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Stainless steel crown vs bulk fill composites for the restoration of primary molars post-pulpectomy: 1-year survival and acceptance results of a randomized clinical trial

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Abstract

Background: A key factor for the success and longevity of the endodontic treatment is sealing of the cavity after restorative treatment.

Aim: The aim of this randomised clinical trial was to evaluate the 1-year survival of endodontic treatment in primary molars restored with stainless steel crowns (SSCs) and bulk fill composite resin (BF). As a secondary outcome, the acceptance of both children and parents was evaluated.

Design: Ninety-one 3- to 8-year-old children with at least one primary molar requiring endodontic treatment were selected. Participants were randomized to SSC or BF and evaluated after 1, 3, 6, and 12 months. An acceptance questionnaire was completed immediately after the treatment. The primary outcome was the endodontic treatment success, evaluated in the intention-to-treat (ITT) population using the Kaplan-Meier and non-inferiority Cox regression analyses, with a non-inferiority limit of 15%. Sensitivity analysis between the success rates after 1 year was performed using Miettinen-Nurminen's method. The Mann-Whitney test was used to compare the treatment acceptance ($\alpha = 5\%$).

Results: The survival rate after 1 year was BF = 75% and SSC = 88% (HR = 1.41; 90% CI 0.57-3.43). ITT analysis showed a success rate of BF = 86.7% and SSC = 82.6% (RR = 0.95; 0.78-1.16). The non-inferiority hypothesis between the survival of endodontic treatment could not be proved in both analyses ($P > .05$). The overall acceptance scores did not differ between the restorative groups ($P > .05$).

Conclusion: This study failed to show non-inferiority of BF compared with the SSC. The materials were well accepted by both children and their parents.

KEYWORDS

bulk fill composite resin, endodontic treatment, randomized clinical trial, stainless steel crown

Trial registration: www.clinicaltrials.gov, NCT03186950.

1 | INTRODUCTION

Endodontic treatment such as direct pulp capping and pulpotomy are indicated for treating extensive tooth decay[1]; however, when an irreversible pulp infection is present, treatment options may involve tooth extraction or pulpectomy.[1] Pulpectomy aims to recover the functional aspects of the affected tooth by eliminating the infection from the root canals and preserving the integrity of the periapical tissue until physiological exfoliation.[2]

A key factor for the success and longevity of the endodontic treatment is complete sealing of the cavity after treatment.[3] Placement of a stainless steel crown (SSC) is the most commonly recommended restoration following endodontic treatment of primary molars,[4] as it provides a good coronal seal, preventing microbial infiltration or restoration failure over time.[5] Nevertheless, dental aesthetics are compromised due to colour characteristics of the SSCs, which may influence child's and parent's acceptance, especially when compared to more aesthetic options such as composite resins (CRs).[6]

The main problem of CR, however, is the high polymerization shrinkage that results in marginal deficiencies, cracked cusps, and material fracture, especially in multisurface restorations after pulp treatment.[6] The fracture of the restoration can lead to a microbial infiltration, resulting in the failure of the endodontic treatment.[6] In order to solve this problem of polymerization shrinkage, bulk fill composite resin (BF) was launched in the market, with promising evidence level in both clinical and in vitro studies[7]; however, no clinical trial has been performed to date using BF as a restorative material after pulp treatment in primary teeth.

Recently, research has been focusing on patient-centred outcomes,[8] therefore the child's and parent's acceptance of the treatment is important. A questionnaire developed by Bell in 2010[9] evaluated the acceptance of SSCs by parents and children. Each question employed a 5-point pictorial Likert scale in order rating the children's treatment experience and their views on SSC. It also explored parents' attitudes towards the SSC and how they felt their child had coped with treatment.[10]

The aim of this randomized clinical trial was to evaluate the 1-year survival rate of endodontic treatment followed by SSCs and BF as a restorative option and also the acceptance of these restorations by the child and parent.

2 | METHODS

This is a two-arm, controlled, 1:1 allocation ratio, non-inferiority clinical trial. This manuscript was written following the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Why this paper is important to paediatric dentists?

- It is not possible to affirm that restorations of teeth with endodontic treatment performed with bulk fill composite resin (BF) are non-inferior to restorations made by stainless steel crowns (SSC).
- Failures in BF restorations lead to a failure of the endodontic treatment.
- In terms of acceptance, both materials were well accepted by both children and their parents.

2.1 | Ethical aspects and registration

This clinical trial was approved by the Local Ethics Committee of Research in Humans (#1.608.421) and is registered in the database for registration of clinical studies (ClinicalTrials.gov, NCT03186950).

Informed consent was obtained from the parent or guardian of each child before participation in the study. All participants were encoded by numbers to ensure data confidentiality. The adverse events of the treatment provided in this study are similar to those inherent to a conventional endodontic treatment performed in primary molars. If the included children needed any other dental treatment, it was performed by the trial's operator.

2.2 | Sample description

The sample size estimation was performed for a binary outcome non-inferiority trial using the website *sealedenvelope.com* based on the primary outcome—success of the endodontic treatment. The calculation was based on the success of the endodontic treatment for primary molars reported by Nakornchai et al[4] of 96% for both groups after one year, considering α of 5% and power of 80%. We considered a value of 15% as a non-inferiority limit. The sample size was increased by 30% to compensate for possible losses during the study. This resulted in a minimal sample size of 86 teeth, where the sample unit was the tooth, and only one tooth was included per child.

Inclusion criteria were as follows: healthy (ASA I) cooperative children aged 3-8 years, who had at least one primary molar indicated for endodontic treatment irrespective of sex or socio-economic status.

- Primary molars with irreversible pulpitis or non-vital pulps with restorable tooth structure (adequate sound coronal tooth structure and periodontal support), confirmed by clinical and periapical radiographic examinations.

2.3 | Exclusion criteria were as follows

- Children with underlying systemic conditions and special healthcare needs.
- The presence, bone rarefaction involving more than a half of the root, severe mobility, or resorption of more than half of the root or root perforations.

2.4 | Randomization

The randomization list was generated using the website www.randomization.com, based on randomly permuted blocks (2, 4, or 6, randomly sampled with equal probability). Opaque, sealed, and sequentially numbered envelopes were used to allocate the participants to the treatment groups (SSC and BF), and they were opened after the endodontic treatment completion.

All the children whose parents sought dental care in the Pediatric Dentistry Clinic at the School of Dentistry of the University of São Paulo were eligible to participate. Only participants with primary molars diagnosed with pulp necrosis or with irreversible pulpitis were included. Patient enrolment was carried out by CRB. ALP generated the random allocation sequence, and MPA assigned the participants to interventions by opening the envelopes. ICO was the operator of the study and conducted all treatments.

2.5 | Study groups

Participants were randomly assigned to two different treatment groups: SSC: restorations using SSC for primary molars (3M ESPE) that were cemented with a glass ionomer cement (GC Fuji Plus C; GC Corp); and BF: restorations using BF (Filtek Bulk Fill, 3M ESPE) using Scotchbond™ Universal Adhesive (3M ESPE).

2.6 | Interventions

All treatments were performed by a single operator (ICO), assisted by another paediatric dentist (CRB) at the Clinical Research Center (CEPEC/FOUSP, Brazil) that provides dental facilities. A full-mouth examination was carried out along with standardized periapical radiographs for any teeth with possible indication of endodontic treatment before the start of the clinical study. All radiographs were taken using radiographic positioners for children.

After clinical and radiographic examination, baseline variables related to demographic and tooth/lesion characteristics were collected. Child's age (3-5 or 6-8 years) and sex, and the presence of fistula, initial diagnosis (necrosis without or without furcal rarefaction or irreversible pulpitis), number of surfaces of the caries lesion (one, two, or more than two surfaces involved), molar (first or second molar), and jaw (upper or lower) were evaluated by the operator of the trial in order to analyse whether those variables could be related to treatment success.

2.7 | Endodontic treatment

All teeth included in this trial received an endodontic treatment following an identical protocol. After local anaesthesia, a rubber dam was secured with a dental clamp. Working length determination was performed using baseline radiography, keeping the length 1mm short of the apices. No electronic apex locator was used for length determination or perforation detection. The pulp chamber was accessed using a spherical bur followed by opening with a non-end-cutting bur. The root canal entrances were located, and the first third was prepared using La Axxess bur (Sybron Endo). Manual instrumentation was performed using paediatric 17-mm hand files (Angie, Angelus®), and each canal was enlarged up to two or three instrument sizes greater than the first file. Endo-PTC was used added by copious irrigation with 1% NaOCl between the use of each instrument. The final irrigation was carried out with 17% EDTA to remove inorganic material and open dentine tubules. The canals were dried using sterile paper points, and the obturator material (Guedes-Pinto Paste, Angelus[11]- rifocort, camphorated paramonochlorophenol and iodoform) was syringed into the canalss. A lentulo spiral file (Dentsply) was used to assure a homogeneous obturation, and Coltosol (Coltene) was used to fill the pulp chamber.

All the pulpectomies and restorations were performed in a single session. After finishing the endodontic treatment, the randomization envelope was opened by a third person (ALP) and the child was treated according to the following treatment groups:

2.8 | Stainless steel crowns

The rubber dam was removed, and the SSC (3M ESPE) was then cemented with a glass ionomer cement (GC Fuji Plus C/ GC Corp). Tooth preparation was only carried out when there was insufficient space to fit the crown.

2.9 | Bulk fill composite resin

The cavity walls were cleaned, etched with a 37% phosphoric acid (Condac, FGM), washed, and dried using 3:1 air/water syringe. For occluso-proximal restorations, a metal contoured matrix and a wooden wedge were used to provide an

appropriate contour. The adhesive system was then applied (Scotchbond™ Universal Adhesive, 3M ESPE) with a microbrush and light-cured for 10s. The restoration was performed using BF (Filtek Bulk Fill/3M ESPE). If the cavity size was greater than 4 mm deep, two increments were applied.

All restorations were light cured using LED light-(Radii plus, SDI), ensuring a minimum irradiance of 400 mW/cm^2. When necessary, a finishing bur was used for adjustments.

2.10 | Endodontic treatment assessment

The primary outcome of this study is the success of the endodontic treatment after 12 months. All treatments were evaluated by a calibrated independent examiner (MPA) using the clinical and radiographical criteria proposed by Brustolin et al.[2] Clinical evaluation took place after 1, 3, 6 as 12 months while radiographical evaluation took place after 3, 6 and 12 months. Clinical failure was considered when the tooth presented with fistulae, abscess, or pathological tooth mobility. Radiographical failure was considered when there was a progression of inter-radicular radiopacities, increased pathological root resorption, or absence of periodontal integrity.

The clinical and radiographic criteria to determine success were the absence of all the conditions described above until the end of the follow-up period. In case of failure of the endodontic treatment, the extraction of the tooth was performed.

In addition to the clinical and radiographical evaluation of the endodontic treatment, the restoration success was also evaluated using Roeleveld et al[12] criteria (marginal integrity, secondary caries, fracture restoration). Furthermore, the SSCs were evaluated for the presence of perforation and crown loss.

2.11 | Questionnaire

The acceptance questionnaire was administered immediately after treatment (Portuguese language) by an external researcher (ALP) who did not participate during the endodontic treatment phase, and who was instructed to read the questions and show the possible answer in the same way for all the participants to avoid interview bias. The new restoration was shown to patients and their parents using a mirror to identify the treated tooth.

2.12 | Children's acceptance

The questionnaire for the children (C) consisted of five questions in Portuguese regarding appearance, acceptability, treatment experience, and their views on the metal crown or composite restoration:

(C1) 'Você está feliz com seu dente que foi concertado?' (EN: Are you happy with your tooth that has been fixed?)
(C2) 'Você vai mostrar o dente que foi concertado aos seus amigos?' (EN: Are you going to show the tooth that has been fixed to your friends?)
(C3) 'Você achou que o dentista tratou você bem?' (EN: Do you think the dentist treated you well?)
(C4) 'Você entendeu tudo que o dentista ia fazer?' (EN: Did you understand everything the dentist was going to do?)
(C5) 'Você se incomodaria se as pessoas perguntassem e quisessem ver o seu dente que foi concertado?' (EN: Would you mind if people asked about your fixed tooth and wanted to see it?).

2.13 | Parent's acceptance

The questionnaire for the parents (P) consisted in five questions in Portuguese regarding their attitudes towards the SSC or composite restoration and how they felt their child had coped with the dental treatment:

(P1) 'Eu entendi o motivo do meu filho necessitar de uma restauração' (EN: I understood why my child needed a restoration).
(P2) 'Não me incomoda a aparência da restauração/dente novo do meu filho' (EN: The appearance of my child's new tooth / restoration does not bother me)
(P3) 'Eu acho que a restauração nova está realmente protegendo o dente do meu filho' (EN: I think the new restoration is actually protecting my child's tooth)
(P4) 'Acredito que meu filho se sentiu bem durante o tratamento' (EN: I believe my child felt good during treatment)
(P5) 'Acredito que a equipe odontológica foi gentil e prestativa durante o atendimento do meu filho' (EN: I believe the dental team was kind and helpful during my child's dental care).

2.14 | Data analysis

All analyses were conducted in the intention-to-treat (ITT) population. The analysis for the primary outcome (endodontic treatment survival) was tested using the two-sample non-inferiority test for survival data using the Cox regression (non-inferiority/alternative hypothesis HR $<$ 1.15; CI = 90%). The proportion of treatment success at 12 months of (using multiple imputation considering baseline variables) was performed as a sensitivity analysis using non-inferiority test p-value and confidence interval (CI = 95%), derived by Miettinen and Nurminen's method.[13] These analyses were performed using the NCSS Statistical software (NCSS 2021, USA).

As secondary analysis, a two-tailed Cox regression analysis was performed to investigate the association between the prognostic factors for endodontic treatment failure. Variables that reached a p-value < 0.20 in the univariate analysis were considered for the adjusted analysis. Treatment survival was evaluated using the Kaplan-Meier survival analysis and log-rank test ($\alpha = 5\%$).

The association between the children's and parent´s acceptance between the groups was analysed using Mann-Whitney test. The analysis was performed for each question (considering the outcome as ordinal variable) and for total score of child's and parent´s answer. The child's and parent´s answers for each question were enumerated from 0 to 4 (0 = strongly agree; 1 = agree; 2 = no opinion; 3 = disagree; and 4 = strongly disagree). Thus, for the total score, all scores from the answers were summarized per children and parents, and the higher the total score, the worse their acceptance in general.

The analyses were performed using Stata 16.0 software (StataCorp LP).

3 | RESULTS

Recruitment took place between January and March 2017, whereas treatments were performed between May and July 2017. The follow-up started in June 2017 and lasted until July 2018. The CONSORT flow diagram for clinical trials is presented in Figure 1. After 12 months, 14 children were not evaluated because they moved to another city or changed their mobile phone numbers (dropout = 15.38%). As all children were evaluated at least once during the evaluation period, all of them were included in the Cox regression analysis (Cox dropout = 0).

A total of 91 children were included in this study and received the interventions. Among the participants, 37 (40.66%) were female and 54 (59.34%) were male and the mean DMFT/dmft was 7.2 (±3.2; min 5–max 14). A total of 46 teeth were restored with BF and 45 with SSC. Baseline demographic and clinical characteristics for each group, together with the dropout distribution, are described in Table 1.

The Kaplan-Meier survival plot is presented in Figure 2. The survival rate after 1 year was BF = 75% and SSC = 88% (log-rank p =.455). The analysis of the primary outcome using non-inferiority Cox regression and ITT analyses is shown in Table 2. The non-inferiority hypothesis between the treatment's survival could not be concluded (HR = 1.41; 90% CI 0.57-3.43, p =.645). Intention-to-treat analysis found that the success rates after 12 months were 86.7% and 82.6% for SSC and BF groups, respectively. An absolute difference of −4% was found, however since the lower confidence limit was −19% the non-inferiority between the groups could not be claimed (RR = 0.95; 0.78-1.16, p =.149).

The analysis of prognostic factors for the failure of the endodontic treatment is presented in Table 3. In the univariate analysis, there was an association between restoration failure and survival of the endodontic treatment; however, as all nine failures of the restoration were in the BF group, this variable was not considered for adjusted analysis. The second primary molars had lower risk of endodontic failure when compared to the first primary molars (p =.026). All other analysed variables (sex, age, size of inter-radicular lesion, presence of fistula, abscess, or mobility) were not associated with the failure of the endodontic treatment in this secondary analysis.

Two parents and two children from the BF group did not answer the acceptance questionnaire after treatment. The reasons for the non-response were as follows: the child was sleeping after the treatment (n = 2) so they were unable to answer the questions; and the parents had to rush to another appointment (n = 2). Those questionnaires were excluded from data analysis due to missing data (response rate = 97.8%). Most of the answers are either 'strongly agree' or 'agree', showing a high acceptance for all responses, regardless of the treatment group.

The statistical analysis of each question (Mann-Whitney test) for both parents and children is presented in Table 4. There was no difference in the child's and parent´s acceptance of –BF and SSC restorations, whether using the individual questions or the total acceptance score ($P > .05$).

4 | DISCUSSION

According to the most recent systematic review on endodontic treatment for extensively decayed primary teeth,[14] the final restoration most commonly reported after iodoform-based pastes were amalgam, glass ionomer cement, composites and SSCs. This is the first clinical trial to evaluate the influence of SSC vs BF in the survival rate and child's and parent´s acceptance of the endodontic treatment in primary molars.

In order to compare SSC to BF we have chosen a non-inferiority hypothesis rather than a trial seeking superiority between the restorative methods.[15] We aimed to evaluate if using BF as a post-pulpectomy restoration material would not be 'inferior' (or not unacceptably worse) to the SSCs, considering endodontic treatment success as the primary endpoint.

The null hypothesis that suggested that BF would provide worse survival compared to SSC beyond the pre-defined non-inferiority margin of −15%. Although the absolute difference was −4%, the confidence interval ranged from −19% to +11%. Therefore, we have not shown that BF composite resin had a significant lower survival when compared to SSC.

We have estimated the sample a *priori* using published data on success rate with SSC of 96%.[4] In this study the success rate was 85.8% in the SSC arm. This lower success rate

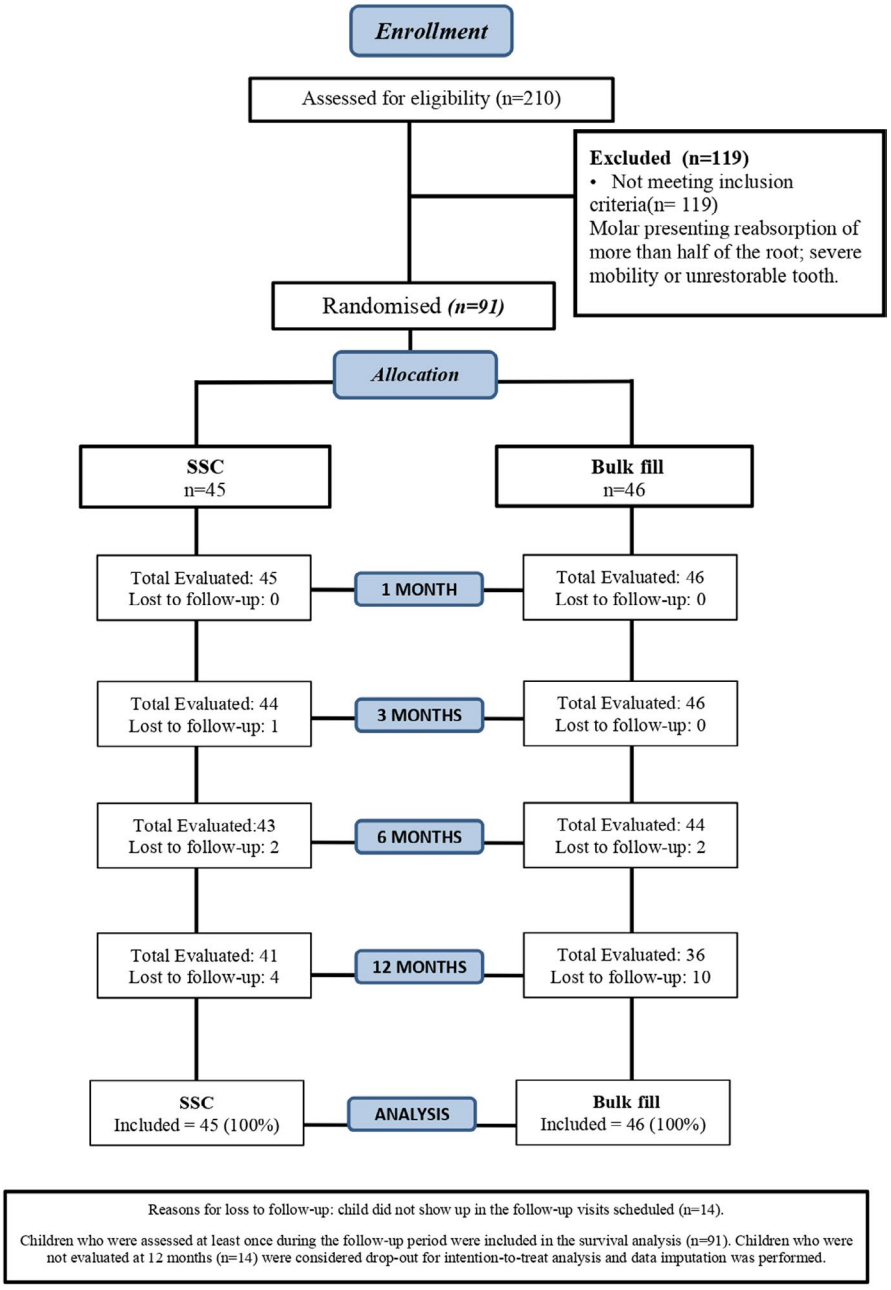

FIGURE 1 Consort flow diagram

is likely due to the wide range of endodontic diagnosis which were candidate for the endodontic treatment in this study compared to the one used for sample estimation. Therefore, although the success rates of the groups were numerically similar in our study, more studies with higher sample size are necessary to confirm whether BF is non-inferior to the treatment with SSC.

The main reason for endodontic failure in primary molars reported in the literature is clinical (fistula and abscess or pathological mobility) and radiological failure (pathological radiolucency or pathological root resorption).[14] In this study, a total of 14 teeth presented endodontic failures (3 = increased pathological radiolucency, 3 = bulk fracture of the restoration and fistula, 4 = bulk fracture of the restoration and increased pathological radiolucency, 1 = abscess, and 2 = root resorption > 2/3 associated with increased pathological radiolucency).

We observed that when restoration failure was noted, there was a significant increase in the risk for failure of the endodontic treatment. There was 19.57% (n = 9) restorations failures all in the BK group, which resulted in 8 failures of the endodontic treatment. The SSC group had endodontic failures (n = 6), but they were not related to the failure of the restoration. This is consistent with findings from a recent systematic review that demonstrated that SSC had the best overall survival compared with all other restorations.[16] When there is a failure in the restoration, bacteria can reach the root canal space again and lead to periapical periodontitis,[17]

TABLE 1 Baseline demographic and clinical characteristics for each group

	Bulk fill	SSC	Stayed in	Drop-out at 12 months[a]
Total N (%)	46 (50.55)	45 (49.45)	77 (84.62)	14 (15.38)
Categorical variables, N (%)				
Sex				
Female	22 (59.46)	15 (40.54)	30 (81.08)	7 (18.92)
Male	24 (44.44)	30 (55.56)	47 (87.04)	7 (12.96)
Age (y)				
2-5	30 (55.56)	24 (44.44)	44 (81.48)	10 (18.52)
>5	16 (43.24)	21 (56.76)	33 (89.19)	4 (10.81)
Number of surfaces involved				
Single surface	10 (47.62)	11 (52.38)	17 (80.95)	4 (19.05)
Multisurface	36 (51.43)	34 (48.57)	60 (85.71)	10 (14.29)
Molar				
First molar	14 (41.18)	20 (58.82)	29 (85.29)	5 (14.71)
Second molar	32 (56.14)	25 (43.86)	48 (84.21)	9 (15.79)
Furcal rarefaction				
No	20 (52.63)	18 (47.37)	30 (78.95)	8 (21.05)
Yes	26 (49.06)	27 (50.94)	47 (88.68)	6 (11.32)
Fistulae				
Present	10 (55.56)	8 (44.44)	15 (83.33)	3 (16.67)
Absent	36 (49.32)	37 (50.68)	62 (84.93)	11 (15.07)
Local abscess				
Present	7 (53.85)	6 (46.15)	9 (69.23)	4 (30.77)
Absent	39 (50)	39 (50)	68 (87.18)	10 (12.82)

[a]Ten children who dropped out were from the bulk fill group and four were from the SSC group (p =.079, Fisher's exact test).

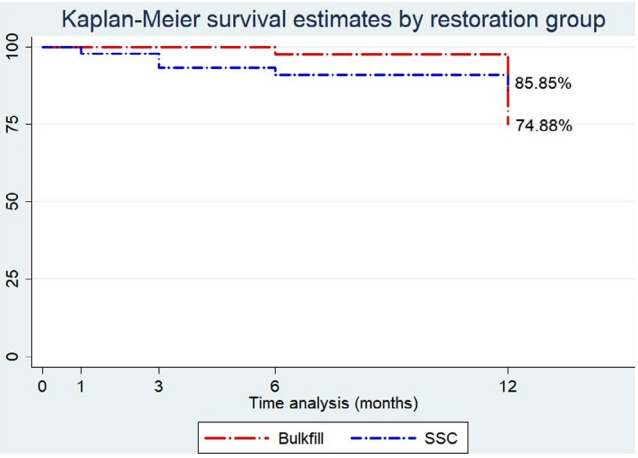

FIGURE 2 Kaplan-Meier survival analysis between groups (log-rank p =.455)

TABLE 2 Primary outcome analysis (endodontic treatment survival) using the non-inferiority Cox regression and intention-to-treat analyses

	SSC	BF	*P*-value
Primary outcome—non-inferiority Cox regression analysis[a]			
% Survival	85.85%	74.88%	.646
HR (90% CL of HR)	1.41 (0.57-3.43)		
Primary outcome—intention-to-treat analysis (12 months)[b]			
N success/N total	39/45	38/46	.095
% Success	86.67%	82.61%	
Absolute difference (95% CI)	-0.04 (−0.19 to 0.11)		.149
Relative risk (95% CI)[b]	0.95 (0.78-1.16)		

Abbreviations: BF, bulk fill composite resin; HR, hazard ratio; SSC, stainless steel crowns.

[a]100(1 − 2α)% confidence interval and p-value for non-inferiority survival data (Wald's test)

[b]p-values and 95% CI were derived by Miettinen and Nurminen's method using non-inferiority test for two proportions.

which often presents as a fistulae and/or abscess during the clinical examination, whereas radiographically, bone rarefaction is present. Another factor that could have negatively influenced the survival of the BF restoration is the socio-economic characteristics of the sample. Children belonging to low socio-economic frequently have higher caries experience and higher prevalence of untreated caries, and this

TABLE 3 Univariate and adjusted Cox regression analysis between endodontic treatment failure and prognostic factors

Variable	Survival rate %	95% CI	HR univariate 95% CI	*P*-value	HR adjusted 95% CI	Two-tailed *P*-value
Group						
SSC (ref)	85.85	71.39-93.46	1.35 (0.47-3.89)	0.580	1.57 (0.54-4.56)	0.406
Bulk fill	74.88	60.99-88.47				
Sex						
Female (ref)	84.93	67.29-93.49	1.13 (0.38-3.37)	0.827	—	—
Male	81.26	67.02-89.79				
Age						
2-5 years (ref)	78.58	63.67-87.92	0.52 (0.16-1.66)	0.272	—	—
>5 years	88.04	71.17-95.34				
Number of surfaces						
Single (ref)	88.24	60.60-96.92	1.87 (0.42-8.36)	0.412	—	—
Multiple	80.85	68.66-88.67				
Molar						
1st molar (ref)	70.21	50.37-83.32	0.30 (0.10-0.90)	0.032*	0.28 (0.09-0.85)	0.026*
2nd molar	89.88	77.33-95.67				
Furcal rarefaction						
No (ref)	83.94	65.47-93.02	1.23 (0.41-3.67)	0.710	—	—
Yes	81.57	67.49-89.98				
Fistulae						
Present (ref)	80.00	49.98-93.07	0.95 (0.26-4.41)	0.938	—	—
Absent	83.20	71.64-90.36				
Abscess						
Present (ref)	88.89	43.30-98.36	1.97 (0.26-15.10)	0.512	—	—
Absent	81.58	70.34-88.89				
Restoration failure						
Absent (ref)	90.66	81.30-95.44	9.07 (3.18-25.87)	<0.001*	Collinearity group (x^2 9.77, p =.002)	
Present	12.70	00.67-42.72				
Total	82.58	72.30-89.32				

Abbreviations: CI, confidence interval; HR, hazard ratio; SE, standard error.

*p <.05.

unhealthy oral environment results in higher rates of treatment failures.[18] These aspects highlight the importance of sealing the cavity after completion of treatment. The susceptibility of composite resin restorations to bulk fracture due to adhesion failures must be considered when compared to full-coverage restorations, especially in endodontically treated teeth.[1]

This study used conventional radiographs for baseline tooth diagnosis (presence of bone rarefaction, root resorptions, and perforations) and for root canal length determination (LD).[19] Although there is in vitro evidence that the use of an apex locator could improve the accuracy of LD, there is no clinical evidence that the use of apex locator influences the success of endodontic treatment.[20] The most common instrumentation method for root canal preparation is performed using hand K-files. Although there is evidence that rotary canal instrumentation could reduce treatment time by up to 3.48 minutes when compared to manual instrumentation, and improve obturation quality,[21] there is no difference in clinical and radiographical success.[22] For this reason, we opted for using hand instruments, as it presents lower costs when compared to rotary instrumentation. In many private and public dental practices in Brazil and in other low-income countries, the apex locator and rotatory instruments are not available. The pulpectomy protocol used in the present trial was based in the simplest evidence-based available protocols

TABLE 4 Association between the parent's and children's acceptance and independent variables (Mann-Whitney test)

	Question 1		Question 2		Question 3		Question 4		Question 5		Total	
	Mean ± SD Median (IQR)	*P*	Mean ± SD Median (IQR)	*P*	Mean ± SD Median (IQR)	*P*	Mean ± SD Median (IQR)	*P*	Mean ± SD Median (IQR)	*P*	Mean ± SD Median (IQR)	*P*
Parent's acceptance between groups												
SSC	0.33 ± 0.47 0 (1)	.528	0.87 ± 0.87 1 (0)	.136	0.35 ± 0.48 0 (1)	.303	0.24 ± 0.43 0 (0)	1.00	0.08 ± 0.28 0 (0)	1.00	1.88 ± 1.69 2 (3)	.223
BF	0.25 ± 0.44 0 (0.5)		0.67 ± 0.89 0 (1)		0.23 ± 0.43 0 (0)		0.25 ± 0.49 0 (0)		0.06 ± 0.25 0 (0)		1.45 ± 1.54 1 (3)	
Children's acceptance between groups												
SSC	0.24 ± 0.77 0 (0)	.179	1.06 ± 1.07 1 (1)	.280	0.95 ± 1.04 1 (2)	.839	1.15 ± 1.24 1 (2)	.882	1.26 ± 1.43 1 (2)	.458	4.68 ± 3.34 4 (6)	.755
BF	0.04 ± 0.21 0 (0)		0.77 ± 0.77 1 (1)		0.93 ± 1.11 0 (2)		1.20 ± 1.27 1 (2)		1.57 ± 1.65 1 (3.5)		4.52 ± 3.82 4 (8.5)	

Abbreviation: Ref = reference variable.

*P-value < .05.

for primary teeth to increase its replication regardless of specific equipment availability.

One of the most important factors that should be considered within the indications for pulp treatment of extensive decayed teeth is the behaviour of the child. Pulpectomy in primary molars is a difficult procedure that requires patient cooperation,[23] since the mean entire treatment time for a pulpectomy to be performed can range from 45 to 70 minutes (including local anaesthesia, rubber dam placement, chemomechanical preparation, obturation, and final restoration). For this reason, the study included only cooperative children.

Clinical studies have suggested favourable results for SSCs on primary molars as an alternative to intracoronal restoration for restoring primary molars with extensive caries[24] and enamel defects, following pulp treatments[1]; however, some dentists still have concerns regarding its use, mainly because of poor aesthetics associated with SSCs.[25] This concern about the patents and child acceptance appears unfounded in our population as no difference was found in acceptability between the two treatment groups, and the overall acceptance scores of children and their-parents towards restoration were good. Similar results were found in many studies comparing the SSC with aesthetic materials for indirect pulp capping, pulpotomy, and dentine caries treatment.[26]

The acceptance is reported in the literature in many different ways: Investigation into the acceptance of various restorations has used various approaches; questionnaires, interview, dentist opinions, and open questions to the children and parents.[9,25] The questionnaire used in this study compiles all the aspects discussed in previous articles, in order to evaluate the opinion of both children and their parents regarding SSC and aesthetic restoration.[10]

The findings reported previously by the literature are heterogeneous. Akhlaghi et al[27] reported a low acceptance by parents (81% of the parents did not like the metallic crown appearance) but a high acceptance by children (77% of the children were happy with the iron tooth). Zimmerman et al[25] reported that most parents were concerned about the color of the SSC. Page et al[28] reported that almost 90% of the children were satisfied with the appearance of crown. Even though composite resin restoration has been considered the most popular material, Fishman et al found that African American children preferred SSC to composites. Bell et al reported that SSC parent and child acceptability was good, and most children thought the treatment process was not difficult.

Among the factors that may explain the different results on treatment acceptance are the economic and socio-cultural characteristics of the participants, questionnaire structure, and the child's age. The participants in this study were unable to pay for dental treatment at private dental clinics and sought treatment at free public health centres. Although the socio-economic status of participants was not evaluated in this study, it is extremely likely that all participants had high

caries experience and low socio-economic status. This factor may be responsible for the high acceptance of the treatment since participation in the research would guarantee the treatment of the child. In addition, all questions in the questionnaire had positive connotation and could have led to an interview bias for more positive responses. Future questionnaires may post questions in a more neutral format.

The structure of and use of the questionnaire should be performed with caution, as participants are notalways able to interpret the questions and respond appropriately. This factor may be influenced by the child's age, since younger children are less able to interpret the questions correctly than older ones, and this cognitive immaturity often makes it difficult for them to communicate verbally.[29] The influence of a childs age was evaluated to determine if acceptance responses could be influenced by the child's age, using two age groups (3-5 and 6-8 years). Interestingly, no difference was found regarding the age of children and their acceptance of treatment. Visibility of the restoration could also influence treatment acceptance since first molars are positioned more anteriorly and possibly lead to poorer acceptance; however, in our study, no difference also was found.

In our study, children's and parent's acceptance rates were high (appearance, acceptability, and experience of treatment) and did not differ between SSCs and BF. Thus, clinicians who have been reluctant to use SSC as a restorative approach post-pulpectomy may be encouraged by these findings.

5 | CONCLUSION

It is not possible to affirm that restorations of teeth with endodontic treatment performed with BF resin are non-inferior to restorations made by SSC; however, failures in BF restorations lead to a failure of the endodontic treatment. In terms of acceptance, both materials were well accepted by both children and their parents.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTION

Isabel Cristina Olegário conceived the ideas, collected the data, analysed the data, and led the writing. **Carmela Rampazzo Bresolin** conceived the ideas and collected the data. **Ana Laura Pássaro** conceived the ideas, collected the data, and reviewed the manuscript. **Mariana Pinheiro de Araújo** collected the data and reviewed the manuscript. **Daniela Hesse** collected the data, analysed the data, and drafted the manuscript. **Fausto Medeiros Mendes and Daniela Prócida Raggio** conceived the ideas, collected the data, and reviewed the manuscript.

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