A randomised controlled trial of three aesthetic full-coronal restorations in primary maxillary teeth

**ABSTRACT**

**Aim** This randomised clinical trial (RCT) compared the clinical outcomes of three aesthetic full-coronal restorations (composite strip crowns, pre-veneered stainless steel crowns (SSCs) and pre-fabricated primary zirconia crowns) in carious and traumatised primary maxillary incisors.

**Materials and methods** One hundred and twenty nine teeth in 39 children aged between 3 to 5 years were included. Children were randomly assigned to one of three treatment groups using a permuted block randomisation technique with a total of 43 teeth in each group. After trainee calibration, restorations were placed and evaluated after 6 months. Outcomes evaluated were restoration failure, tooth wear of opposing teeth and gingival health.

**Results** The retention rate was highest for zirconia crowns (100%) followed by pre-veneered SSCs (95%). Strip crowns were the least retentive (78%). Zirconia crowns showed low grade abrasion in four opposing teeth. Teeth restored with resin composite and pre-veneered SSC showed an increase in mean gingival index score, while corresponding values decreased in zirconia crowns.

**Conclusion** Resin composite strip crown is a highly sensitive technique leading to lower retention rate. Pre-veneered stainless steel crowns showed increased incidence of facial veneer fracture. Zirconia crowns are highly retentive and biocompatible but cause low grade of abrasion of their opposing natural dentition at the 6-month follow-up.

**Keywords** Aesthetics; Full-coverage restoration; Primary incisors.

**Introduction**

Early Childhood Caries (ECC) continues to be a public health problem of global proportions, which entails the early carious involvement of the primary maxillary incisors followed by the maxillary and mandibular first primary molars and the mandibular cuspids [Wayne, 2001]. Aesthetic restoration of these carious or traumatised primary anterior teeth can be challenging especially due to their small size, close proximity of pulp, relatively thin enamel leading to lesser surface area for bonding as well as issues related to child behaviour and cost of treatment [Donly, 2002; Usha et al., 2007]. Nonetheless, it is essential to restore them in order to preserve the integrity of primary teeth until their exfoliation and eruption of permanent teeth [Mendes et al., 2004].

Numerous treatment approaches have been proposed to address the aesthetics and retention of restorations in these teeth. Intra-coronal tooth-colored restorations include glass ionomer cements, resin-modified glass ionomers (RMGI), polyacid-modified resins or resin composites. Full-coronal aesthetic restorations can also be used such as free-hand buildup of crown structure with tooth-colored materials like RMGI [Mandrolip, 2003] and composite, using celluloid strip crowns [Mendes et al., 2004], or ready-made crowns like pre-veneered stainless steel crowns [Usha et al., 2007], and the recently introduced pre-fabricated primary zirconia crowns. Each method of restoration has its own distinct advantages and disadvantages.

The aim of this clinical research was to evaluate and compare three aesthetic full-coronal restorations on primary maxillary central and lateral incisors over a period of 6 months in terms of restoration failure, abrasion on the opposing dentition and gingival response. The three restoration types included were Resin Composite Strip Crowns, Pre-Veneered Stainless Steel Crowns, and the newly introduced Pre-Fabricated Primary Zirconia Crowns.

**Materials and methods**

**Study design**

The design of this randomised controlled clinical trial followed the guidelines published by Consolidated Standards of Reporting Trials (CONSORT) [Schulz et al., 2010]. The study was approved by the Research Ethics Committee of the College of Dentistry, AUST (no. 12-02). Prior to enrollment, every child’s parent/guardian received and signed an informed consent form.

**Sample size**

Based on the primary outcome of restoration failure, and looking for a clinically important difference in proportion of restoration failures of 25% between groups (2-tailed alpha=0.05 and power of 0.80), a minimum of 35 crowns were required in each group,
totaling 105 teeth. Given the possibility of 10% attrition in subsequent follow-ups, an additional 24 teeth were included in the study ensuring 43 primary incisors in each group. Therefore, a total sample of 129 teeth was included at baseline. The subjects were allocated to one of the following groups.

- **Group A** (Fig. 2): Resin composite strip crowns (Pedoform strip crowns forms, 3M® St. Paul MN).
- **Group B** (Fig. 3): Pre-veneered stainless steel crowns (NuSmile® Pediatric Crowns, Houston, TX).
- **Group C** (Fig. 4): Pre-fabricated primary Zirconia crowns (Zirkiz® crowns, Hass, South Korea).

**Eligibility criteria and randomisation**

Forty six children/148 teeth were examined initially and 39 children/129 teeth were then selected who met the inclusion/exclusion criteria described in Figure 1.

Subjects selected had 3-5 years of age, enjoyed good general health, had the mandibular primary incisors present and showed carious primary maxillary incisors, with minimum of two surfaces involved, out of which one must be palatal caries and with DMFT of $\geq 3$ (WHO Index) [Federation Dentaire Internationale, WHO, 2006]; moreover, primary maxillary incisors requiring full coronal restoration following trauma involving enamel or dentine only; primary maxillary incisors with at least two third of the root length; adequate root support with no mobility. Children would to be managed by behavioral management techniques and physical restraint only.

Randomisation was done by a statistician using permuted block randomisation. Randomisation was conducted on children rather than individual teeth. Block sizes of three individuals were used. Each block consisted of children who required similar number of full coronal restorations. Therefore, a child who required multiple restorations was only entered in the study when two other children who required a similar number of restorations were available. Forty-three children were randomly assigned as per the permutation within each group; however children could not be randomised on the basis of their dmft status as it was difficult to find permuted blocks with similar number of children having the same dmft and number of teeth to be replaced. The distribution of 43 teeth in each group at baseline is shown in Table 1.

**Trainees’ calibration**

Prior to study initiation, three trainees were calibrated on tooth preparation and crown placement on 10 children, total of 21 crowns, 7 crowns for each group. In order to maintain consistency in restoration methods, each intern was evaluated by two specialists with regards to their clinical technique, and rated for each restoration prepared on a Likert scale from 1-5, 1 being not acceptable, and 5 being highly acceptable. The consistency in ratings between specialists for each trainee was also tested for consistency using the Kappa test. During the calibration for consistency in restoration methods, specialists consistently scored high ratings for the restorations by each intern, emphasised by a high Kappa score of 0.93. Each intern prepared only one type of crown. A general dental practitioner (GDP) was also selected and trained in evaluation of: restoration failure; abrasion in the opposing dentition (visual and photographical assessment method); gingival health of the restored teeth and; photographic technique. Ten percent of results of the 21 crowns (i.e. three crowns), were re-evaluated to confirm the reproducibility of the evaluation scores.

**Methods of outcome measures evaluation**

At baseline, only gingival health was measured, while at the 6-month follow-up, all three outcome measures were evaluated. The description of the criteria used to record the clinical parameters is shown in Table 2.

**Evaluation of restoration failure**

This was clinically evaluated with visual assessment of the restoration, according to the US Public Health Service “USPHS”, Alpha criteria rating system [Ryge, 1980].

**Evaluation of tooth wear on opposing teeth**

Tooth wear was evaluated according to the Smith and Knight Tooth Wear Index [Bardsley, 2008; Smith
and Knight, 1984]. The incisal and labial surfaces of the teeth opposing the full-coronal restorations were clinically observed for any sign of abrasion. In addition, photographs were taken with a Canon Digital SLR® camera using focus 1:3 frontal, teeth parted, 1/60 sec, f 22 and 1:1.5 frontal upper 1/60 sec, f 22 at baseline and at the 6-month follow-up.

**Evaluation of gingival health**
This parameter was evaluated using a blunt periodontal probe (Double ended probe Williams 1-2-3-5-7-8-9-10 Goldman Fox Flat) according to the Löe and Silness gingival index [Löe, 1967]. After the selection of correct crown size, proper isolation with rubber dam and local anaesthesia were achieved. Caries was excavated and in cases of very deep lesions, an application of a resin modified GIC liner/base (Viterbond, 3M-ESPE Dental products, St.Paul, Minn®) was applied for pulp protection. The tooth was prepared using a No. 330 carbide bur to reduce the incisal edge by approximately 1.5 mm and the interproximal contact opened. A coarse tapered round diamond bur was used to reduce the tooth both labially and palatally by 1-1.5 mm, followed by a fine tapered round-end diamond bur to smoothen the preparation and to refine it 1 mm subgingivally. The tooth preparation principles followed were similar in all three groups.

**Resin composite strip crown placement procedures**
After cutting the gingival margin of the celluloid crown form to achieve a good fit, the shade of the resin composite (3M, Filtek™Z250 Universal Restorative®) was chosen and squeezed into the celluloid crown form. The tooth surfaces were etched for 20 seconds with a 37% phosphoric acid solution (3M™ESPE™Etching Liquid®), and then the light cure bonding adhesive (3M, Scotchbond-Universal-Adhesive-Refill-Vial-41258®) was brushed onto the etched tooth surfaces. The celluloid crown then inserted and excess resin was removed and polymerised, followed by celluloid crown form removal. Finishing and occlusal adjustments were performed, if required, using polishing discs (3M ESPE, Sof-Lex® Polishing-Strip).

**Pre-veneered SSC placement procedures**
A trial fit of the crown was carried out after the tooth reduction ensuring that it did not sit more than 1 mm subgingivally. The shape and length modification of the crown was kept as minimum as possible in order to have a proper fit if required. Contouring and crimping of the lingual aspect was done. Final fit of the crown was confirmed and cemented with type II GIC (Ketac® 3M ESPE, St.Paul, Minn) applying digital pressure only.

**Pre-fabricated primary zirconia crown placement procedure**
After a trial fit of the crown, adjustments were done for labial and lingual borders only if required, with high-speed fine diamond bur under lot of water because excess heat could cause micro-fractures in the crown. Final passive fit of the crown was confirmed and cemented with type II GIC (Ketac® 3M ESPE, St.Paul, Minn).

**Statistical analysis**
Comparisons of the age of participants as well as

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>GRADES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restoration failure</td>
<td>0</td>
<td>Crown appears normal: no cracks, chips, or fractures</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Small but noticeable area of loss of material</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Large loss of crown material</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Complete loss of crown</td>
</tr>
<tr>
<td>Tooth wear</td>
<td>0</td>
<td>No loss of enamel surface characteristics, no loss of contour</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Loss of enamel surface characteristics, minimal loss of contour</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Loss of enamel exposing dentine for less than one third of surface, loss of enamel just exposing dentin, defect less than 1 mm deep</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Loss of enamel exposing dentin for more than one third of surface, loss of enamel and substantial loss of dentin, defect less than 1–2 mm deep</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Complete enamel loss, pulp exposure, secondary dentin exposure, pulp exposure or exposure of secondary dentin, defect more than 2 mm deep, pulp exposure, secondary dentin exposure IMMAGINO SIA COSI, NON SI CAPIVA COME LO AVEVANO SCRITTO</td>
</tr>
</tbody>
</table>

**Gingival Health**

<table>
<thead>
<tr>
<th></th>
<th>GRADES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>No obvious signs of inflammation</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Mild marginal gingivitis, tissue slightly reddened and edematous</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Moderate marginal gingivitis-tissue obviously reddened and swollen</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Severe gingivitis, tissue is very swollen: spontaneous bleeding</td>
</tr>
</tbody>
</table>

**TABLE 1** Distribution of 43 teeth in each group at baseline.

<table>
<thead>
<tr>
<th>NO. OF TEETH RESTORED PER CHILD</th>
<th>NO. OF CHILDREN IN EACH GROUP</th>
<th>TOTAL (43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
<td>28</td>
</tr>
</tbody>
</table>
baseline gingival health scores between groups were performed using a one way ANOVA and post hoc Tukey tests. Changes in gingival health within each group between baseline and 6 months were evaluated using paired sample T tests. Comparisons of change in gingival health between the three groups were also evaluated using a one way ANOVA and post hoc Tukey tests. Chi square analyses for proportions were applied to test for differences in restoration failure and tooth wear indices between groups at 6 months. Analyses were performed using the Statistical Package for Social Sciences (SPSS, versions 20.0.0 for Windows).

Results

Full-coronal restorations were placed on 129 primary maxillary incisors consisting of 66 central and 63 lateral incisors of 39 children (21 male, 18 female) (Table 3) The average age of children at the baseline was 4.5 years and dmft -5. There was a drop out of 6 children/18 teeth at the 6-month follow-up reducing the sample to 33 children /111 teeth.

Restoration failure

Two crowns each out of 36 resin composite strip crowns (group A) and 37 pre-veneered SSCs (group B) respectively had small but noticeable areas of loss of material, while 6 out of 31 resin composite strip crowns (group A) were completely lost after 6 months (Table 4). When comparing the 3 groups, there was a statistically significant difference between groups A and B (p=0.04) and between groups A and C (p=0.02) (Table 5).

Tooth wear of opposing dentition

Four opposing primary dentition of 38 pre-fabricated primary zirconia crowns (group C) had shown loss of enamel surface characteristics - minimal loss of contour which was statistically not significant but could be clinically significant. None of the resin composite strip crowns (group A) and pre-fabricated Zirconia crowns (group B) showed any sign of tooth wear. When comparing the tooth wear results between the groups,

<table>
<thead>
<tr>
<th>PRIMARY MAXILLARY INCISORS</th>
<th>COUNT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Lateral (52)</td>
<td>33 (26%)</td>
</tr>
<tr>
<td>Right Central (51)</td>
<td>32 (25%)</td>
</tr>
<tr>
<td>Left Central (61)</td>
<td>34 (26%)</td>
</tr>
<tr>
<td>Left Lateral (62)</td>
<td>30 (23%)</td>
</tr>
</tbody>
</table>

TABLE 3 Baseline data of teeth restored.

<table>
<thead>
<tr>
<th>OUTCOME MEASURES</th>
<th>GROUP A (N=36)</th>
<th>GROUP B (N=37)</th>
<th>GROUP C (N=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>grades</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Restoration failure</td>
<td>0 28 (78%)</td>
<td>35 (95%)</td>
<td>38 (100%)</td>
</tr>
<tr>
<td></td>
<td>1 2 (5%)</td>
<td>2 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>2 0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>3 6 (17%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Tooth wear</td>
<td>0 31 (100%)</td>
<td>32 (100%)</td>
<td>34 (90%)</td>
</tr>
<tr>
<td></td>
<td>1 0 (0%)</td>
<td>0 (0%)</td>
<td>4 (10%)</td>
</tr>
</tbody>
</table>

TABLE 4 Restoration failure and tooth wear results at the 6-month follow up.
there was no statistically significant difference between them at the 6-month follow-up (Table 6).

**Gingival health of the restored teeth**

At baseline there was no statistically significant difference in mean gingival health scores (MGI) between the groups. At the 6-month follow up, the mean was increased in group A and B, while in teeth restored with Zirkiz crowns (group C) the MGI score was significantly reduced ($p=0.01$). When comparing the difference in the mean gingival health between all groups, there was statistically significant difference only between groups A and C and B and C ($p=0.00$) (Table 6).

**Discussion**

Primary incisors have enjoyed less retention of intracoronal restorations with tooth colored materials such as composite, compomer and conventional or resin modified glass ionomer due to morphology of the pulp, dentin and enamel as reported by Waggoner [1994], Piyapinyo and White [1998] and Kopel & Beaver [1967].

**Composite strip crowns**

The success rate of these crowns in our study after 6 months was 78% and only behavior management techniques and physical restraints were used to manage the children. However, they were still uncooperative, restless and stressed during the treatment, which made moisture control inadequate for this highly technique sensitive restoration. Eidelman et al. [1997] reported better results for strip crowns placed by graduate students under general anaesthesia than for those done under sedation. General anaesthesia allows treatment to be rendered under theoretically optimal conditions; implying outcomes would be more successful. Success rate between 80% - 88% were found in the studies done by Waggoner et al. [2005]; Ram and Fuku [2006] and Kupietzky et al. [2003]. High failure rate of 51% over period of 2 years was seen in a study by Tate et al. [2002], where strip crowns were placed under general anaesthesia and endodontically treated teeth were included as well. Endodontic treatment can also affect the overall retention as these teeth are usually more destructed [Kupietzky et al., 2005].

**Pre-Veneered SSC**

Preveneered SSCs are a good restoration for anterior teeth with significant decay and do not require extensive additional chair time [Shah et al., 2004]. Long-term retention and resistance to fracture of the veneer has been shown to be somewhat low [Gupta et al., 2008]. The dentist is limited in the choice of resin shades, and the crowns are sometimes so white that they appear artificial [Croll and Helpin, 1996; Croll, 1998; Wickersham et al., 1998]. In the present study, only 5% of the NuSmile crowns failed. This occurred due to partial loss of composite veneer at the metal-resin interface which is machine compressed on the metal labial surface of the crown but they were never dislodged. Waggoner [1994] stated that breakage of the veneer is probably due to traumatic forces, and not incisive forces. Lin [2005] concluded in his study that, due to the physical properties associated with resin veneers over stainless steel, the resin has minimal flexure and can dislodge with the tensile and shear stress associated with typical mastication. A lower failure rate of these crowns in our study can also be attributed to the fact that children with increased overjet and overbite were excluded and secondly, they were followed-up for only 6 months.

**Pre-fabricated primary zirconia crown**

Current research on the clinical success of prefabricated primary zirconia crowns for primary incisors is limited. In the present study, the retention rate of Zirkiz crowns was 100% after 6 months. These monolithic crowns have no facial upper structure, as they are made up of solid zirconia leading to no chance of facial veneer fracture

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**TABLE 5**

Mean gingival health score of 3 groups at baseline & after 6 months.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Restoration failure</th>
<th>Tooth wear</th>
<th>Gingival health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A - B</td>
<td>0.04</td>
<td>NA</td>
<td>0.93</td>
</tr>
<tr>
<td>Group B - C</td>
<td>0.23</td>
<td>0.239</td>
<td>0.00</td>
</tr>
<tr>
<td>Group A - C</td>
<td>0.02</td>
<td>0.238</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**TABLE 6**

$p$-value of comparison between groups.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean gingival health (baseline)</th>
<th>Mean gingival health (6 months)</th>
<th>Difference in MGI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strip Crown</td>
<td>n 43</td>
<td>1.65 (0.50)</td>
<td>1.97 (0.44)</td>
<td>0.32</td>
</tr>
<tr>
<td>NuSmile Crown</td>
<td>n 43</td>
<td>1.71 (0.50)</td>
<td>1.95 (0.61)</td>
<td>0.24</td>
</tr>
<tr>
<td>Zirkiz Crown</td>
<td>n 43</td>
<td>1.67 (0.56)</td>
<td>1.35 (0.60)</td>
<td>-0.32*</td>
</tr>
</tbody>
</table>

* MGH score reduced over a period of 6 months
[Manicone et al., 2007]. The flexural strength of zirconia oxide materials has been reported to be in the range of 900 to 1,100 MPa. This is approximately twice as strong as alumina oxide ceramics currently in the market and 5 times greater than standard glass ceramics [Manicone et al., 2007]. Another important property is their fracture toughness making them perdurable and a highly strong restoration [Denny and Holloway, 2010].

**Tooth wear**

A slight tooth wear in natural dentition is considered normal [Warren et al., 2002]. If restorative dental materials have different wear properties compared to the natural teeth, they can affect the wear rate of antagonist natural teeth [Sulong and Aziz, 1990]. Therefore, wear occurring between enamel and dental restorations is an important factor that should always be considered in the selection of restorative materials in clinical practice [Delong et al., 1989]. Segheli et al. [1991] has suggested that a restorative dental material should have a wear degree similar to that of the enamel. There are different methods of tooth wear evaluation such as using a three-dimensional profiling system and ANSUR 3D software [Jung et al., 2010], but they are not easy to perform in children. Recent research from the University of Zurich also demonstrated that improperly polished and only glazed zirconia can be destructive to the opposing tooth structure [Donovan, 2008].

**Gingival health**

The increased mean gingival health score of teeth restored with composite strip crowns can be affected by tooth preparation and cementation [Hackmyer and Donly, 2010]. Waggoner et al. [2005] also reported similar results in their studies. It is preferable to keep the restoration margins coronal to the free gingival margin [Padbury et al., 2003]. Obviously, subgingival margin placement is often unavoidable for primary teeth. Retention of full-coverance crowns for primary teeth comes mainly from subgingival placement [Lee, 2002]. The degree of gingival inflammation is directly related to the location of crown margin. Newcomb [1974] stated that as the margin goes from supra to a sub-gingival position, the gingival health deteriorates.

Teeth restored with the NuSmile crowns also showed an increase in the MGI score after 6 months. This could be due to plaque retention on the labial composite veneered surface of SSSCs. Improper contouring of metal margins and remnants of the cement in the sulcus also irritate the gingiva causing gingival inflammation [Maclean et al., 2007]. Teeth restored with Zirkiz crowns showed a significant decrease in MGI score. Zirconia as tooth material is highly biocompatible and possesses a polished and smooth surface leading to less plaque accumulation and hence less gingival irritation. Previously published studies on FPDs with zirconia framework in permanent dentition arrived at the same conclusion of lower plaque accumulation [Schmitt et al., 2009; Sailler et al., 2007].

**Conclusion**

Resin composite strip crowns have lower success rate and higher gingival inflammation. Pre-veneered SSSCs are retentive, but can have facial veneer fracture. Pre-fabricated zirconia crowns are retentive and gingival friendly but cause non-significant abrasiion of opposing teeth.

**Conflict of interest statement**

The authors declare that they do not have any commercial or associative interest that represents a conflict of interest in connection with this work.

**References**

- Hackmyer SP, Donly K. Restorative dentistry for the pediatric patient. Tex Dent J 2010, 11; 1185-1171.