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An investigator-blinded, 24-month, parallel-group, non-inferiority study to compare aesthetic restorations in primary anterior teeth in a paediatric dental clinic: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality-of-life problems related to the oral health of the child and their family. There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centred outcomes and even longevity of the restoration. Thus, this project aims to evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared with the effectiveness of conventional restoration.

Methods and analysis This study proposes to conduct a randomised clinical trial, composed of a sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified International Caries Detection and Assessment System (ICDAS) C+ score (active and extensive stage caries: ICDAS 5 and 6), with involvement of more than two surfaces. This sample will be divided into two experimental groups, both with selective removal of carious tissue: a group in which conventional restoration will be performed using opaque resins, and another group with monochrome resin with chameleon effect and polyvinyl crowns. The explanatory variables—gender, age, toothbrushing, use of fluoridated toothpaste and dental floss, and socioeconomic status—will be collected through a questionnaire with open questions. The progression of caries lesions after 24 months of follow-up will be considered as the primary outcome. Secondary outcomes will include tooth survival, longevity of restoration, quality of life, perception and satisfaction of the participants' parents/guardians.

Ethics and dissemination This protocol has been approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos (protocol number: 6.019.297. Approved 24 April 2023). Results will be submitted to international peer-reviewed journals and presented at international conferences.

Trial registration number NCT05875064.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study employs a randomised clinical trial design with random allocation and investigator blinding, ensuring a high level of scientific evidence and minimising selection and detection bias.
⇒ The trial may face challenges in maintaining participant adherence during the 24-month follow-up, potentially impacting the final sample size and the comprehensive assessment of secondary outcomes.
⇒ The use of self-reported questionnaires to collect socioeconomic and oral hygiene data may introduce response bias, affecting the accuracy of some explanatory variables.
⇒ The reliance on a single examiner for radiographic assessments is a potential limitation. Standardised radiographic criteria and periodic intrarater reliability will be performed to minimise bias.
⇒ One possible limitation relates to the fact that the comparison involves two different techniques performed with two different materials, which may lead to confusion about what contributes to a potential difference between the groups: the technique itself or the material used.

INTRODUCTION

Severe early childhood caries has been defined as the presence of one or more decayed, missing or filled primary teeth in children aged 71 months (5 years) or less.[1] Children who suffer from severe caries in childhood may affect their growth and development as

a result of nutritional problems. Subsequently, this may negatively affect the quality of life related to the oral health of the child and their family.[2 3] In addition, the interference of oral health in school performance and school attendance was proven, also with negative impact.[4]

Probably, all these negative impacts are related to the difficulty of chewing, phonation and pain that these patients are subject to.[2 3] In addition, there is aesthetic impairment, not only by the presence of cavitation in the anterior teeth, but in many cases these teeth are found with blackened tissue. This coloration, usually associated with the expulsivity of these lesions and the difficulty of managing children at a young age, makes the aesthetic-functional rehabilitation even more challenging. Furthermore, child behaviour poses a significant challenge when restoring anterior teeth in paediatric patients. Infants and preschool children often exhibit fear and limited cooperation during dental procedures, which can complicate treatment and require careful behaviour management strategies to ensure success.

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures.[5 6] Likewise, the development of new restorative materials that allow the use of thicker layers and unique colouration, promoting an effect called chameleon, mimics the colour of the tooth.[7]

The evidence about rehabilitation of anterior teeth is scarce and mostly comes from case reports or techniques not based on the philosophy of minimal intervention. Recent studies have explored the application of minimally invasive techniques for the restoration of anterior primary teeth, highlighting their potential for aesthetic and functional success. For instance, Zulekha *et al*[5] demonstrated that composite resin restorations in primary maxillary incisors provide satisfactory retention rates and aesthetics over 12 months. Similarly, Ozdemir *et al*[8] reported comparable performance between composite resin and preformed zirconia crowns in terms of clinical outcomes and parental satisfaction. Also, recent studies have examined the success rates and longevity of zirconia crowns in treating anterior primary teeth, demonstrating promising results.[9 10] Although long-term evidence in paediatric patients remains limited, these studies establish a foundation for the use of composite resin as a viable control group. This technique aligns with the philosophy of minimally invasive dentistry, focusing on preserving healthy dental structures while achieving functional and aesthetic rehabilitation. However, there are no studies that have compared two minimally invasive rehabilitative techniques for primary anterior teeth in terms of patient-centred outcomes or even restoration longevity.

METHODS

This protocol follows the SPIRIT[11]Standard Protocol Items for Randomised Trials recommendations, as displayed in table 1.

Hypothesis

The null hypothesis (H_0) for each primary and secondary outcome independently are:

Table 1 Schedule of enrolment, interventions and assessments of the study

	Study period						
	Enrolment	Allocation	Postallocation				Close-out
TIME POINT	$-t_1$	0	t_1	6mo	12mo	18mo	24mo
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Conventional restoration			X				
Polyvinyl crowns			X				
ASSESSMENTS:							
Socioeconomic, habits questionnaire	X	X					
Caries lesions progression				[redacted]			
Tooth survival				[redacted]			
Longevity of restorations				[redacted]			
OHRQoL			X	[redacted]			
Perception and Satisfaction of parents			X	X			

mo, months; OHRQoL, Oral Health-related Quality of Life.

H0 for caries lesion progression (primary outcome): polyvinyl crowns are inferior to conventional restorations in preventing the progression of caries lesions after 24 months.

H0 for restoration longevity (secondary outcome): polyvinyl crowns are inferior to conventional restorations in the survival rates of restorations after 24 months.

H0 for patient-centred outcomes (secondary outcome): polyvinyl crowns are inferior to conventional restorations in terms of parental perception, satisfaction or quality-of-life impact.

Confidentiality

The confidentiality of participants will be strictly maintained through the use of identification code numbers. Participant identifiable information will be stored securely in locked filing cabinets within a restricted-access room. Medical information will only be accessible to the dental team.

Ancillary and post-trial care

On completion of the study, participants will continue to receive dental treatments as needed in our dental clinics, ensuring continuity of care beyond the trial period.

Objective

The aim of this study is to evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared with the effectiveness of conventional restoration.

Trial design

A randomised controlled clinical trial with two parallel arms, with an allocation ratio of 1:1 will be designed. A sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified International Caries Detection and Assessment System (ICDAS) C+ score (active and extensive stage caries: ICDAS (5 and 6)),[12] with involvement of more than two surfaces will be divided into two experimental groups: a group in which conventional restoration will be performed using opaque resins, and another group with monochrome resin with chameleon effect and polyvinyl crowns, both after selective removal of carious tissue.

Participants

The children will be randomly selected from a pool of enrolment forms of children (12–60 months) who seek dental care at the Pediatric Dentistry clinic of Universidade Metropolitana de Santos (UNIMES).

Inclusion and exclusion criteria

Inclusion criteria

Children with ages ranging from 12 to 60 months with at least one active cavitated caries lesion involving more than two surfaces (C+ score)[12] in deciduous upper incisors will be included.

Exclusion criteria

Patients with special needs, with general health conditions that may affect the oral cavity and whose guardians do not sign the Inform Consent Form will be excluded. In addition, children having teeth with pulp exposure, spontaneous pain, mobility, presence of swelling or fistula near the tooth and teeth with previous restorations; less than two-thirds of root (radiographically assessed), teeth without an antagonist, and teeth with previous restorations and children with bruxism and/or deep bite will also be excluded.[8]

Participant timeline

Each participant is enrolled in the study for about 25 months in total (1-month RCT—diagnosis and treatment, followed by a 24-month observational period). Table 1 shows participant timeline. The planned start date will be November 2024 and end date will be November 2026.

Sample size

To perform the sample size calculation with independent samples, it was considered that the retention of previous restorations of primary teeth is 80%[5] and that a clinically relevant difference of 10% (based on previous studies evaluating restorative longevity and caries progression in primary teeth[5 13]) and a non-inferiority limit of 5% are expected. Thus, considering a two-tailed test and adopting a significance level of 0.05 and a power of 0.80, we reached the number of 69 teeth per group. Since each child can contribute more than one tooth, we added 20% (cluster per child) and another 20% for a possible sample loss. Thus, a final required number of 97 teeth per experimental group was obtained, totaling 194 teeth for the study (https://www.sealedenvelope.com/power/binary-noninferior/).

Recruitment

Children with ages ranging from 12 to 60 months will be selected, who seek dental care at the Pediatric Dentistry clinic of UNIMES. Potentially eligible children will be referred for clinical examination.

Allocation: sequence generation

The participants will be selected from a pool of enrolment forms of children who looked for dental treatment in our school, using a sequence of random numbers generated by software by an external participant. The randomisation procedure will be done per blocks of different sizes. The randomisation will be done after the inclusion of the child.

Allocation concealment mechanism

Only at the time of the interventions will the generated sequences be known. These will be distributed in opaque envelopes and sealed to the operators. More than one tooth per patient may be included in the research, but all teeth included in the same patient will be treated with the same technique, but on different days to avoid patient fatigue and lack of cooperation.

Training and calibration of examiners and operators

There will be one examiner involved in the process of screening and two operators involved in treating patients, all specialists, PhD and professors in Pediatric Dentistry. The calibration will be carried out among the two operators to detect caries lesions, through the evaluation of photographs, and the decision whether or not to include the teeth in the research. The n used in this stage will be 10% of the total sample and we will calculate the kappa statistic to evaluate the agreement between the examiners.

These will be assisted by undergraduate students, who, in addition to clinical assistants, will be responsible for opening the treatment randomisation envelopes. Clinical outcomes will be evaluated by a specialist professor, MSc and PhD in Pediatric Dentistry not involved in inclusion and operative steps.

Implementation

The examiner who will perform the screening will have the initial x-ray, but will not have a part in the randomisation or treatment of the patients. The assistants, undergraduate students, will be responsible for opening the opaque brown envelopes. Then, the two operators will perform the treatments.

Blinding (masking)

The examiners who will evaluate the outcomes during the follow-up will be blinded regarding the allocation group.

Behavioural evaluation and management

Children's behaviour will be assessed using the Frankl Behavioral Rating Scale (FBRS) both before and after the dental procedures. The FBRS is widely recognised for its ability to categorise child behaviour into four levels: definitely negative, negative, positive and definitely positive, allowing for a standardised assessment of cooperation during treatment.[14] This evaluation will provide a baseline for behavioural tendencies and a measure of improvement or deterioration following treatment.

Behaviour management strategies

Considering that the study involves infants and preschool children—who may exhibit limited cooperation due to fear or unfamiliarity with dental settings—specific behaviour management strategies will be employed to ensure effective and minimally stressful treatment. These strategies include:

Tell-Show-Do technique: a step-by-step explanation of the procedure, demonstration using nonthreatening instruments and gradual introduction of the actual procedure to build trust and reduce anxiety.[15]

Positive reinforcement: use of verbal praise or small rewards (eg, stickers or toys) to encourage cooperative behaviour during the session.[16]

Parental presence: in cases where additional comfort is needed, caregivers will be allowed to stay in the operatory room to provide reassurance, minimising the child's distress.[15]

Behavioural management strategies will be adapted to the individual needs of each child, considering their developmental stage and initial behaviour as determined by the FBRS assessment.

These measures align with recommendations from the American Academy of Pediatric Dentistry (AAPD), emphasising the importance of creating a positive dental experience for young children while facilitating successful completion of dental procedures.

Interventions

Initially, a clinical examination will be performed in a dental office using a reflector, a mirror, tweezers and a WHO probe, after prophylaxis, by the operators. For this evaluation, the diagnostic criterion used will be the ICDAS.[17]

Treatments for the control of caries lesions

All teeth with caries lesions will be treated according to the philosophy of selective removal of carious tissue, differing only in the restorative technique. The teeth allocated in the conventional restoration group (control) will receive restorations in resin composed by incremental technique, using opaque resin. For this, 37% phosphoric acid (Condac37, FGM Dental Group) will be applied for 15 s in enamel and 7 s in dentin, and then, after washing and relative drying of the surface, with an etch-and-rinse approach, followed by the application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire dental surface, photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 s (Radii Xpert, SDI, peak 1500 mW/cm^2). The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The teeth allocated in the experimental group will have the restorations carried out through monochromatic composite resin with a chameleon effect in a single insertion through a polyvinyl crown. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 s in enamel and 7 s in dentin, and then, after washing and relative drying of the surface, application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire tooth surface, photoactivation of the adhesive and adaptation of the crown matrix in acetate filled with resin in the tooth. Photoactivation will be done for 20 s per dental face, and the acetate matrix is then removed. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The remaining teeth identified with caries lesions that are not included in the research will be treated according to the diagnosis by the researchers involved in this study. If there is a need for more complex procedures, patients will be referred for specialised treatment.

Follow-up visits

The patients who have been selected will undergo reassessment at 6, 12, 18 and 24 months after the commencement of treatment. During the time between these consultations, various strategies will be employed to ensure strong adherence and return rates, including (1) scheduling consultations at the most suitable times, (2) maintaining telephone contact with the caregivers, (3) providing an active cell phone for unforeseen circumstances and (4) offering gifts to children at the conclusion of each consultation.

Throughout the 24-month duration of the study, the research participants will be continuously monitored by the responsible professionals. If any additional treatment is required, the child will receive comprehensive support without any negative impact.

Outcomes

The explanatory variables, including gender, age, toothbrushing habits, fluoride toothpaste usage and dental flossing, will be gathered using a questionnaire that consists of open-ended questions. Additionally, a socioeconomic questionnaire consisting of closed-ended questions will be administered. To ensure participant confidentiality, each individual will be assigned an identifying number. The time spent on the treatments will be timed by the auxiliary from the beginning to the end of the polishing to compare the durations of both techniques.

The primary outcome of this study will be the progression of caries lesions through clinical criteria and longevity of restorations after a 24-month follow-up period. Secondary outcomes will encompass progression of caries lesions by radiographic criteria, change in the perception of parents/guardians, change in the satisfaction of parents/guardians and change in the impact of treatments in children's oral health-related quality of life.

The examination of the reported outcomes will be conducted by paediatric dentists who are not involved in the treatments performed and have received appropriate training. These examiners will evaluate the outcomes in a blinded manner.

Assessment of progression of caries lesion by radiographic criteria

For assessing caries progression, the modified periapical radiographic examination for preschoolers will be employed. The radiographic protocol will involve the use of E-speed children's film (E-speed, 22×35 mm, Eastman Kodak, Rochester, USA), a 0.4 s exposure time, and the Spectro 70X device. The bisection technique will be used for radiographic measurements of anterior teeth in preschool children, accompanied by the use of an apron and lead collar for radiation protection. The films will be processed either manually using the time/temperature method (with a temperature of approximately 27°C, developer solution for 2 min, fixative solution for 10 min and water washing for 20 min) or digitally. A total of six radiographic images will be taken per patient: one before the restorative procedure, one for screening, one immediately after the procedure and subsequent follow-up images at 6, 12, 18 and 24 months. The images will be compared in pairs to determine whether there has been any progression of caries, assessed by a trained and calibrated senior researcher, without the aid of any magnification loops and while blinded regarding the chronological order of the radiographs.

a. Absent progression: no increase in the radiolucent area of the lesion.
b. Progression present: increase in the radiolucent area of the lesion.

Teeth demonstrating caries lesion progression with signs of pulp involvement will be treated accordingly with restorative or endodontic procedures appropriate for the observed condition.

Radiographic outcomes: the presence or absence of radiolucency in the periapical region, progression of caries and assessment of root resorption associated with physiological exfoliation. These outcomes will be assessed at 6, 12, 18 and 24 months, ensuring comprehensive follow-up data.

Assessment of progression of caries lesion through clinical criteria and longevity of restorations

During the follow-up visits at 6, 12, 18 and 24 months, a visual clinical examination will be conducted to assess the condition of caries lesions and the longevity of restorations. This examination will involve inspecting the restoration's integrity and its adaptation on all dental surfaces, and identifying any potential issues such as structural fractures, resin wear, maladaptation or functional maintenance problems with the restored tooth.

The clinical evaluation of restoration retention will be performed at 6, 12, 18 and 24 months, using the criteria described by Pardi et al.[13]:

- RT (total retention): complete preservation of the restoration.
- PP1 (partial preservation 1): the presence of resin in two-thirds of the surface of each dental face.
- PP2 (partial preservation 2): the presence of resin in one-third of each face of the dental surface.
- PT (total preservation): complete loss of resin on the surface of the dental face.

Furthermore, the degree of tooth mobility and its correlation with the normal exfoliation period will be assessed in teeth from both groups. The teeth will be clinically assessed by the examiner in accordance with the ICDAS criteria for CARS as suggested by the ICDAS Coordinating Committee[17]: (0) sound tooth surface with restoration or sealant, (1) first visual change in enamel, (2) distinct visual change in enamel/dentin adjacent to a restoration/sealant margin, (3) carious defects of <0.5 mm with the signs of code 2, (4) marginal caries in enamel/dentin/cementum adjacent to a restoration/sealant with underlying dark shadow from dentin, (5)

distinct cavity adjacent to a restoration/sealant and (6) extensive distinct cavity with visible dentin.

Radiographic evaluation of dental exfoliation and tooth survival will involve examining the amount of absorbed deciduous tooth root in the radiographs taken at 6, 12, 18 and 24 months, comparing them with the initial radiograph. Clinical outcomes: the association between exfoliation and/or the maintenance of restorations without extensive structural failures, such as marginal integrity, absence of recurrent caries and restoration retention, will determine the success, or absence of caries progression, of restoration longevity and tooth survival in the restored tooth. These outcomes will be assessed at 6, 12, 18 and 24 months, ensuring comprehensive follow-up data.

Perception of parents/guardians

To evaluate the parents' or guardians' perception of the treatment received, the 'Child's and Parent's Questionnaire about Teeth Appearance'[18] will be administered immediately after the first treatment session and again after 6 months of treatment. The examiners will provide guidance to ensure an honest expression of their opinions.

Satisfaction of parents/guardians

Parents or guardians will be asked about their satisfaction with the treatment provided to their child after 6 months of treatment. The examiners will guide them to provide their genuine opinions.

As parental satisfaction and perception are prone to bias, the parents/guardians will be blinded to the intervention performed. They will not be informed whether their child received a conventional composite restoration or a polyvinyl crown. Additionally, satisfaction and perception will be evaluated using validated questionnaires with structured Likert-scale questions to standardise responses and minimise reporting bias.

Quality of life

A questionnaire, specifically the validated Brazilian version of the Early Childhood Oral Health Impact Scale,[19] will be used to assess the impact of the treatments on the oral health-related quality of life of children. The parents or guardians of the participants will complete this questionnaire during the initial consultations and at each follow-up visit.

Data collection methods

Data collection and returning assessments will be made by researchers who have experience in clinical research. They will be blinded to group allocation, and they will be the same examiners at all time points for each participant to minimise interobserver variability.

Data management

The clinic data will be directly entered into predesigned sheets to ensure efficient data management. To maintain data quality, validation checks will be conducted, which will include identifying missing data, out-of-range values, illogical responses and invalid entries.

Statistical analysis

The efficacy of each treatment will be evaluated through three primary outcomes:

1. Control of cavitated active lesions: Kaplan-Meier survival analysis will be used to estimate the probability of lesion control over time, with the log-rank test employed to compare survival curves between the two groups. The absolute risk difference will be calculated to quantify the difference in lesion control rates, with a 95% CI reported.
2. Longevity of restorations: Kaplan-Meier survival analysis will also be used to evaluate restoration longevity, with comparisons made using the log-rank test. Cox regression analysis will be performed to assess the influence of additional variables on restoration longevity. The absolute risk difference and its 95% CI will be provided to highlight the comparative effectiveness of the treatments.
3. Patient-centred outcomes: for comparing patient-centred outcomes between the two groups, the Student's t-test will be used for normally distributed data, while the Mann-Whitney U test will be applied for non-normally distributed data. The absolute risk difference for patient-centred outcomes will also be calculated, and a 95% CI will be reported.

For all statistical analyses, the significance level will be set at 5%.

Data monitoring

Since adverse events related to dental treatments are unlikely, there is no Data Monitoring Committee. However, independent oversight of the collection, management and analysis of trial data will be carried out by TG (name of person/organisation responsible). TG, as the chief investigator, holds overall responsibility for the study and acts as the custodian of the data.

Harms

The procedures performed will follow the biosafety standards and will be performed by a trained professional, so no damage is foreseen. The possible risks are minimal and the same as any restorative procedure, such as discomfort during the placement of cotton and application of resin.

Auditing

The entered data will be audited on a monthly basis by the coordinator. Data queries will be raised as necessary, and any discrepancies identified will be promptly corrected and systematically recorded.

DISCUSSION

Until now, no randomised clinical trial has been conducted to compare conventional restorations and the use of polyvinyl crowns in primary anterior teeth with extensive caries lesions. Symmetry plays a pivotal role

in the aesthetic success of anterior teeth restorations, particularly in central incisors. Restorations must achieve harmonious proportions and balance to mimic the natural dentition. Techniques that simplify this process, such as polyvinyl crowns, aim to enhance symmetry while reducing operator variability.[20] With the expected results, we aim to provide clinical evidence for a better treatment decision by the paediatric dentist. Currently, research has focused on testing different restorative materials, but only case reports address the different possible techniques for restoring these teeth. Considering that the two techniques that will be tested start from the same assumption of selective removal of carious tissue but are conducted with a different step-by-step procedure it becomes important to verify if there is any better technique. Given that one of the techniques involves the restoration in a single increment of resin, through the polyvinyl crowns, probably its execution time will be faster, but will the quality and longevity of the restoration be similar to the conventional technique? To the best of our knowledge, this is the first randomised clinical trial to compare the two rehabilitative techniques of primary anterior teeth affected by extensive caries lesions.

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