

**Study Title: A comparison of anterior pediatric zirconia crowns and bonded
composite resin strip crowns: one-year feasibility study**

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Background

Bonded composite resin strip crowns (strip crowns) are routinely used by pediatric dentists to restore carious primary incisors.⁷ Advantages of strip crowns include: good esthetics, ease of repair, ability to restore crowded incisors, and the availability of various shades.^{5, 6} Unfortunately, strip crowns are technique sensitive and intolerant to moisture contamination from saliva or blood during placement.^{5, 6} Furthermore, shade mismatch, unaesthetic crown contours, loss of composite resin, marginal defects and marginal gingivitis have been reported at follow-up.⁹ Parents reported overall good satisfaction for strip crowns, regardless of their dissatisfaction for color, shape and appearance, but reported overall poor satisfaction when their child's strip crown was lost.⁸ Retention rates of 49% at 6 months¹, 70% at 6 to 27 months², 78% at more than 3 years⁹, 85% at 6 to 24 months⁴ and 88% at an average follow-up of 18 months were reported in the literature. However, retention was not consistently defined in those studies. Times to failure were also incorrectly depicted due to the unclear follow-up protocols in those studies.

In 2008, zirconia crowns were introduced to pediatric dentistry as an alternative restorative option.⁷ Purported advantages of the pediatric zirconia crowns included: excellent esthetics, resistance to fracture, biocompatibility, reduced plaque accumulation, color stability, and potentially less technique sensitivity.^{5, 7, 10, 12, 13} Excellent esthetics were reported by clinicians and parents.¹⁰ Resistance to fracture was measured in vitro, using an inappropriate model that did not represent physiologic forces applied to teeth.^{12, 13} Biocompatibility and reduced plaque accumulation were found to be due to the polished surface of zirconia crowns leading to less gingival inflammation, when compared to veneered stainless-steel crowns.^{10, 15} Color stability

was reported but not measured, being visually compared to natural adjacent teeth.¹⁰ The statement of decreased technique sensitivity was questionable, as zirconia crowns need to be cemented with glass ionomer cements, which are sensitive to moisture contamination. Those conjectured advantages of zirconia crowns were supported by studies with little validity due to extensive exclusion criteria, unsatisfactory sample sizes, unreproducible protocols or unclear data collection criteria.

One of the demonstrated disadvantages of the zirconia crowns compared to strip crowns was increased tooth reduction necessary, due to its inflexibility and thickness, in order to fit the zirconia crown to the tooth.⁷ The amount of tooth reduction required for zirconia crowns was demonstrated in vitro using typodont teeth, weighted before and after tooth reduction. Anterior zirconia crowns required more than double the amount of tooth structure reduction, when compared to anterior stainless steel crowns.⁷ Furthermore, limited shade selection, limited potential to alter the shape of the crown, and the cost per crown represented additional potential disadvantages of zirconia crowns.^{5, 7, 10}

Pediatric zirconia crowns have a reported survival outcome ranging from 80.2% to 100% at 6 to 30 months.^{10, 11, 14, 15, 16} Literature on primary zirconia crowns is limited to retrospective studies, case reports, one prospective study and one randomized control trial. The lowest survival rate (80.2%) was found at 24 months in a prospective study using an unconventional restorative method. In that study, one operator restored maxillary primary incisors that were deemed non-restorable with conventional techniques.¹⁴ No details were given in regard to the definition of “conventional techniques”. Severely degraded primary maxillary incisors were included in the

study after parents requested treatment rather than extraction. The incisors were treated with a method using glass ionomer (Fuji IX) post and core following pulpectomy, and then restored with zirconia crowns. This same study revealed a survival rate of 95.3% at 12 months.¹⁴ Survival was defined as presence of the zirconia crown. As this method does not mimic clinical reality, zirconia crowns potentially present a retention rate of 96 to 100% at 6 to 30 months, according to the current literature representative of clinical practice.^{10, 11, 12, 15, 16} With always only one time point included during the follow-up of the investigations, these studies provide an incomplete picture of time to failure. Once again, retention was not consistently defined in studies.

To date, only one randomised controlled trial comparing full coronal coverage restorations for primary maxillary incisors (pre-veneered stainless steel crowns, bonded resin composite strip crowns and zirconia crowns) has ever been performed. In this randomized controlled trial, 39 healthy patients underwent dental treatment done by 3 trainees of unspecified level, using local anesthetic and physical restraint only. Teeth requiring pulp therapy secondary to carious exposure or trauma were excluded from the clinical trial, as were teeth in children requiring sedation, special needs patients, patients with a deep bite, bruxism or presenting signs of attrition on lower incisors. The results showed a retention rate of 100% for zirconia crowns at 6 months, followed by 95% for pre-veneered stainless-steel crowns and 78% for bonded resin composite strip crowns.¹⁵ The strict exclusion criteria limited the validity of the study, as it may not represent clinical practice.

Despite the apparent increase in popularity of the zirconia crowns in the practice of pediatric dentistry, studies examining their clinical outcomes are extremely variable as they are based on

expert opinions, case reports, retrospective studies and one randomised controlled trial of questionable design. This indicates the lack of good scientific evidence to justify the clinical use of zirconia crowns. To assess the clinical outcome of pediatric zirconia crowns and to provide evidence-based treatment, a prospective, well controlled study would be beneficial. Due to a lack of existing outcome data for bonded resin strip crowns and zirconia crowns, a feasibility study is indicated to establish the basis for randomized controlled trial design. The goal of this feasibility study is to compare the clinical outcomes of the zirconia crowns and bonded composite resin strip crowns in primary maxillary incisors.

Aims

1. To statistically compare the one-year survival of resin composite strip crowns and zirconia crowns in primary maxillary incisors.
2. To statistically compare the frequency of pulp therapy required for placement of zirconia crowns and resin composite strip crowns in primary maxillary incisors.
3. To measure the frequency at which teeth randomized to zirconia crowns are deemed restorable with strip crowns only, and not zirconia crowns.

Null hypotheses

1. There is a statistically significant difference between the one-year survival of resin composite strip crowns and zirconia crowns in primary maxillary incisors.

2. There is no statistically significant difference between the frequency of pulp therapy required for placement of zirconia crowns and resin composite strip crowns in primary maxillary incisors.
3. The frequency at which teeth randomized to zirconia crowns are deemed restorable with strip crowns only, and not zirconia crowns, is 0.

Alternative hypotheses

1. There is no statistically significant difference between the one-year survival of resin composite strip crowns and zirconia crowns in primary maxillary incisors.
2. There is a statistically significant difference between the frequency of pulp therapy required for placement of zirconia crowns and resin composite strip crowns in primary maxillary incisors.
3. The frequency at which teeth randomized to zirconia crowns are deemed restorable with strip crowns only, and not zirconia crowns, is greater than 0.

Materials and methods

Eligible children will meet the following inclusion criteria: i) 18 to 48 months of age, ii) ASA I and ASA II who will receive treatment under general anesthesia at The Hospital for Sick Children, and iii) one or more carious or fractured primary maxillary incisors that require full coverage restoration based on clinical judgement and criteria listed below.

Inclusion criteria for zirconia crowns and strip crowns are the same: ¹⁶

1. Incisors with large carious lesions not restorable with intra-coronal restorations
2. Incisors that have received pulp therapy
3. Incisors that have been fractured and have lost an appreciable amount of tooth structure
4. Incisors with multiple hypoplastic defects or developmental disturbances
5. Incisors with small interproximal lesions with large areas of cervical decalcification

Incisors will be ineligible if i) patient is ASA III or higher, ii) associated with signs and symptoms of irreversible pulpitis and/or clinical evidence of an odontogenic infection, iii) there is radiographic evidence of pathological root resorption, root fracture secondary to trauma or periapical radiolucency, iv) lacking adequate dental coronal structure to allow restoration with full coverage restoration, and v) patient has non-English speaking parents.

Prior to commencement of the project, one of the investigators (SL) will review screening and eligibility criteria with the Department of Dentistry at The Hospital for Sick Children. Clinical staff in the Department of Dentistry will identify potentially eligible patients during regular ambulatory clinic scheduling of patients for oral care in the OR.

The department research coordinator will obtain consent from prospective patients to participate in the research project. The treating pediatric dentists (EJB, MJC, GG) will confirm continuing consent on the day of the treatment under general anesthesia.

After induction of general anesthesia, following the confirmation of incisor restorability by the treating dentist, each study participant will be randomly allocated to either the strip crown or the zirconia crown group. The assignment will be done using a computer-generated simple random number sequence with a one to one allocation ratio in a Research Electronic Data Capture (REDCap) database . The treatment will be consistent for each patient for all eligible teeth, although the experimental unit is the incisor. If one of the incisors in one patient is deemed non-restorable, this incisor will no longer be eligible for the study. If all of the incisors in one patient are deemed non-restorable, the patient will no longer be eligible for the study.

The treating dentists are staff pediatric dentists at The Hospital for Sick Children. Training in zirconia crown technique will be provided by the manufacturer of the crowns used in this study. As the strip crowns are the current standard full coverage restoration provided for primary incisors, and the treating dentists all have similar education and experience, additional training for strip crowns will not be required.

The restorative techniques will be carried out under general anesthesia, in the usual fashion for the strip crowns (Appendix 1), and following the manufacturer's protocol for the zirconia crowns (Appendix 2).

Commonly, four maxillary incisor teeth are affected by severe early childhood caries. Due to the nature of this study sample, i.e. pre-cooperative children with severe early childhood caries, tentative treatment plans are made prior to treatment in the operating room (OR). Radiographic

and clinical examinations are completed in the OR while the patient is anesthetized, and the treatment plan is finalized at that time. Therefore, on occasion, teeth that were planned to be restored with crowns at the ambulatory consultation, may be deemed non-restorable in the operating room regardless of the treatment group that they were randomized into. These teeth would be withdrawn as they will not receive crowns of either type.

When a tooth is restorable with a crown, it may also require pulp (nerve) treatment if dental caries extends to the dental pulp. Pulp outcomes are largely independent of the restoration placed on the incisor. If the pulp treatment fails during the follow-up period (a small risk), the consequence would be odontogenic infection and extraction of the affected tooth is indicated, even if the restoration is intact. Any remaining crowned incisors that are enrolled will continued to be followed in a child who loses a tooth to pulp therapy failure.

Failure of a crown (fracture of the crown, dislodgement of the crown, etc.) will be documented as a treatment failure. The family will be offered replacement of the crown and not withdrawn from the investigation. The remaining crowned incisors will be followed for the study duration. All crowned incisors will be kept in the study and followed for outcomes unless the patient chooses to withdraw.

Each research participant will be reassessed clinically at 6 and 12 months after treatment.

Follow-up appointments will be scheduled by the department of Dentistry. Clinical reassessment will be conducted by one investigator (SL). Intra-oral photographs will be acquired at 6 months and at 12 months. All photographs will be taken by the same investigator (SL), using a standardized imaging format. Two photographs per patient will be acquired: one extra-oral photograph, limited to the maxillary right cuspid (tooth 53) to left cuspid (tooth 63); and one extra-oral maxillary occlusal photograph, limited to the maxillary right cuspid (tooth 53) to left

cuspid (tooth 63) (Appendix 3). Photographs will be taken with a Canon Rebel XSi and a Canon ring flash Macro Ring Lite MR-14EX II, using the following settings: shutter speed 1/200, ISO 200 and aperture f25. Photographs will be stored in the Hospital for Sick Children's online photograph database (Apollo).

Parents will also take 2 photographs of their child's using their own camera or phone. They will be provided with an example of those photographs (Appendix 4). Photographs found in appendix 4 were taken with an iPhone X. They will send the photographs to the investigators via a secured Sickkids e-mail. Only the research investigators and the research coordinator will have access to the secured e-mail. Pictures sent by the parents will be stored on Appollo. A reminder to take the pictures at 6 and 12 months after the surgery will be sent using the secured e-mail. Photographs taken by the parents will be used for the photographic assessment if clinical photographs are unsuccessful at the follow-ups and if they are of sufficient quality for assessment based on the investigators' judgment.

If the parents and the investigators cannot obtain photographs of a participant, the participant will no longer be eligible for the survival assessment.

Clinical assessment, photographic assessment and data collection

Treated incisors will be assessed for survival and clinical outcomes on a number of clinical criteria. The outcomes are as follows:

1) Survival outcome

Clinical assessment

Clinical assessment will be conducted by one investigator (SL), at the time of the follow-up appointments. The investigator will be a pediatric dental resident. She will clinically assess the incisors for restoration survival. The survival outcome measures will be statistically compared. The assessed criteria are: presence of the tooth (teeth lost prior to general anesthesia or during general anesthesia will be excluded from statistical analysis), presence of the restoration, integrity of the restoration, recurrent decay and discoloration. Each incisor will be classified as follows (Appendix 5):

I: Intact

D: Damaged; restoration present but not intact, clinically acceptable (minor chip of material, discoloration due to leakage); no immediate treatment recommended

TR: Treatment required; restoration absent or restoration present with major failure or presence of recurrent decay on restored incisor; re-treatment or extraction required

Photographic assessment

Photographic analysis will be conducted by two blinded disinterested expert raters. They will be two staff pediatric dentists. They will assess the photographs for restoration survival. Expert raters will be subjected to measures of intra-rater and inter-rater reliability. The survival outcome measures will be statistically compared. The assessed criteria are: presence of the tooth (teeth lost prior to general anesthesia

or during general anesthesia will be excluded from statistical analysis), presence of the restoration, integrity of the restoration, recurrent decay and discoloration. Each incisor will be classified as follows (Appendix 6):

I: Intact

D: Damaged; restoration present but not intact, clinically acceptable (minor chip of material, discoloration due to leakage); no immediate treatment recommended

TR: Treatment required; restoration absent or restoration present with major failure or presence of recurrent decay on restored incisor; re-treatment or extraction required

2) Frequency of pulp therapy

On the day of treatment under general anesthesia, the treating dentist, the dental assistant or the nurse will fill out the pulpotomy data collection form. Each treated tooth will be marked as having received a pulpotomy (**P**), or not having received a pulpotomy (**X**) (Appendix 7).

3) Treatment plan alteration

On the day of treatment under general anesthesia, the treating dentist, the dental assistant or the nurse will fill out the restorative treatment data collection form. Each form will be filled with the randomly assigned treatment and the completed treatment: zirconia crowns (**ZC**) or composite resin strip crowns (**CRSC**). The following questions will also be answered on the form (Appendix 7):

- Did the patient receive the restorative treatment originally assigned?

- Yes
 - No
- Deviated from randomly selected treatment because:
 - Severe attrition (bruxism)
 - Deep bite
 - Crowding
 - Other

Storage of patient information

Participants will be assigned to a unique study identification number. A password-protected code-breaking file that corresponds to each unique identification number with patient's identity name, DOB and MRN will be created. This file will be only accessible by the research investigators and the research coordinator. It will be stored separately from the study database. All study participants paper data collection forms and consent forms will be stored in individual participant research study charts, separate from the clinical charts. The charts will be kept in a locked filing cabinet in a locked office. Each participant's chart will be labeled by the individual study identification number and have no patient identifiers. All collected data will be entered and stored in a REDcap database, on a password-protected computer, in a locked office. The data entered in the database will be de-identified by using only the unique study identification number to enter each patient's data. The REDcap database will only be accessible to the research investigators and the research coordinator. The collected patient data entered into the REDCap database will include:

1. Date of initial examination
2. Participant demographics: age and sex
3. Number of carious maxillary incisors included in study
4. Date of general anesthesia
5. OR pulp data collection
6. OR treatment data collection
7. Date of first and second recall
8. Photographic data collection
9. Date of extraction of incisor and reason, if applicable

Upon the conclusion of data collection, the data will be exported into an Excel spreadsheet for statistical analysis.

Statistical Analysis

Statistical analyses will be performed using SPSS. All treated teeth will be included in statistical analyses. A general estimating equation will be used to compensate for the lack of independence. The two groups will be statistically compared for sex distribution with a chi-square test and for age at the time of treatment with a sample t test. Logistic regressions will be corrected for age, sex, tooth and provider, and their effect will be compared with chi-square tests. A sample size calculation will be done to assess feasibility of a future randomized controlled trial.

Outcomes analyses:

1. Survival outcome

Expert raters will be subjected to measures of intra-rater and inter-rater reliability, using Cohen's kappa test. The outcome measures will be statistically compared. Chi-square tests will be used to compare **I**, **D** and **TR** outcomes for strip crowns and zirconia crowns. Difference in survival of strip crowns and zirconia crowns will be calculated with log-rank tests. Kaplan-Meier survival curves will be derived for strip crowns and zirconia crowns.

2. Frequency of pulp therapy

Frequency of pulp therapy for strip crowns and zirconia crowns will be compared using a chi-square test.

3. Frequency of treatment plan alteration

Frequency of treatment plan alteration will be demonstrated using a chi-square test.

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