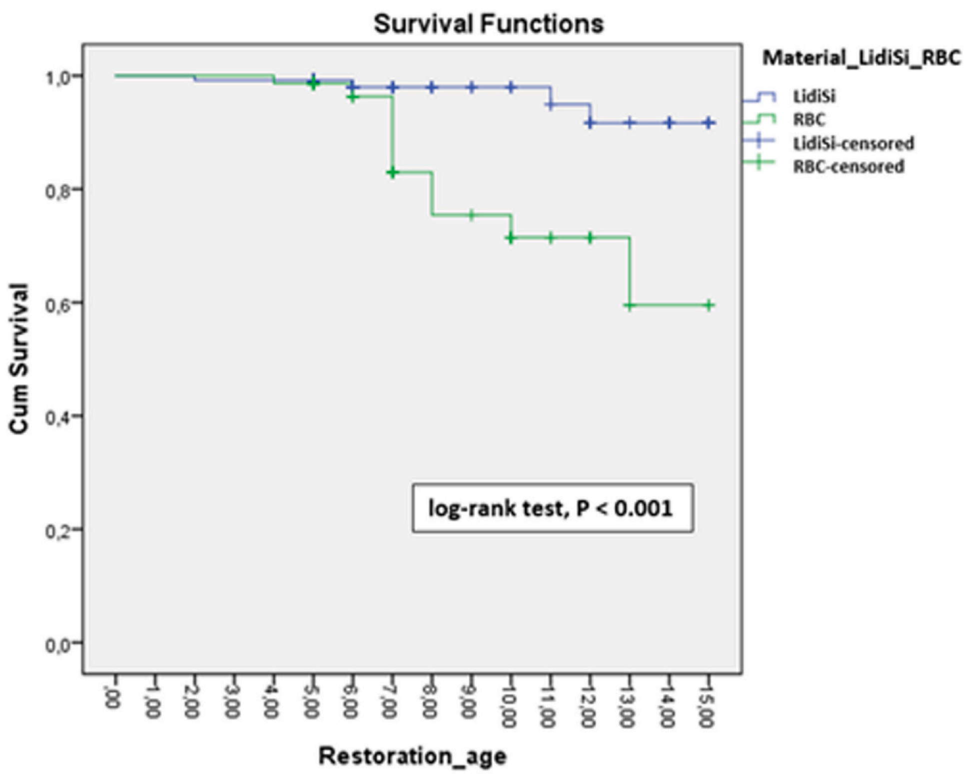

Fig. 1. Kaplan–Meyer survival analysis with log-rank test of LidiSi and resin-based composite (RBC) restorations.

Table 3
Influence of evaluated risk factors on the occurrence of defects of LidiSi and resin-based composite (RBC) indirect restorations.

Variable	*Odds Ratio*	*95% CI Lower*	*Upper*	*P-value**
Oral hygiene (unsatisfactory vs. satisfactory)	**2.5**	1.7	3.8	**< 0.001**
Occlusal stress (yes vs. no)	**1.9**	1.2	2.6	**0.003**
Tooth type (molar vs. premolar)	1.3	0.8	2.1	0.288
Tooth location (lower vs. upper)	1.3	0.9	1.9	0.115
Tooth status (root canal treated vs. vital)	1.4	0.9	2.2	0.156
Material of restoration (RBC vs. LidiSi)	**4.1**	2.8	5.9	**< 0.001**
Extension of restoration (onlay/overlay vs. inlay)	1.0	0.4	2.4	0.990
Age of filling (≥10 years vs. < 10 years)	**2.0**	1.2	3.2	**0.006**

Abbreviations: CI, Confidence Interval
* Wald Chi-Squared test

oral hygiene and marginal discoloration [Odds Ratio (OR): 11.6, $CI_{95\%}$: 2.9–46.3], which decreased the power of the material's effect in the multivariate model. Oral hygiene was found to be significantly better in female patients compared to males (OR: 1.6, $CI_{95\%}$: 1.1–2.4). Bruxism related occlusal stress as a patient-related risk factor had a very weak effect on the restoration fracture (OR: 0.9, $CI_{95\%}$: 0.8–0.9) irrespective to the restoration's material Statistical analysis was also performed to detect whether the material (LidiSi vs. RBC) as restoration-related risk factor resulted in more fractures in bruxing patients. The correlation was insignificant between the exposure (material) and the outcome (restoration fracture in the bruxing patients) (OR: 1.0, $CI_{95\%}$: 0.9–1.1).

Fig. 2 shows the number of deteriorations occurring within one restoration. More than 50% of LidiSi restorations survived the observation period without any defects, while in the case of RBCs this was only 10%. In general, the rest of the LidiSi restorations showed 1 of the evaluated criteria to be deteriorated, while in the case of RBCs, deteriorations within 2–6 criteria occurred more often within one restoration.

4. Discussion

In this retrospective clinical study, the long-term clinical performance of indirect LidiSi and RBC partial restorations were analyzed over an extended period of time. The results confirmed that the clinical performance of LidiSi heat-pressed glass-ceramic inlays/onlays/overlays was significantly better compared to the inhomogen microfilled

Table 4
Occurrence of deficiencies (B, C scores) and risk estimation for the evaluated criteria of LidiSi and RBC indirect partial restorations.

Criterion	*Occurrence of deficiencies (%)*		*Odds Ratio*	*95% CI*		*P-value**
	LidiSi	***RBC***		*Lower*	*Upper*	
Marginal gap	7.2	28.8	**1.19**	1.06	1.34	**0.003**
Marginal stain	38.8	54.8	0.99	0.87	1.12	0.836
Color mismatch	0.0	22.6	**1.13**	1.02	1.25	**0.018**
Surface roughness	0.0	58.1	**1.80**	1.58	2.05	**< 0.001**
Anatomical form	0.0	61.3	**1.69**	1.48	1.93	**< 0.001**
Proximal contact	0.0	9.7	**1.08**	1.01	1.15	**0.035**
Restoration fracture	2.4	6.8	1.04	0.97	1.11	0.230
Tooth fracture	0.8	0.0	0.99	0.98	1.01	0.316
Loss of retention	0.0	1.4	1.01	0.99	1.04	0.311
Secondary caries	0.8	1.4	1.01	0.98	1.05	0.528
Endodontic failure	0.8	1.4	1.03	0.97	1.08	0.331
Total failure	3.2	15.1	**1.14**	1.04	1.24	**0.004**

Abbreviations: CI, confidence interval; RBC, resin-based composite
* Wald Chi-Square test

laboratory-processed RBC restorations according to the evaluated parameters set out in the USPHS criteria. Hence, the first null-hypothesis was rejected. Furthermore, among the evaluated patient-, tooth-, and restoration-related risk factors oral hygiene, occlusal stress, and restoration material had a significant impact on the performance of the restorations. Thus, the second null-hypothesis was partially rejected.

The results of this study suggest that when the patients and indications are selected appropriately a satisfying clinical performance could be achieved for both LidiSi glass-ceramic and lab-processed RBC indirect restorations with an overall survival rate of 97% and 85%, respectively, after a mean observation period of 7.8 ± 3.3 years. However, the long-term danger of restoration failure when the tooth is restored with RBC inlay/onlay/overlay is found to be statistically significant.

Although, several clinical trials are available, which analyze the survival of ceramic or RBC partial restorations [18–23], there is a lack of information regarding the long-term differences between layered indirect RBC and glass-ceramic indirect restorations [32]. Based on the results of a recent systematic review and meta-analysis neither intracoronal lithium disilicate restorations nor indirect RBC restorations were inferior to the other on a short observation period. [32] According to systematic reviews and meta-analyses, the estimated survival rate for partial glass-ceramic restorations ranged between 91% and 95% over a 5–10-year period meanwhile, the 9-year survival of RBC inlays/onlays was found to be 85% [22,30]. However, due to the absence of long-term comparative studies, most of the meta-analyses concluded that insufficient evidence exists for the justification of a difference in clinical performance of RBCs indirect restorations compared to ceramics [32]. In line with a more recent systematic review and meta-analysis, the high survival rate of LidiSi and indirect composite inlays, onlays, and overlays found in our comparative clinical trial may provide more evidence that these restorations are a safe treatment [39]. However, the multiple logistic regression model in our study demonstrated a strong correlation between the material of the restoration and the quality of all the evaluated criteria. Not only the acceptable imperfections (B scores), but also failures (C scores) occurred more frequently if the restoration was fabricated from RBC. Our results were supported by systematic reviews and meta-analysis, which concluded that more favorable failure risk for LidiSi could be expected over RBC indirect restorations [30,31].

Although, the distribution was significantly different, the most frequent failures for both LidiSi and RBC restorations were bulk fracture with broken onlay cusp, and minor chip fracture of the restoration or tooth, endodontic complication, secondary caries and loss of retention. This is in line with the data available in the literature [30,31]. Fatal failure leading to extraction of the tooth was not detected in our study, all deteriorated or failed LidiSi and RBC indirect restorations were treated with repair or replacement and retained in function. This aspect was crucial and advantageous regarding the survival of tooth itself.

Multiple logistic regression model using patient, tooth, and restoration related variables as controls in the model showed that for marginal stain the significant effect seen for material selection was weakened by poorer oral hygiene when present as a further risk factor. Unsatisfactory oral hygiene – with a higher incidence in male patients – increased the occurrence of marginal stain weakening the effect of the material of restoration. The term "unsatisfactory oral hygiene" was used in our study to describe those patients whose oral hygiene was slightly worse than the 'very good oral hygiene' (satisfactory). 'Bad oral hygiene' was not detected among the recalled patients. From the outset, the indication of indirect restoration required good oral hygiene, which was emphasized later, during the regular follow-ups as well. Food, drink and microbial pigments can bind to the deteriorated resin luting agent. This mechanism could be accelerated by poorer oral hygiene. As no significant correlation between marginal integrity and oral hygiene

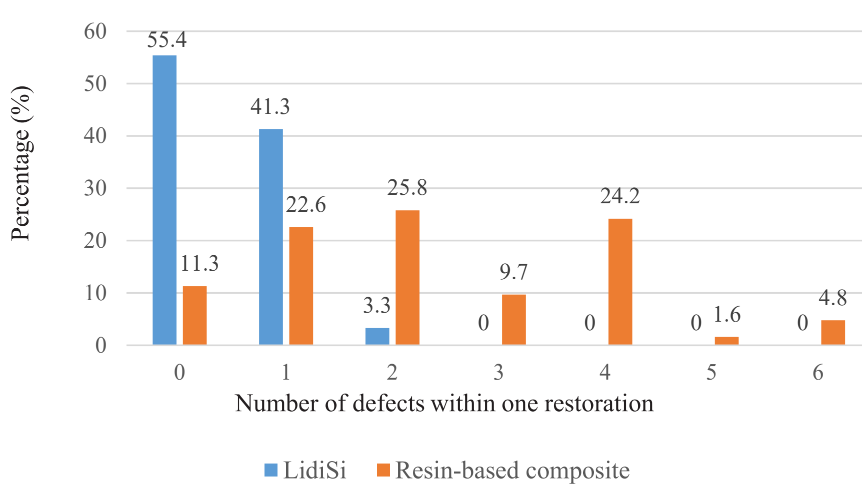

Fig. 2. Number of defects occurring within one restoration.

was apparent, probe-detectable or visible disintegration of margins are not mandatory for pigment accumulation at the interface. Cracks, bond strength failures, solubility, enzymes- and chemicals induced degradation may increase the porosity of the luting cement at the interface and absorb extrinsic discoloring agents leading to visible color-change of the restoration margins [40,41]. Marginal stain can primarily decrease the esthetics of a restoration but it does not necessarily increase the risk of secondary caries, however, poor marginal quality may be likely to decrease clinical longevity due to the misdiagnosis of secondary caries [42].

Although, secondary caries is one of the most frequent failure modes of dental restorations, including indirect LidiSi and RBC inlays/onlays/overlays as well, present study demonstrated a low level of occurrence of secondary caries after 15 years. This is line with the findings of a systematic review and meta-analysis comparing ceramic and RBC indirect restorations with 1% of secondary caries occurrence [30]. In contrast, Beier et al. detected 29.6% secondary caries in their retrospective study over a 20-year observation period, which is considerably higher rate compared to ours [43]. Although, significant correlation between secondary caries and oral hygiene was not demonstrated by the statistical analysis in our study, the low case number could limit the power of the statistical findings and other influencing factors involved in the model may modify the real connection.

Bruxism related occlusal stress was considered as a risk factor for restoration failure, since excessive occlusal load is supposed to subject the tooth to tenfold masticatory forces compared to a balanced occlusion [44]. A systematic review analyzing the longevity of ceramic onlays concluded that regardless of the ceramic type, it is prone to failure – especially fracture – in a highly stressful environment such as patients with parafunctional habits/bruxism [45]. On the contrary, the overall result from another meta-analysis did not favor any association between bruxism and increased odds of failure for ceramic restorations [46]. In line, a significant effect of bruxism (OR: 1.9) on the overall occurrence of failure was observed in our study, regardless of material. However, an effect of bruxism on restoration fracture was only observed with an odds of 0.9 ($CI_{95\%}$: 0.8–0.9), which indicated a weak association. This effect might be strengthened with a higher case number. While RBC was considered to be the most successful material offering the most fracture-resistant restoration in patients suffering from bruxism [47], our results cannot confirm this, since both LidiSi and RBC restorations performed similarly under occlusal stress. LidiSi have been found to be suitable for occlusal veneer restoration even with a reduced layer thickness of 0.8 mm due to their excellent toughness, residual flexural fatigue strength, and wear resistance [14,48]. Tooth fracture (broken cusp), as a failure, has occurred only in one LidiSi onlay, however, this was not related to bruxism.

Among the tooth related risk factors, such as tooth type (premolar vs. molar), tooth location (upper vs. lower) and tooth status (vital vs. root-canal treated), none of them had significant impact on the survival and occurrence of defects. This is in agreement with the finding of Schulte et al., who concluded that factors such as tooth type, position of tooth, extent of restoration, endodontic condition of tooth in addition to operator experience or gender of patient had no significant influence on the survival probability of the ceramic restorations [49]. A systematic review and meta-analysis reported a similarly insignificant association of tooth type with failure [30]. According to Derchi et al., however, the comparison between restored premolars and molars showed a statistically significant difference in favor for premolars regarding anatomical form and marginal integrity after 3-year follow-up. During the 12-year follow-up the discrepancy between premolars and molars was still observable but insignificant [50].

Considering the vitality of the restored teeth, our results showed, that it had no impact on the survival rate compared to the endodontically treated teeth. It should be highlighted, that root-canal treated teeth were restored with onlays or overlays without exception in order to provide occlusal protection in the unfavorably changed biomechanical situation. Cusp coverage of root-canal treated teeth with onlay or overlay has demonstrated favorable outcomes in tooth survival with more than 96% success rate in medium-term, due to the reduction of the cuspal deformation [51]. In contrast, Beier et al. found increased failure rate of ceramic inlays/onlays in nonvital teeth [43]. Morimoto et al. concluded from their systematic review and meta-analysis, that tooth vitality is a significant factor for indirect RBC restoration survival, since the chance of failure was 80% less in vital teeth compared with root-canal treated teeth [30]. Another recent systematic review and meta-analysis concluded that indirect partial restorations on endodontically treated posterior teeth, regardless of material, displayed overall acceptable outcomes in a medium follow-up period (4.3–10.7% failure rate), however after 12–30 years of function the failures (20.9%) increased considerably. The most frequent failures were related to the loss of dental elements, although most of the failures were reparable or replaceable [52]. Although there is no consensus regarding material selection in large restorations and for cusp coverages, monolithic LidiSi presenting 100% long-term survival rate can be considered as a great option [53].

Regarding the extension of the restoration (inlay vs. onlay and overlay) no statistically significant influence was attributed to any type of failure or defect. However, it should be mentioned, that the number of inlays were low in both study groups. The physical improvements, sophisticated stratification techniques and cost benefit of RBC materials allow it to be used in a direct fashion, therefore the indication field of inlays nowadays is quite narrow. In addition, the prudent analysis of remaining tooth structure and careful preparation of cavity design ensured a safe as possible restoration in order to avoid restoration or residual cusp fracture. Increased cavity size entails increased deformation ability for RBCs and hence their strength decreases with increasing cavity size and can only approach that of the unaltered tooth in the case of small, conservative cavities [54]. Similar to our results, the size of the restoration was not shown to have an effect on deteriorations in other studies [20]. Although, Beier et al. detected the worst survival rate for ceramic inlays with three surfaces. On comparison of all restoration types no significant differences were found between the single-, two-, or three-surface inlays and onlays [55]. Regarding RBCs, multi-surface restorations revealed significantly better results for marginal integrity compared to the one- or two-surface restorations [49].

As one of the restoration related risk factors age was introduced. Medium-term category included restorations aged between 5 and 9 and long-term category included the restorations which were 10–15 years old. In line with other studies [43,49], our results also concluded a significant increase in the incidence of restoration defects over time. This increase of failure probability was much more significant in the case of indirect RBC restorations. The Kaplan-Meier analysis revealed a significant drop to ∼80% of RBCs' survival after 6 years, which further decreased by the end of the observation period, resulting only in 60% of survival probability after 15 years. Meanwhile the probability of survival remained high (> 95%) in long term for LidiSi restorations. The material composition of RBC and LidiSi shows significant differences, which is reflected by the aesthetic and mechanical properties, as well as in its aging pattern. The complex, dynamic oral environment poses a multitude of biological, mechanical, physical, and chemical challenges, which may more easily degrade the organic-based RBCs, despite the recent developments and enhancements [56]. It was concluded in a review paper, that the main cause of failure for most indirect RBCs is the breakdown of the resin matrix and/or the interface between the matrix and the filler. This process is further assisted by inhomogeneity of the RBC structure resulted from incomplete polymerization, pre-existing voids, and flexure-induced microcracking [57,58]. In clinical studies, it appeared that failure in the first 5 years is an age-related restoration issue [57]. In line with other long-term studies, the parameters, which are sensitive to fatigue, were deteriorated with the highest odds (surface roughness, anatomical form, marginal integrity) in case of RBC restorations [31]. LidiSi, on the other hand, is considered as the best glass-ceramic currently with excellent mechanical properties and esthetics in the short and long-term [59], although, LidiSi potentially be prone to fracture due to fatigue induced internal cracks [58]. On the contrary, a systematic review and meta-analysis concluded, that the survival rate of RBC and ceramic indirect restorations remained high, irrespective of the follow-up time [30].

Similar to our findings, other clinical trials observed a gradual increase in marginal deterioration with the extended time in both ceramic and RBC restorations [22,45]. Generally, the poor wear resistance of luting cement has been thought to be responsible for loss of marginal integrity, regardless of the indirect restoration's material [22,49]. It has been also hypothesized that the more similar the wear of the restoration material is to the wear of the interface material, the better the marginal integrity [60]. However, our results revealed significantly higher occurrence of marginal gap of RBC restorations (28.8%) compared to the LidiSi (7.2%) in spite of the same dual-cured adhesive cement used. Marginal gap formation is a complex phenomenon, since several contributing factors play an important role in its development [61]. While the preparation design and the odontotechnological processing method has a great impact on the fit of the indirect restoration, the cementation can further increase the marginal discrepancy [62]. The examination of the marginal and internal fit of IPS e-max Press onlays showed 45.5 and 63 µm gap before and after cementation, respectively [63]. Similar fit of laboratory processed RBC inlays (~58 µm) was detected [64]. An insufficient adaptation of the indirect restorations can result in mechanical and chemical wear and biodegradation of the resin cement [65]. The supposedly similar adaptation of the two restoration types, similar oral conditions and the use of the same adhesive cement in this study can exclude the effect of these factors on the discrepancy in marginal gap formation between RBC and LidiSi restorations. Therefore, the reason for the significant difference in marginal gap can primarily be found in the different properties and behavior under load of these materials. Although the volume of the adhesive resin cement is partially restricted to the cementing gap, its polymerization shrinkage may also contribute to the gap formation and the shrinkage stress's magnitude depends on the Young's modulus of the indirect restorative material [66]. Yu et al. demonstrated in their finite element analysis, that the restorative material could contribute to the stress distribution and extent of damage within enamel-inlay bonded interfaces [67]. For ceramic inlay they found a greater portion of the contact load concentrated in the ceramic structure, resulting in minimal damage in the adjacent interface and occlusal enamel margins. In line with the aforementioned findings, our results demonstrated only shallow depressions along the LidiSi margins. In contrast, RBC inlays concentrated larger stress in the adjacent enamel, which caused the development of cracks and their propagation to the inner enamel. This finding was supported by the significantly more and severe deteriorations (C scores) of RBCs in our study. Based on the above results, wear of the interface was found to be dependent on the difference in mechanical properties of the tooth structure and restorative material [67]. In addition, under pressure, ceramic inlays/onlays with higher elastic modulus systematically exhibit a lower amount of interfacial tensile stress generation on dentin compared to RBCs which show an increase of interfacial tension, especially for those materials with low elastic modulus [54]. Limited displacements and stress absorption of LidiSi at the margins and on the internal walls was comparable to a sound tooth [66]. In addition, it is assumed that the different coefficient of thermal expansion of the tooth, RBC, and LidiSi may be partially responsible for the differences found in marginal gap formation between LidiSi and RBC restorations. Temperature induced volumetric change may jeopardize the materials' integrity and the adhesive interface, leading to microleakage. The coefficient of thermal expansion for tooth is approximately $11–17 \times 10^{-6}/°C$; higher values have been demonstrated in RBCs depending on the filler content ($20–40 \times 10^{-6}/°C$), while this value in porcelain is considered to be more ideal, as it is close to that of tooth ($13–16 \times 10^{-6}/°C$) [68].

Luting of each restoration was performed with the same brand of dual-cured cement. Dual-curing provides adequate degree of conversion and better mechanical properties of the resin-based luting agent through the different thicknesses of indirect restoration [69]. However, dual-cured resin cements may affect esthetics on restoration margins due to inferior color stability [70]. In addition, color change was also caused by brown pigment deposits as it was detailed above. According to our results, marginal discoloration was found to be the most frequent defect for both types of restoration, which occurred in a higher proportion in RBCs. LidiSi are generally superior to polymer-based materials in terms of flexural strength, abrasion resistance, and marginal/material discoloration [71].

The wear resistance of LidiSi was also confirmed by our long-term results, as no wear was detected on the ceramic restorations during the observation period. On the other hand, increased wear on the occlusal surfaces of RBC restorations was the most frequently detectable deterioration. Loss of detailed anatomical form of RBC restorations demonstrated decreased mechanical resistance against abrasion. Wear and fatigue are the consequent of sliding contacts, which induce localized stresses slightly below the surface if the forces applied to the RBC exceed the mechanical strength of the material. Generated stress leads to crack formation and damage of the occluding contacts [72]. The increased wear specifically affected the restorations with a larger surface area such as onlays and overlays. This supports Ferracane's claim that a wear resistance of RBCs may still be a concern for very large restorations in direct occlusal contact [73].

In the present study for RBC restorations, the defect with the highest risk of occurrence was shown to be loss of gloss of the entire RBC restoration and surface roughness Most often seen defect was loss of gloss which led to micro-roughness. Apart from esthetics, a smooth and glossy surface prevents plaque and discoloring pigment accumulation, and may decrease the coefficient of friction subsequently decreasing wear rate of the restoration or the antagonist [74]. In agreement with our findings, indirect RBC restorations deteriorated frequently due to loss of surface polish according to a twelve-year longitudinal clinical evaluation [49]. In our study, indirect RBC restorations made from an inhomogen microfilled light-curing laboratory RBC (SR Nexco) were involved. Although microfill RBCs are considered to maintain surface smoothness and gloss over the long term, pattern of filler dispersion and the inter-particle spacing, as well as polishing protocol play an important role in surface protection [74,75]. Besides the filler particle size, factors such as degree of monomer conversion, monomer type, and refraction index can also influence the gloss retention of RBC [76]. In addition, restorations are subjected to mechanical and chemical challenges in the oral environment. Changes in RBCs are influenced by the mutual chemical reactivity of the polymer matrix with the surrounding environment and the rate of diffusion. Diffusion as a physical process leads to swelling and softening of the polymer, in which macromolecules are moved apart leading to microcrack formation and hydrolysis along the resin-filler interface [77]. Despite the high stability, RBCs' long-term degradation can be manifested in decreased mechanical and esthetic properties, as it was demonstrated in the present study. In the context of chemical challenge, the cross-link density of resin-matrix, the monomers' nature, their resistance to degradation, and solvent sorption may influence the degradation rate of RBCs [76]. Mechanical degradation, such as toothbrush abrasion can induce loss of gloss, which is attributed to the change of surface topography and increase in roughness by abrasion of the softer RBC matrix and loss of exposed surface fillers [78]. While correlation between surface gloss and roughness exists, the change in gloss is not necessarily associated with increased surface roughness [76]. The fatigue can contribute to the loss of surface smoothness, loss of anatomical form, decrease in marginal integrity, and can lead to color change of the restoration [31]. Although chemical degradation of ceramics has been demonstrated in association with the elution of alkaline ions [79], due to its more homogeneous structure and toughness, LidiSi showed much greater resistance to chemical and mechanical degradation in the long term [20].

Loss of retention was detected only in case of one RBC onlay at 8 years. This patient had a parafunctional habit with ice chewing. It is supposed, that the frequent and extreme temperature induced volumetric change damaged the adhesive surface leading to loss of retention. Apart from this unusual case, the well-working surface treatment protocol of ceramics, the increased surface of the RBC achieved by air-abrasion, and the total-etch technique applied to the enamel/dentin ensured long-term retention for the restorations. Furthermore, no basing or lining with conventional cement was applied in order to obtain a maximum area in dentin for adhesion. To improve the homogeneity of the study group and standardization of surface treatment protocol, cases with absence of marginal enamel or large dentin surfaces covered with RBC (i.e. deep margin elevation) were excluded from the investigation. Comparing the clinical performance of indirect restorations with or without deep margin elevation is a future plan for the authors. Krämer and Frankenberger included cases with absence of enamel in proximal boxes and did not find any influence on retention or marginal performance investigating inlays and onlays [80].

Due to endodontic complications, one ceramic and two RBC restorations had to be changed. Beier et al. compared the number of endodontically treated cases before and after the restoration cementation and revealed no significant differences between the groups [55]. It highlights, that as the most important considerations, previous dental treatments, the depth of the cavity and the condition of the pulp should be primarily taken into account before the restorative intervention instead of the restorative material.

One of the limitations of our study is the unequal sample size in the two compared groups. To provide enough power for the statistics it was necessary to increase the case number in LidiSi group, as the failure number for some evaluated parameters proved to be low. This fact necessitates for prudent interpretation of the results. Further evaluation with increased sample size is needed to overcome this limitation. A further limitation of our study is its retrospective nature. In the absence of indication standardization and treatment protocols the strength of clinical evidence provided by retrospective studies is lower compared to prospective clinical trials. However, to overcome the limitations and provide clinically valuable results, strict criteria were applied to provide as homogenous experimental groups as possible in a retrospective study. Patients who were involved in the study were treated by the same operator therefore ensuring that the indications were implemented and preparation was carried out according to the same concept and skills. Dental technical processes were carried out by the same dental laboratory, ensuring standardized steps and quality for all the included restorations. The use of the same resin cement and adhesive system eliminated the diverse results which may arise from the different material chemistry. Additionally, the decision-making process and restorative procedures are described to a great level of detail. In support, a meta-regression by Morimoto et al. indicated that the study design (retrospective vs. prospective) did not affect the survival rate of ceramic and RBC inlays, onlays, and overlays [30].

5. Conclusions

Within the limitations of this retrospective study, the following conclusions can be drawn regarding the comparison between posterior ceramic and RBC indirect partial restorations:

Consideration for correct indications, following established preparation and luting protocols can ultimately result in high survival rates for both LidiSi (96.8%) and RBC (84.9%) indirect partial restorations after a 5–15-year observation period. However, the clinician should expect higher risk for failure or occurrence of defect in case of RBC inlay/onlay/overlay restorations after 6-year service. Among the evaluated risk factors, the material of the restoration influenced significantly several examined parameters, bruxism related occlusal stress had weak negative effect on the restoration fracture, and unsatisfactory oral hygiene increased the occurrence of marginal stain. The occurrence of deteriorations significantly increased as time progressed.

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