

Two-Year Survival of Ceramic Endocrowns and Partial Coverage Ceramic Restorations with Fiber Post: A 2-Year Double-Blind Randomized Clinical Trial

Keywords

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ABSTRACT

Purpose: This double-blind randomized clinical trial (RCT) aimed to evaluate the 2-year survival rates of endocrowns and partial coverage ceramic restorations (PCCR) with fiber posts. *Material and Methods:* Forty (40) participants fulfilled the eligibility criteria, and they were randomly allocated in 2 groups: Endocrown or PCCR-post. The survival rates were assessed based on USPHS modified and radiographic examinations. A Chi-square test was used to assess the distribution of characteristics between groups. Kaplan-Meier and Log-rank tests were used to estimate the survival rate. To evaluate the association between survival of the restorations and the explanatory variables, the Multivariate Cox regression model was used. Only variables presenting $p < 0.20$ were maintained in final model ($\alpha = 0.05$). *Results:* The highest 2-year survival rates were recorded for the Endocrown group (100%), whereas the PCCR-post group exhibited the lowest performance (66.7%). Most of the restoration failures was due to lack of marginal adaption, fracture, and recurrent caries. Cox Regression unadjusted analysis showed that only type of restoration presented a significant effect ($p < 0.20$). Thus, adjusted analysis was not performed. *Conclusions:* Endocrowns appear to be a promising conservative restorative option and to be feasible and reliable approach restoring endodontically treated posterior teeth, showing higher 2-year overall survival rates than the PCCR-post.

INTRODUCTION

Restorations of endodontic treated teeth have an 80% higher chance of failure than restorations of vital ones, implying that tooth vitality is a significant factor for restoration survival.¹ The problem is aggravated in posterior teeth with considerable destruction of the crown structure and thin remaining walls. The successful restoration of such teeth depends on the correct selection of restorative approaches that conserve the remaining dental structure and restore function.^{1,2,3,10-12}

Depending on the amount and resistance of the remaining coronal structure, several treatment options are available. Indirect restorations (crowns, partial coverage restorations, and endocrowns) are used to overcome some problems associated with direct restorations, such as low mechanical and wear resistance and the difficulty in restoring proximal and occlusal anatomy.^{1,2,12,13}

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Partial coverage ceramic restorations with fiber post (PCCR+post) and endocrowns are conservative restorations.^{2,3,9,13-16} Although the endocrown restorations were introduced more than twenty years ago, many dentists still use the classical post and core approach to restore endodontically treated posterior teeth with extensive coronal loss.¹⁶ Intra-radicular posts are used to increase the restoration retention in teeth with extensive destruction of the crown.^{6,16,17} However, the additional removal of sound tissue for fitting the post into the root canal weakens the structure, increases the risk of root fracture, and often hinders the possibility of further interventions.^{7,11}

Alternatively, endocrown monoblock restorations are retained by adhesive cementation using the pulp chamber and remaining coronal tooth structure for retention.^{2,7,11} This minimally invasive treatment concept could present advantages in comparison with the classical post and core approach: (1) dental tissue preservation, (2) reduced risk of catastrophic failures (root fractures or perforation; contamination of the endodontic treatment and failures related to the amount of adhesive interfaces to create), (3) no need of sufficient interocclusal space; (4) less appointments, and (5) decreased cost.¹⁶

The estimated survival rate for glass-ceramics and feldspathic porcelain inlays, onlays, and overlays is 91% in 10 years.¹ Primary studies^{3-5,8,9} systematic reviews and overviews^{14,15} also reported a high survival rate (90-100%) for endocrowns. Systematic reviews,^{2,7,15} based on *in vitro* and clinical studies,^{3-5,17-21} suggest that endocrowns may perform similarly or better than conventional treatments such as post and core crowns, and direct composite resin or inlay/onlay restorations. I-Dabbagh (2020)² performed a meta-analysis of clinical studies, concluding that there were no significant differences in overall 5-year survival and success estimates between endocrowns (91.4% and 77.7%, respectively) and conventional crowns (98.3% and 94%, respectively).

To date, there is limited evidence to suggest an advantage of endocrown over the PCCR+post, since few clinical trials are available, and most have small sample sizes, high risk of bias, and short follow up periods (6 months to 4 years).^{2,15} There is no double-blind, randomized clinical trial in the literature comparing the survival rate of endocrowns and partial coverage ceramic restorations (PCCR) with fiber posts. The study design produces high-quality scientific evidence, which could provide a foundation for evidence-based clinical decisions, whether ceramic endocrowns are a feasible option.^{2,7,15}

This study aimed to evaluate the survival rate of endocrowns and PCCR+posts. The null hypothesis was that both restorative techniques have similar clinical performance for over two years.

MATERIALS AND METHODS

STUDY DESIGN - ETHICAL ASPECTS AND METHODOLOGY

The study protocol was approved by the Research Ethics Committee of São Paulo University (CAAE no. 73845317.2.0000.0075), following the Consolidated Standards of Reporting of Trials (CONSORT and CONSORT PRO) guidelines,²²⁻²⁴ and registered at clinicaltrials.gov (NCT03064516).

This non-inferiority, double-blind, parallel-arm randomized clinical trial, with a 1:1 allocation ratio, was conducted by one previously trained operator (RMF), who performed all the restorative procedures.

The survival rate of inlay/onlay ceramic restorations (96.6% after 2-year) was considered for sample size calculation. With a significance level of 0.05 and a 0.80 power, considering one tooth per patient, using a one-tailed test and 15% non-inferiority limit, adding 20% for possible losses, the final number of teeth per group was 20, corresponding to a total of 40 teeth.²⁵

PARTICIPANTS - RECRUITMENT, ELIGIBILITY, RANDOMIZATION, AND ALLOCATION

All participants were recruited from the Military Police Dental Center (São Paulo, Brazil) by one researcher (SM), based on clinical and radiographic exams. The clinical steps were carried out in a private dental office from July to December 2018.

Participants were selected with no distinction between sex, race, or ethnicity, according to the following inclusion criteria:

1. endodontic treated;
2. molars or premolars;
3. minimum of one cusp with 3-mm thick;
4. having dental antagonists;
5. supragingival margins;
6. good oral hygiene (without white spot lesions and with reasonable biofilm control);
7. minimum of 18 years of age.

The exclusion criteria were:

1. participants who did not agree to sign the free informed consent form;
2. tooth pain, unsatisfactory endodontic treatment, or signs of periapical lesions at the time of radiographic or clinical examination;
3. pregnant women;
4. volunteers who did not fit into the research timetable;
5. teeth with restorations, cracks, hypoplasia, or carious lesions on the remaining adjacent surfaces;
6. participants wearing orthodontic braces. Different dentists had carried out endodontic treatments with no date specification.

Eligible participants were randomly assigned to one of the study's arms, in blocks of 4 and 6, using the website www.sealedenvelope.com. Allocation concealment was ensured by using sealed brown envelopes numbered serially and kept in possession of an independent researcher until the operator opened them at the beginning of treatment. The envelope's contents indicated the experimental group to which the participant would be assigned: Endocrown group (test) or PCCR+post group (control).

RESTORATIVE TECHNIQUES FOR THE EXPERIMENTAL GROUPS

Photographs were taken at baseline and after removing carious tissue and old restorations, cavity preparation and cementation for each group (Figure 1).

Radiographs were taken at baseline, cementation, and the final follow-up. All participants received instructions on diet and oral hygiene.

Endocrown group: The space of the pulp chamber was included in the preparation. A 2-mm round cervical chamfer was created in the finish line along the margin using cylindrical-conical diamond burs (846KR and 846KRF.021- Jota) at high rotation and undercooling, using a 1:5 multiplier contra-angle (S-MAX M95L- NSK). Figure 2 shows the endocrown restoration immediately after cementation and 2-year follow-up.

PCCR+post group: A fiber post (White post, FGM) was cleaned with alcohol, dried, and treated with Monobond (Ivoclar Vivadent); Multilink primer A+B components at a 1:1 ratio were mixed and applied to the tooth (Ivoclar Vivadent), without previous acid etching, and then air-dried. After that, the post with a size compatible with the main canal was inserted half-way in the canal and luted with Multilink resin cement (Ivoclar Vivadent), followed by light-curing for 20 seconds. The teeth were filled with composite resin – shade A2 (Tetric N Ceram bulk fill- Ivoclar Vivadent) in 1-2-mm increments, and each layer was light-cured for 20 seconds. Occlusal and proximal boxes were prepared, leaving a maximum of 2 mm for ceramic thickness. A 2-mm round chamfer finish line was created along the crown's outside margin using a cylindrical-conical diamond burs (846KR and 846KRF.021- Jota) at high rotation and undercooling, in a 1:5 contra-angle multiplier (1:5 S-Max M95L, NSK). Figure 3 shows PCCR+post immediately after cementation and 2-year follow-up.

In both groups, the cusps were preserved whenever possible. In cases where veneering was needed, the occlusal surface was abraded to allow a 1.5-to-2 mm space for the veneer. The proximal contact point was removed with metal files. The color was chosen using the Vita classical shade guide (Vita Zahnfabrik).

The double impression technique (Virtual heavy and regular body - Ivoclar Vivadent) and double cord technique (Ultra-pack- Ultradent) were used. The provisional restorations were fabricated with acrylic resin and cemented with Temp Bond NE (Kerr Corporation).



Figure 1: Cavity preparations for Endocrown and PCCR+post groups- A: Remaining coronal tooth structure, post and core included in the preparation; B: Partial coverage ceramic restoration after cementation; C: Pulp chamber and remaining coronal tooth structure included in the preparation; D: Endocrown after cementation.

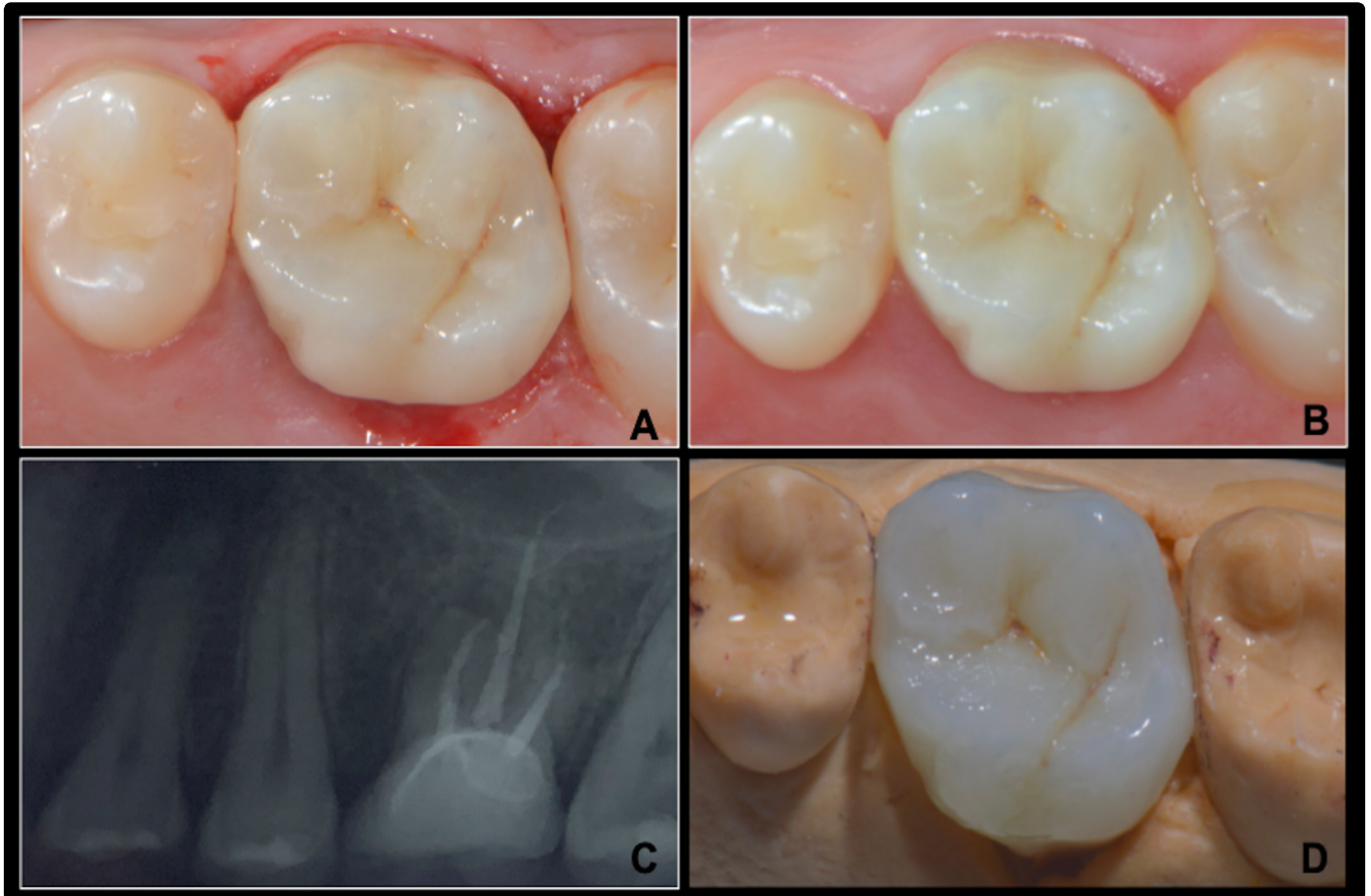


Figure 2: Endocrown group- A: Immediate (after cementation); B: 2-year follow up; C: Radiographic image; D: Occlusal view of ceramic restoration on the stone model.

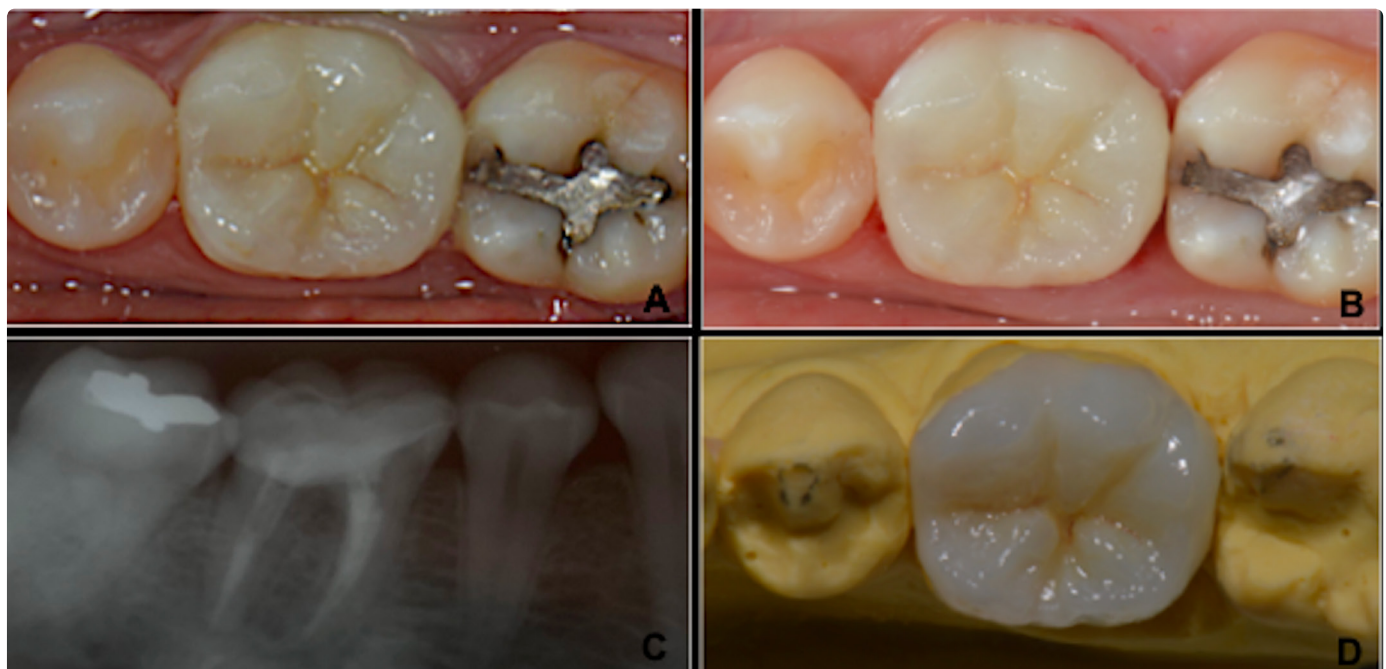


Figure 3: PCCR+post group- A: Immediate (after cementation); B: 2-year follow up; C: Radiographic image; D: Occlusal view of ceramic restoration on the stone model.

LABORATORY PHASE - CERAMIC RESTORATION MANUFACTURE

Monolithic restorations were milled (Cerec In Lab Mx1) with lithium disilicate glass-ceramic (IPS e.max CAD- Ivoclar Vivadent) was pigmented and glazed.

SESSION 2- TESTING, FITTING, AND CEMENTATION OF THE CERAMIC RESTORATION

After testing and fitting the specimen in the mouth, rubber dam isolation was used to adhesive cementation in both groups. Enamel and dentin were etched with 37% phosphoric acid gel (N-etch; Ivoclar Vivadent) for 15-20 seconds, followed by rinsing and fast air jets. The specimens were etched with 5% hydrofluoric acid (IPS Ceramic Etching Gel; Ivoclar Vivadent), silanized for 1 min (Monobond N; Ivoclar Vivadent), and luted with Tetric N-bond and Multilink N dual cement (Ivoclar Vivadent). Light polymerization was performed with a Radium-Cal device (SDI- 1200 mW/cm²) for 20 seconds on each surface. The occlusal adjustment was performed, and the restorations were polished with rubber points (Opra Fine Ivoclar Vivadent).

CLINICAL EVALUATION

Restorations were evaluated at the 1 and 2-year follow up by a blinded and calibrated examiner (TKT) according to FDI World Dental Federation - Clinical Criteria for the Evaluation of Direct and Indirect Restorations.²⁶ This examiner was calibrated by referring to intraoral photographs of 10 partial ceramic restorations, following the described criteria. The intra-examiner agreement Cohen's Kappa was 0.9. Clinical evaluation was made under dental operating light with an oral mirror, a dental probe, and a three-way syringe. After the clinical evaluation was completed, the other two researchers (SM and RMF) entered the room, evaluated the radiographs, and decided if the restoration had to be repaired or replaced.

Restorations with scores 1-3 were considered clinically acceptable (success), and with scores 4 were clinically unsatisfactory, but reparable, and those with scores 5 were clinically unacceptable with failures that required restorations' replacement.²⁶ Fractures of the tooth, the restoration, or the post were also assessed. The definition of survival and success should be very clear to avoid divergences, and this lack of standardization of concepts could be the cause of heterogeneity in outcome measures. Survival was defined as the restoration being in place (intact or with small repair/ burnish with scores lower than 4), and success as the restoration being in place and without significant failures (scores 1-3).²⁶ Chipping and fracture are different type of failures, and sometimes not even considered as failure to be a censorship if the patient agreed to having a burnish or composite repair performed in scores 4. Then, in the case of failures after the clinical evaluation was completed by a blind researcher (TKT), the other two researchers (SM and RMF) evaluated the radiographs and clinically, then in consensus they decided if the restoration had to be repaired or replaced.

STATISTICAL ANALYSIS

Kaplan-Meier analysis was used to estimate the survival of restorations. The differences between the groups were verified by Log-rank test. To evaluate the association between the survival of the restorations and the explanatory variables, the Multivariate Cox regression model was used. Only those variables presenting $p < 0.20$ were maintained in final model. The significance level for all analysis was set as 5%. Statistical analysis was performed using survival and survminer packages in the RStudio, version 1.1.45 statistical software, version 4.0.2 (R Core Team, 2012, Vienna, AUT).

RESULTS

Study stages are listed in the flowchart (Figure 4).

Characteristics of participants at baseline for each experimental group are shown in Table 1. There was no significant difference for characteristics between groups ($p > 0.05$). Most of the participants were male (65%) and over 40 years old (65%). Endocrowns were placed in maxillary and mandibular teeth equality, whereas eight PCCR+post were placed in the maxilla and 12 in the mandible.

The Kaplan-Meier curve of the survival analysis is displayed in Figure 5. The 2-year survival of Endocrowns and PCCR+post were 100% and 66.7%, respectively. The log-rank test showed a statistically significant difference between the groups ($p = 0.04$).

The reasons for failure are presented in Figure 6. The most common were marginal adaptation, fracture, and caries at restoration interface.

Three (15%) PCCR+post fractured (2 in males and 1 in a female) and one man (5%) had secondary caries at the 2-year follow-up, and these were computed as censored cases. Of the fractures in PCCR+post group, a man had fractured dental (vestibular and distal) and restoration (mesial) on tooth 37 (Figure 7-A and B) and was referred to treatment with a ceramic crown. The other man with a severe fractured restoration (tooth 37) was seen in an emergency unit, and it was not possible to have a photograph taken. Subsequently, the participant underwent periodontal surgery, and the tooth was restored with a metallic core and ceramic crown. The female participant developed Sjögren's Syndrome, and her oral condition worsened, including the fracturing of the restoration, marginal discoloration and percolation (tooth 47) (Figure 7- C and D). The male participant who presented recurrent caries reported having a cariogenic diet and not flossing (tooth 27). All of these cases had score 5²⁶ in consensus by researchers, subsequently they were considered clinically unacceptable and restorations' replacement were necessary. None of these participants reported having bruxism or tightness. No debonding was observed.

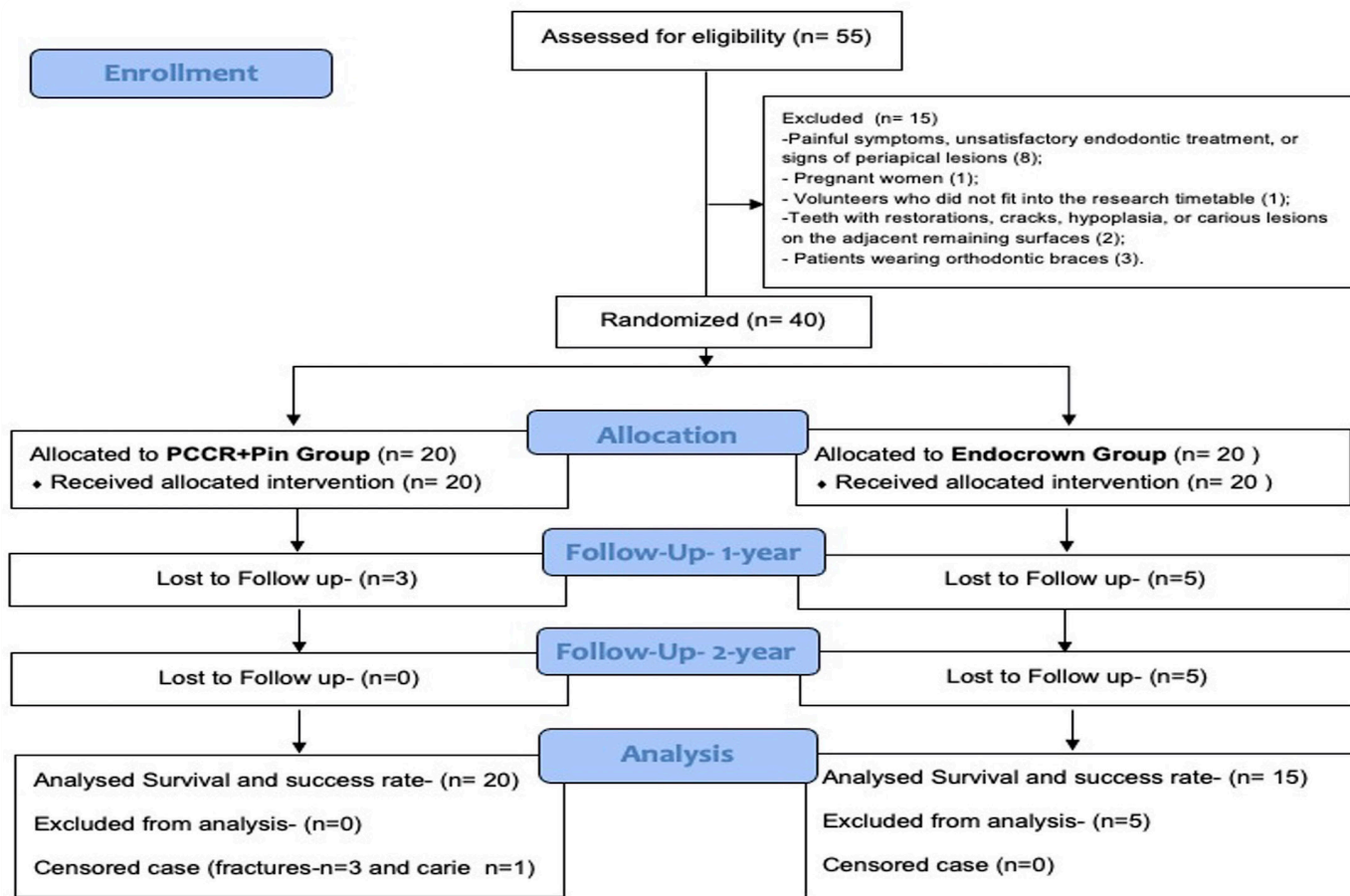


Figure 4: Flow diagram of the progress through the phases of a parallel randomized trial of two groups²⁴

Table 1. Baseline characteristics of participants in the experimental and test groups.

Characteristics	PCCR	Endocrown	p value
Sex	Female	6 (15)	0.184
	Male	14 (35)	
DMFT index	DMFT <3	0 (0)	0.549
	DMFT ≥3	20 (50)	
Age	20 - 39	5 (12.5)	0.507
	≥40	15 (37.5)	

DISCUSSION

Survival rate of Endocrowns and PCCR+post were, respectively, 100 and 66.7% at the 2-year evaluation. Five (25%) of the 20 PCCR+post restorations had to be completely replaced. No restoration was repaired.

Previous studies^{3,5,8,9,14,15,16,27} report high survival rates (90-100%) for endocrowns. A systematic review¹⁵ found that the success rate of Endocrowns is 94-100% in 6-36 months of follow-up. Al-Dabbagh (2020)² performed a meta-analysis of the clinical studies, concluding that the overall 5-year survival

and success estimates for endocrowns were 91.4 and 77.7%, respectively, while estimated survival rates for glass-ceramics and feldspathic porcelain inlays, onlays, and overlays were 91% at 10 years.¹

The most common failures found in this study were fractures, marginal integrity, and caries, confirming previous findings,^{3-5,20,21} and indicating that even with major advances in ceramic materials, adhesive procedures, and techniques, other clinical factors might lead to failures. However, it is almost impossible to identify clinically the causative factor of failure, but the RCT is a study design that isolates the effect of a factor (type of restoration), keeping confounding variables

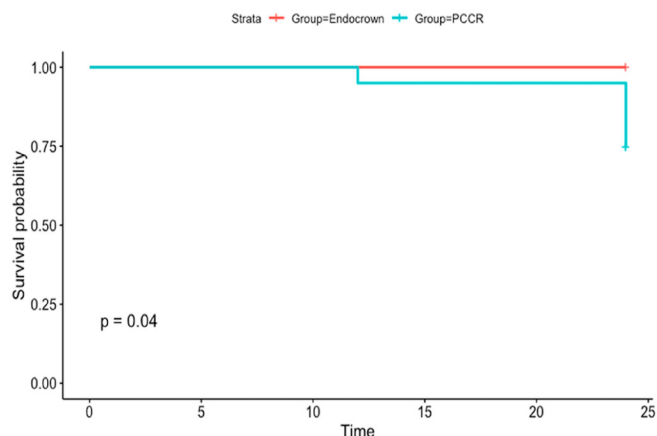


Figure 5: Kaplan-Meier curve of the survival analysis from experimental groups.

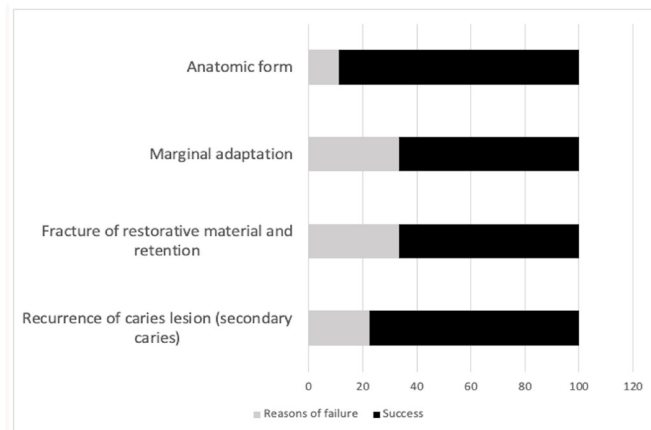


Figure 6: Distribution of reasons of the failures according FDI World Dental Federation- Clinical Criteria for the Evaluation of Direct and Indirect Restorations²⁶.

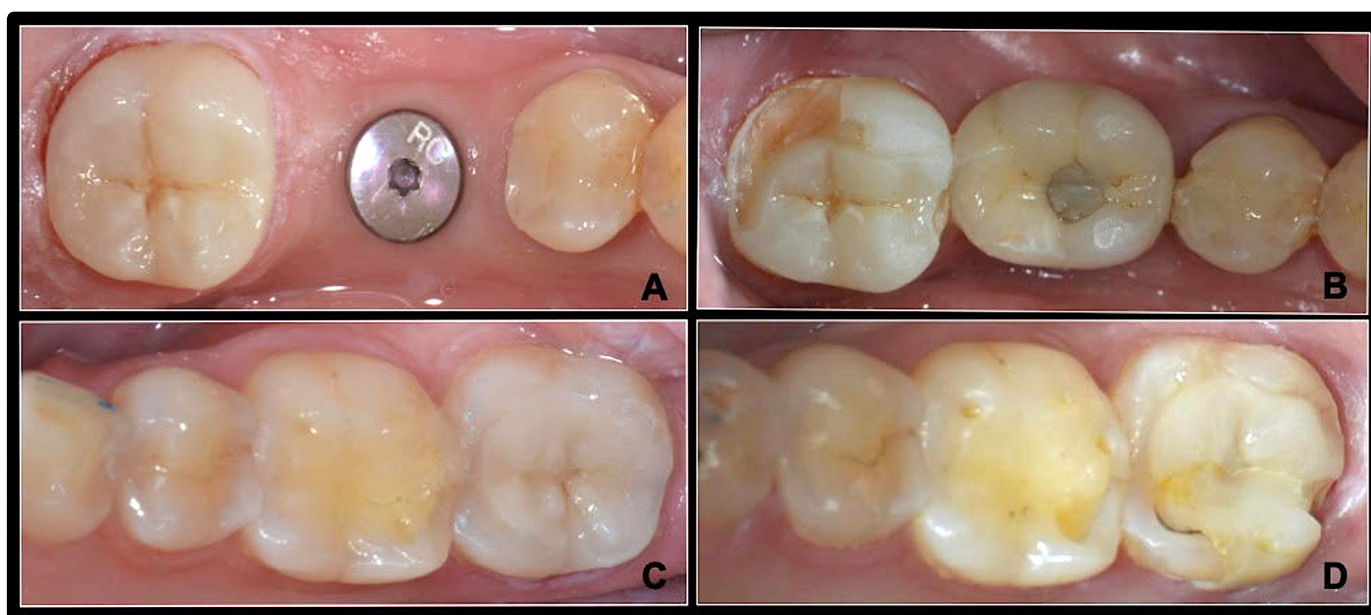


Figure 7: Fractures in PCCR+post group- A: Occlusal view (tooth 37) immediately after cementation; B: Fracture after the 2-year follow up; C: Occlusal view (tooth 47) immediately after cementation; D: Fracture after the 2-year follow up (female participant with Sjögren's Syndrome).

evenly distributed in the groups. When each factor was assessed separately, none of the variables showed correlation with failure risk (Table 2), indicating that variables related to the restoration procedure are the cause of failures. Thus, hypothetically, three factors may have contributed to the higher failure of the PCCR+post restorations: ceramic thickness less than that of the endocrowns; the triple adhesive interface (ceramic/ resin core and pin/ dentin) and these high number of restorative materials, each with a different elasticity modules.

Endocrown is defined as a mono-block ceramic crown bonded to depulped posterior tooth, which is anchored to the internal portion of the pulp chamber and to the cavity margins.²⁷ However, there is no exact definition of the endocrown, particularly about preparation and the amount of residual tooth tissues.¹⁶ In our study, number of faces haven't showed correlation with failure risk (Table 2) and this finding is in agreement with another study that states that Endocrowns were

shown to constitute a reliable approach to restore severely damaged molars and premolars, even in the presence of extensive coronal tissue loss.¹⁶

The preparation for the PCCR+post restoration was done to allow a 1.5 to 2.0-mm thickness of the ceramic²⁸⁻³⁰ while the occlusal thickness of endocrowns varies from 3 to 7 mm.¹⁵ *In vitro* studies³¹⁻³³ have found that the occlusal thickness is related to longevity and failure. Clinical reports have demonstrated that fractures may occur if the occlusal surface of the tooth was not reduced sufficiently to create a space for a restoration thickness of 2-4 mm.^{34,35}

Due to the strong bond strength of the tooth to the ceramic, bonded ceramic restorations (inlays and overlays) increase the strength of the remaining dental structure, reduce cusp deflection, and create a cusp stiffness comparable to intact posterior teeth.³⁶ Failures related to the interface tooth/cement/

Table 2. Unadjusted model of Cox regression analysis (Hazard Ratio; 95% Confidence Interval) for failure of restorations according to explanatory variables.

Variables		Survival N(%)	Unadjusted HR (95% CI)	p value
Age	Up to 39	13 (37.1%)	Ref.	0.445
	≥ 40	22 (62.9%)	2.4 (0.2621.0)	
Sex	Female	14 (40%)	Ref.	0.350
	Male	21 (60%)	2.8 (0.32-25.0)	
Jaw	Upper	15 (42.9%)	Ref.	0.296
	Lower	20 (57.1%)	3.2 (0.36-29.0)	
Number of Faces	2-3	16 (45.7%)	Ref.	0.485
	4-5	19 (54.3%)	0.53 (0.008-3.2)	
Presence of Endodontic Lesion	No	20 (57.1%)	Ref.	0.404
	Yes	15 (42.9%)	2.1 (0.36-13.0)	

ceramics are the most commonly cited in the literature.³⁷⁻⁴² Previous research⁴³ reported fractures of veneers bonded on teeth with large composite fillings. The lower adhesion of the veneer to the large composite surface and a large exposed dentin surface were considered the most likely reasons for these failures. The authors concluded that the presence of composite fillings had a negative influence on the overall clinical performance, but did not increase the loss of restorations in that study, which is in agreement with our findings.

PCCR+post are usually prepared using materials with different elastic moduli, i.e. glass fiber-reinforced resin for the post and resin composites or ceramics for the core/crown portion. As known, the differences in hardness between dentin, luting cement, and the restorative system may influence stress distribution, and the higher the number of interfaces between distinct materials the lower the stress distribution. Thus, being a monoblock, the endocrown would support higher stress loading than the multi-interfacial characteristic of PCCR+Post restorations.^{2,7,15,44}

In the first part of this RCT, we addressed from the perspective of patient-reported outcome measures (PROMs) and operative time. Results showed that Endocrown and PCCR+Post had similar procedure time and patient perception, however, endocrowns allow less clinical steps.⁴⁵

In this study, no participant reported sleep bruxism (SB), so its relationship with restoration failure could not be assessed. However, clinical studies⁴⁶⁻⁴⁹ found no correlation between SB and failures. A systematic review⁴⁸ reported that SB increased hazard and odds of failure only for anterior ceramic veneers. On the other hand, some studies⁵⁰⁻⁵² report a relationship between restorations failure and SB. Due to the lack of strong

evidence concerning this topic, the absence of participants with bruxism in this study was considered an advantage for the analysis.

The most used treatment for restoring endodontically treated teeth is the placement of a crown and metal core or even the PCCR+post, as dentists believe this treatment has the highest longevity. The preparation technique, however, requires a great loss of tooth structure and lengthier chair time, with more clinical steps. The use of post and core systems does not seem to substantially influence tooth longevity when there is a considerable amount of remaining dentin, but preservation of the coronal structure appears to be a critical factor for long-term longevity of endodontically treated teeth,¹⁰ added to the other possible factors listed in this study.

A limitation of this study concerns that different dentists had carried out endodontic treatments with no date specification, it could interfere in the overall failure of restorations of endodontically treated teeth. Helpful data like cost effectiveness and levels of patient's satisfaction over time should be approach to decide between these treatments. In addition, as both techniques depend on the operator, and as we decided for standardization, using a single operator, his perception was not obtained.

This blind RCT generated scientific evidence that could help clinical decisions about the best restorative method for endodontically treated teeth. The findings of this study encourage the use of endocrowns as an alternative approach that is both minimally invasive and durable, since preservation of remaining tooth structure is essential.¹⁸ Other advantages include easy placement, low cost, patient satisfaction and, consequently, better patient compliance with treatment steps.^{3,5,6,8,9,13,14,21}

CONCLUSIONS

Endocrowns seem to be a feasible and reliable approach to restore endodontically treated posterior teeth, with higher 2-year overall survival rates than the conventional PCCR+Post treatment. The most common failures to PCCR+Post treatment were fracture of restoration.

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