Evaluation of the Clinical Performance of Pedo Jacket Crowns in the Treatment of Maxillary Anterior Teeth with Early Childhood Caries: A Prospective Clinical and Laboratory Study

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science
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ABSTRACT


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To assess the clinical performance of Pedo Jacket crowns for the treatment of ECC-affected primary anterior teeth in a prospective longitudinal clinical study and in vitro. Crowns were assessed in 54 children (142 teeth) by 4 clinicians calibrated w.r.t. crown placement/assessment. Pedo Jacket crowns were evaluated for factors including ease of use, wear, crown loss, discoloration, oral hygiene, and overall clinical success at 6 and 12-month follow-ups. The shear bond strengths of crowns cemented with 4 different preconditioning methods were assessed in vitro (N = 10/group). Results from 48 children (129 teeth) indicated an overall success rate of 86%. Marked discoloration, wear and crown loss were found in 13.1%, 5.4%, and 7.6% of children, respectively. There was an increase in mean SBS in vitro (29%) when either chemical or mechanical retention were incorporated (N.S.). Pedo Jacket crowns may be a viable treatment alternative for primary anteriors in pre-cooperative children.
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<table>
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<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ECC</td>
<td>Early childhood caries</td>
</tr>
<tr>
<td>S-ECC</td>
<td>Severe early childhood caries</td>
</tr>
<tr>
<td>PI</td>
<td>Principal investigator</td>
</tr>
<tr>
<td>RMGI</td>
<td>Resin-modified glass ionomer</td>
</tr>
<tr>
<td>PFM</td>
<td>Porcelain fused to metal</td>
</tr>
<tr>
<td>HEMA</td>
<td>Hydroxyethylmethacrylate</td>
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<tr>
<td>SBS</td>
<td>Shear bond strength</td>
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<tr>
<td>GI</td>
<td>Glass ionomer</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeter</td>
</tr>
<tr>
<td>MPa</td>
<td>Megapascal</td>
</tr>
<tr>
<td>ppm</td>
<td>Parts per million</td>
</tr>
<tr>
<td>SEM</td>
<td>Scanning electron microscopy</td>
</tr>
<tr>
<td>N</td>
<td>Newton</td>
</tr>
<tr>
<td>lbs</td>
<td>Pounds</td>
</tr>
<tr>
<td>psi</td>
<td>Pounds per square inch</td>
</tr>
<tr>
<td>S.D.</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>S.E.M.</td>
<td>Standard error of the mean</td>
</tr>
<tr>
<td>PJ</td>
<td>Pedo Jacket crown</td>
</tr>
<tr>
<td>RMGIC</td>
<td>Resin-modified glass ionomer cement</td>
</tr>
<tr>
<td>g</td>
<td>Grams</td>
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<tr>
<td>µL</td>
<td>Microliter</td>
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1. INTRODUCTION

Early childhood caries (ECC) is a chronic multifaceted disease that remains prevalent in children, particularly those from families of low socioeconomic status and First Nations communities (Dye et al., 2007; Harrison et al., 1993; HealthCanada, 2000; Leake, 1992; Locker et al., 2000; Peressini et al., 2004). Early childhood caries is defined as “the presence of one or more decayed (noncavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child under the age of six years” (AAPD, 2011). Severe early childhood caries (S-ECC) is an advanced form of the disease, classified according to the number of carious lesions and age of the child. In children under three years of age, any sign of smooth-surface caries is indicative of S-ECC (AAPD, 2011). From ages three to five, S-ECC is “one or more cavitated, missing (due to caries), or filled smooth surfaces in primary maxillary anterior teeth or a decayed, missing, or filled score of greater than or equal to four (age 3), greater than or equal to five (age 4), or greater than or equal to six (age 5) surfaces” (AAPD, 2011). For the past two decades there has been an increasing trend of ECC in preschool children in the United States (Dye et al., 2007), and a comparable trend may exist in Canada due to similarities among North American populations.

Figure 1: Three year-old child with severe early childhood caries affecting the maxillary primary incisors. (a) Clinical photograph. (b) Maxillary occlusal radiograph. (Images courtesy of Dr. G. Kulkarni)
One of the main challenges that pediatric dentists face is the treatment of carious primary maxillary incisors in ECC-affected children (Figure 1). The restoration of severely decayed primary incisors is complicated by their small crowns, thin enamel and large pulp spaces (Croll, 1998). Conventional treatment involves the placement of bonded composite resin strip crowns under compromised conditions such as in children with ECC and an unhealthy gingiva with a predisposition for hemorrhage (MacLean et al., 2007). Due to their young age and associated behavioral complexities, dental treatment often involves less than ideal restorative procedures in pre-cooperative children or alternatively, treatment under general anesthesia. Operative procedures under general anesthesia are performed under more optimal conditions and with better quality of treatment, but entail increased dental care costs and health risks (Tate et al., 2002). As a result, there is a need for additional non-invasive, easy to place, durable and esthetically pleasing alternatives for the treatment of early childhood caries.

2. REVIEW OF LITERATURE

2.1 Full Coverage Restorations

2.1.1 Stainless Steel and Open-Faced Stainless Steel Crowns

Figure 2: Four primary maxillary incisors restored with: (a) Stainless Steel Crowns; (b) Open-Faced Stainless Steel Crowns (Schwartz, 2012).
In severely decayed primary incisors with minimal enamel remaining for bonding, subgingival caries, and uncontrolled moisture and hemorrhage, stainless steel crowns (Figure 2a) are the restorations of choice (Croll et al., 1996; Guelmann et al., 2003). Over the years, many clinical studies including the longitudinal studies by Messer et al. (1988) and Einwag et al. (1996) have demonstrated the superiority of stainless steel crowns in restoring primary molars with multisurface involvement (Einwag et al., 1996; Messer et al., 1988; O'Sullivan et al., 1991; Paphathanasiou et al., 1994; Randall, 2002; Roberts et al., 1990; Tate et al., 2002). However, there are no published studies that have reported on the use of stainless steel crowns for primary anterior teeth. Despite this lack of data, stainless steel crowns appear to be the most durable and technique-friendly restorations to place on decayed primary anterior teeth (Lee, 2002; Waggoner, 2005). The main drawback of these preformed metallic crowns is their unaesthetic appearance (Lee, 2002; Waggoner, 2005). For this reason, they are most often used in the restoration of anterior teeth that are less visible, such as the primary canines and mandibular incisors (Waggoner, 2005). However, living in an era where esthetic dentistry is steadily becoming the norm, it is expected that parents desire and demand primary anterior restorations that demonstrate not only longevity but are also more pleasing in appearance than metal.

One way to improve the poor esthetic appearance of anterior stainless steel crowns is to cut a window on the labial aspect of the crown and place a composite resin material (Hartmann, 1983; Helpin, 1983; Kopel et al., 1967; Wiedenfeld et al., 1994). Such modified crowns are referred to as open-faced stainless steel crowns (Figure 2b). The drawbacks of this procedure are the increase in chair time due to the placement of a custom-made labial fenestration, and also the metallic appearance of the crown cannot be entirely masked (Croll, 1998; Croll et al., 1996; Helpin, 1983). There is also no published data on these open-faced
stainless steel crowns for the restoration of decayed primary incisors, and thus, there is no evidence to demonstrate their longevity.

2.1.2 Pre-Veneered Stainless Steel Crowns

Figure 3: Four primary maxillary incisors restored with pre-veneered stainless steel crowns (NuSmile, 2012).

Another form of full-coverage crown exists, which combines the strength and durability of stainless steel crowns with the esthetics of composite resin strip crowns. These are pre-veneered stainless steel crowns (Figure 3), which are fabricated with a tooth-colored resin material on the facial surface of the crown. There are a variety of different manufacturers that distribute these crowns. To name a few, there are the Kinder Krowns (Mayclin Dental Studios, Inc., St. Louis Park, MN 55426, USA) NuSmile crowns (Orthodontic Technologies, Houston, TX 77210 USA), Cheng Crowns (Peter Cheng Orthodontic Laboratory, Exton, PA 19341 USA), and Dura Crowns (Success Essentials/Space Maintainers Labs, Chatsworth, CA 91311 USA). There are nuances in each type, such as their ability to be crimped on the lingual only (NuSmile, Cheng Crowns, Kinder Krowns) or both on the lingual and facial surfaces (Dura Crowns) (Waggoner, 2002); there are different veneer shades and crown lengths (Waggoner, 2002); the manner by which the facing is affixed also differs between manufacturers (Waggoner, 2002).
The common denominator in all of these crowns is that they are stainless steel crowns that are pre-fabricated with a resin facing material. Unlike open-faced stainless steel crowns or composite resin strip crowns, they can be used when saliva and hemorrhage cannot be adequately controlled (Baker et al., 1996; Roberts et al., 2001; Waggoner et al., 1995), as well as in cases where carious lesions extend subgingivally (Shah et al., 2004). The other advantage that these crowns have over open-faced stainless steel crowns is that no additional chair time is necessary for the incorporation of the resin facing (Croll et al., 1996; Waggoner, 2005). Lastly, pre-veneered stainless steel crowns are indicated when there is insufficient tooth structure remaining for surface bonding, making bonded-type of restorations impossible to place (Shah et al., 2004).

The clinical performance of some of these crowns have been studied and reported in literature. In a retrospective study, Roberts et al. (2001) evaluated the clinical success and parental satisfaction of a type of pre-veneered stainless steel crowns called Whiter Biter II Crowns (Whiter Biter Inc.). Over a period of 32 months (mean 20 months), 32% of the crowns (12 out of 38 crowns in 12 children) exhibited partial or complete loss of the resin facing (Roberts et al., 2001). Despite the high failure rate, parents demonstrated an excellent acceptance of the crowns. These Whiter Biter II crowns are, however, no longer commercially available. Shah et al. (2004) also investigated the clinical success and parental satisfaction with Kinder Krowns (Mayclin Dental Studios, Minneapolis, MN 55426 USA) in a retrospective cross-sectional study. This study, which had a similar sample size and follow-up period (mean of 18 months) as the previous study by Roberts et al., found a comparable failure rate. The authors found that 39% of the crowns showed fracture or wear of its resin facing (Shah et al., 2004). Figure 4 is a clinical example of a young girl with four maxillary anterior teeth restored
with preveneered crowns, showing fracture and loss of the resin facings on both primary maxillary lateral incisors.

Figure 4: Clinical case showing primary maxillary lateral incisors (52 and 62) with fracture loss resin facings of preveneered stainless steel crowns in contrast to intact crowns on central incisors (51 and 61). (Images courtesy of Dr. G. Kulkarni)

In another retrospective study by Maclean et al. in 2007, the clinical outcomes of NuSmile anterior pre-veneered stainless steel crowns (Orthodontic Technologies, Houston, TX 77210 USA) were appraised. Twelve percent of the crowns (27 out of a total of 226 crowns) had fractured facings and 29% (65 crowns) showed noticeable incisal wear and attrition over a period of at least 6 months with a mean of 12.9 months (MacLean et al., 2007). Both Roberts et al. and Shah et al. analyzed crowns that were placed under ideal conditions with the children treated under general anesthesia. In the study by Maclean et al., the majority of patients (42 children) were treated under general anesthesia while the remainders were treated either with non-pharmacological behavior management techniques (1 patient), nitrous oxide (2 patients) or oral sedation (1 patient). Of the patients treated with non-pharmacological methods or mild sedation, 96% were considered to have a positive behavior, which was significantly related to the overall appearance of the preveneered crowns. Champagne et al. (2007) as well as two of the above retrospective studies also reported on the parental acceptance of pre-veneered stainless steel crowns. There was a high overall satisfaction with the crowns, but the resin
veneers tended to break down over time or exhibit significant wear and chipping (Champagne et al., 2007; Roberts et al., 2001; Shah et al., 2004).

The retrospective nature of these studies, as well as the relatively small sample sizes and short observation periods preclude one’s ability to accurately predict the long-term clinical success of these pre-veneered crowns, but the high rate of failure of the resin facings is of concern. A few laboratory studies have attempted to characterize the shear strength and bond failures of the resin veneers. Waggoner and Cohen tested four types of veneered primary incisor stainless steel crowns (Kinder Krowns, Whiter Biter Crown II, NuSmile, Cheng Crowns) and found that the Whiter Biter Crowns had the highest shear bond strength (686.5 ± 181.4, N ± S.D., N = Newton; S.D. = Standard deviation) compared to the Kinder Krowns (397.2 ± 53.0 N), NuSmile (447.2 ± 78.5 N) and Cheng Crowns (511.9 ± 83.4 N) (Waggoner et al., 1995). These results contrasted with those of Baker et al. (1996) who also tested the same four crowns and found that the Whiter Biter Crowns had the least amount of resistance to shear forces and Cheng Crowns had the highest (Baker et al., 1996). The forces required to dislodge the veneers from this study were recorded in pounds (lbs), with 107.8 ± 17.3 lbs for Cheng Crowns, 100.2 ± 18.2 lbs for NuSmile, 91.3 ± 27.4 lbs for Kinder Krowns, and 81.5 ± 21.6 lbs for Whiter Biter II. This discrepancy may have been due to several factors, including changes in the manufacturing process of the crowns of different generations, and the longer period of water immersion which may have led to increased water sorption by the composite materials of the veneers (Baker et al., 1996; Waggoner et al., 1995). Another laboratory study by Yilmaz et al. (2004) found that repairing dislodged facial facings with either a flowable composite resin (226.25 ± 8.468 N) or a crown and bridge veneering resin (158.75 ± 24.408 N) had significantly lower fracture resistance than the original veneer material (385 ± 25.82 N), namely 58% to 48% of the mean shear strength of the initial veneer material (Yilmaz et al.,
2004). These results raise doubt on whether it would be worthwhile repairing a damaged pre-veneered stainless steel crown rather than replacing it. Although the existing published reports in the literature provide some basic information on pre-veneered stainless steel crowns, prospective clinical studies with larger samples and longer follow-up times are necessary to better assess the clinical performance of these crowns.

Despite the combination concept of metallic strength and improved esthetic appearance, the pre-veneered stainless steel crowns present limitations in their application and use. In addition to the white facings being prone to fracture under pressure, these crowns have other drawbacks. These include their requirement for significant tooth reduction, the higher cost than stainless steel and composite resin strip crowns, they do not allow for esthetic repair but rather they must be replaced, their bulkiness presents a challenge when placing multiple adjacent crowns especially in areas with tight contacts or where space loss has occurred, and there is a steep learning curve in their placement (Croll, 1998; MacLean et al., 2007; Waggoner, 2006). Another disadvantage is the limited ability to crimp the pre-veneered crowns. Stainless steel crown retention relies on the luting cement, but also on the crimping of the gingival margin of the crown (Myers et al., 1981; Rapp, 1966; Waggoner, 2005). The pre-veneered variety generally only allows for crimping on the lingual surface to avoid potential damage to the resin veneer on the facial surface (Waggoner, 2002). Dura Crowns are the only type that may be crimped on both the lingual and facial surfaces (Waggoner, 2002). Guelmann et al. (2003) investigated whether crimping and cementation (Rely-X ARC, 3M Dental Products, St. Paul, MN 55144-1000) improved the retention of 3 different pre-veneered (Kinder Krowns, NuSmile Primary Crowns, Dura Crowns) and plain Unitek stainless steel crowns (3M Dental Products, St. Paul, MN 55144-1000) in an in vitro experiment (Guelmann et al., 2003). The authors found that the combination of both crimping and cementation significantly enhanced crown
retention when subjected mechanically to tensile forces. Interestingly, despite all around crimping, the Dura Crowns (154 N) did not exhibit higher retentiveness than the other 3 crowns tested (228 N for Kinder Krowns, 172 N for NuSmile, and 111 N for Unitek crowns). An additional negative aspect to the pre-veneered crowns is that the shade of the resin veneer cannot be selected or modified, and reshaping of the veneer may be necessary (Croll et al., 1996). Lastly, once a crown has been fitted in the oral cavity it cannot be heat sterilized because of the potential for damage to the veneering material (Croll, 1998; Waggoner et al., 1995). In summary, although pre-veneered stainless steel crowns are reported to be the most durable and retentive primary anterior crowns, they have multiple disadvantages. Therefore, there is a need for alternate crown options in which durability, ease of placement and esthetics merge.

2.1.3 Acrylic Resin Crowns

Another treatment approach that has been attempted to meet both the functional and esthetic requirements of primary anterior crowns is the acrylic resin crown. This technique involves the use of a preformed celluloid crown form which is filled with a tooth-colored, self-curing acrylic resin that is seated onto a prepared primary incisor (Daniels et al., 1966; Sherman et al., 1966). Once the acrylic resin is cured, the celluloid crown form is removed, the excess acrylic resin is trimmed from the margins of the remaining crown, and a zinc-phosphate or acrylic cement is used to cement the acrylic resin crown onto the prepared tooth (Daniels et al., 1966; Sherman et al., 1966; Stewart et al., 1974).

The clinical success of these acrylic resin crowns remains anecdotal as there are no published studies that report on the longevity of these crowns. The differences between acrylic crowns and open-faced or pre-veneered stainless steel crowns is that they are more similar to a
natural primary tooth and do not have a metallic display. However, the downside of these crowns is that they are porous and tend to discolor quite easily (Stewart et al., 1974). In 1979, Doyle introduced a technique to help increase the retention of acrylic crowns, which he referred to as acrylic jackets. The author described acid etching the prepared primary tooth and using a composite resin to fill the acrylic jacket, which is then seated onto the tooth, the composite resin is allowed to set, and the margins are finished with a bur (Doyle, 1979). Nonetheless, the advent of many other full coverage crowns for primary incisors have allowed practitioners to draw away from the use of acrylic resin crowns.

2.1.4 Polycarbonate Crowns

Several authors have described the use of polycarbonate crowns, another type of preformed full coverage crown for primary incisors with extensive decay. Polycarbonate crowns (Figure 5) are preformed crowns that are thinner and more flexible than acrylic resin crowns, making them more easily adaptable to a prepared tooth (Stewart et al., 1974). Although there are no published studies that have evaluated their clinical success, there are a few descriptive reports in the literature that outline the placement technique for these crowns (Miller, 1973; Stewart et al., 1974). Stewart (1974) described the indications and contraindications for polycarbonate crowns. The indication for such a crown is the same as for
any of the other types of primary anterior crowns as previously discussed, which includes the
restoration of primary incisors or cuspids with extensive decay (Myers, 1975; Stewart et al.,
1974). Conversely, the use of polycarbonate crowns are cautioned in cases where there is
insufficient remaining tooth structure for retention, and also in cases of bruxism and deep
overbites, as these crowns have a lower resistance to heavy forces (Myers, 1975; Stewart et al.,
1974). Crowding of the dentition also precludes the restoration of carious primary anterior
teeth, as there must be enough space to accommodate the crowns (Myers, 1975). The
placement of polycarbonate crowns is similar to the technique described by Sherman et al.
(1966) for acrylic resin crowns; a preformed crown of adequate size is selected to fit the
prepared incisor and the crown form is cemented onto the tooth with an acrylic resin (Stewart
et al., 1974). Alternately, a composite resin material can be used to fill the crown form, which
is also seated onto the tooth and held in place until the composite resin has set (Stewart et al.,
1974). Finishing of the margins and polishing of the polycarbonate crown are the final steps in
the placement of polycarbonate crowns (Stewart et al., 1974).

Among the problems with polycarbonate crowns is their tendency to fracture or
dislodge from the prepared tooth (Nitkin et al., 1977; Stewart et al., 1974). In 1975, a modified
technique to help overcome the problem of crown fracture and loss was proposed (Myers,
1975). Firstly, the author suggested adding cervical undercuts on the interproximal surfaces in
addition to the labial surface (Myers, 1975). Secondly, the author advised against forcing the
crown into a prepared tooth to prevent stretching forces which may cause eventual splitting of
the crown form (Kopel et al., 1976; Myers, 1975). Lastly, it was recommended that an escape
hole be placed on the lingual surface of the polycarbonate crown during cementation to allow
for the dissipation of stress forces upon seating of the crown (Myers, 1975). Although these
methods have been suggested to help increase crown retention, due to the lack of clinical
studies in the literature, it is not possible to precisely determine the long term retentiveness of polycarbonate crowns.

Kopel and Batterman (1976) investigated different types of cementing agents to determine which would aid in the retention of polycarbonate crowns *in vitro*. The authors found that composite resin produced the highest resistance to dislodgment from tensile forces (508.1 ± 163.5 psi, psi = pounds per square inch), followed by a polymethacrylate resin (430.9 ± 252.4 psi) which may have the ability to chemically bond to the crown (Kopel et al., 1976). The least desirable luting cement with the lowest retentive force was zinc oxide-eugenol cement (121.3 ± 31.9 psi), for which it was hypothesized that the eugenol attacks the polycarbonate material (Kopel et al., 1976). Wiggins et al. (1978) also tested various cementing agents and found that, regardless of the incorporation of retention grooves, unfilled intermediary resins had the best results for crown retention, followed by polycarboxylate or zinc phosphate cements (Wiggins et al., 1978). Tensile strengths in this study by Wiggins were illustrated through bar graphs comparing the different test groups however, the exact values and standard deviations were not reported. The tensile forces were recorded in pounds, with values ranging from 21 lbs to 28 lbs for unfilled resins, and 15 lbs to 18 lbs for filled resins. However, the *in vitro* nature of these studies and the small sample size used (seven and two teeth per test group, respectively) may limit the value of these results.

Another complication of polycarbonate crowns is the fact that the crown form may separate from the intermediate luting agent, leaving the luting agent on the tooth (Nitkin et al., 1977). A laboratory study by Nitkin and co-workers (1977) evaluated various cementing methods and compared the magnitude of the forces needed to dislodge the crown form from the different luting agents. The experiment consisted of five test groups; the first three groups
utilized cement only, whereas the last two groups had an additional step to prime the internal aspect of the polycarbonate crowns with either a methyl methacrylate monomer or a mix of methyl methacrylate monomer and powder. The reasoning behind the priming was the fact that methyl methacrylate is known to react with polycarbonate (Kopel et al., 1976). This reaction may help to create a chemical union between the polycarbonate crown and the resin filling material, thus aiding the crown in resisting dislodging forces (Kopel et al., 1976; Nitkin et al., 1977). The results of this study by Nitkin et al. (1977) showed that priming with either methyl methacrylate monomer alone or in combination with a loose powder mix of methyl methacrylate did enhance the bond between the composite resin filling material and the crown form (Nitkin et al., 1977). Similarly, Pedo Jacket crowns, which are the topic of this research study, can also present with separation of the crown from the filling material and different methods of countering this problem in vitro will be discussed later.

Polycarbonate crowns surmount some of the disadvantages of the previously discussed primary full coverage crowns. To summarize, they have a more esthetic appearance than any of the different types of stainless steel crowns, the crowns are pre-fabricated and do not require additional chair time, and they are relatively simple to place. On the other hand, polycarbonate crowns have been shown to lack adequate retention, either by the crown being lost from the prepared primary tooth or from the intermediate cementing agent. Although the various laboratory studies from the 1970s showed some potential in improving crown retention, the popularity of polycarbonate crowns has since declined and they are no longer used.
2.1.5 Composite Resin Strip Crowns

Figure 6: Strip crowns for anterior teeth by 3M ESPE, USA (3MESPE, 2013).

The most popular type of preformed esthetic crowns for primary incisors is the composite resin strip crown (Figure 6). This type of crown was first introduced in 1979 by Webber and colleagues (Webber et al., 1979). The indications for strip crowns include extensive decay of the primary anterior teeth, fractured or malformed teeth, teeth that exhibit discoloration, and as coverage for teeth that have received pulp therapy (Drummond, 1993; Pollard et al., 1991; Webber et al., 1979). Conversely, strip crowns are contraindicated in cases where primary teeth are too severely decayed that they present with insufficient tooth structure for retention and bonding, deep overbites, and in children with periodontal disease (Webber et al., 1979).

Composite resin strip crowns are now widely accepted because of their better esthetics as they resemble more closely the natural appearance of teeth (Croll, 1995; Lee, 2002; Ram et al., 2000; Waggoner, 2002). There are numerous case reports and articles in the literature that describe the technique for placement of these crowns (Croll, 1990; Drummond, 1993; Kupietzky, 2002; Pollard et al., 1991; Ram et al., 2000; Webber et al., 1979). The technique involves the reduction of all surfaces of a primary anterior tooth and caries removal (Figure 7b), selection of an adequately-sized celluloid crown form (Figure 7c), trimming of the crown form (Figure 7d), acid etching and conditioning of the prepared tooth, filling of the crown form with a composite resin material, and seating of the filled crown onto the tooth (Croll, 1990;
Drummond, 1993; Kupietzky, 2002; Pollard et al., 1991; Ram et al., 2000; Webber et al., 1979). The composite resin is then polymerized, the celluloid crown form is peeled off or “stripped” with a hand scaler (Figure 7e), and the remaining composite resin is finished at the margins and polished using a bur (Croll, 1990; Drummond, 1993; Kupietzky, 2002; Pollard et al., 1991; Ram et al., 2000; Webber et al., 1979).

![Composite resin strip crown technique](image)

**Figure 7: Composite resin strip crown technique** (Kupietzky, 2002). a) Decayed primary maxillary incisors. b) Caries removal. c) Fitting of strip crown. d) Trimming of strip crown with scissors. e) Peeling off the strip crown shell. f) Restored primary maxillary incisors.

Some authors have introduced modifications to the technique of strip crown placement. An author described the “sandwich technique” in which a layer of resin-modified glass ionomer is placed to cover all exposed dentin prior to the seating of the crown form filled with
composite resin (Margolis, 2002). This dentin replacement with a resin-modified glass ionomer was used to prevent debonding of composite materials in areas where enamel was lacking, including the gingival margins (Margolis, 2002). However, there are no existing clinical studies to substantiate whether there is improved durability and retention of the composite resin strip crowns with the placement of an underlying resin-modified glass ionomer. Kenny et al. (1986) introduced the composite resin short post, or “mushroom undercut” in the dentin, to aid in the retention of the crown (Kenny et al., 1986). The authors evaluated retrospectively the clinical performance of 243 patients with 625 composite resin strip crowns with the short post technique. They found that with proper case selection and mechanical design of the short post, as well as adequate crown-root ratio, these composite resin strip crowns could be retained until normal exfoliation. The authors did not report on the details of the retrospective study and the lack of a controlled study design was a major limitation. However, this short post technique was further evaluated by Judd and colleagues (1990) in a prospective clinical study with a 1-year follow-up. The study reported a 100% retention rate of the composite resin strip crown in a sample of 92 teeth (Judd et al., 1990). Grosso et al. (1987) and a case report by Mendes et al. (2004) also described the use of a composite resin short post in the pulpal chamber of an anterior tooth that had received a pulpectomy (Grosso, 1987; Mendes et al., 2004).

Another method for increasing intra-canal retention was the placement of an omega-shaped stainless steel wire in which the ends hooked into the root canal opening (Mortada et al., 2004). The remaining loop of the omega wire is then extended into the coronal aspect of the prepared primary incisor to help increase the surface area for attachment (Mortada et al., 2004). In a prospective clinical study of 25 children (96 teeth total), the authors determined that approximately 81.2% of the teeth that were restored with composite resin strip crowns with the added “omega wire extension” showed complete or partial retention of the crown after 18
months (Mortada et al., 2004). This study, along with those mentioned above, show that there are techniques available that have the potential to increase crown resistance to dislodgement. However, larger prospective clinical studies with a longer follow-up and better study design, including a control group for comparison, are necessary to corroborate these findings.

Despite the popularity of composite resin strip crowns, the literature on their clinical efficacy is limited. The vast majority of clinical studies that evaluate strip crowns are retrospective. For example, Kupietzky et al. (2003) reported on the clinical and radiographic success of 112 composite resin strip crowns in 40 children (Kupietzky et al., 2003). It was determined that the crowns had an 88% retention rate with a mean follow-up time of 18 months. Although none of the crowns were completely lost, partial loss of the resin occurred in 12% of the teeth. Other than loss of resin material, less than ideal crown contour and crown discoloration, mainly in pulp treated teeth, were the main drawbacks of the crowns (Kupietzky et al., 2003). The same retrospective study sample was used 1 year later to assess parental satisfaction with the esthetic appearance of the strip crowns (Kupietzky et al., 2004). 78% of parents reported to be “very satisfied” with crowns, with durability being significantly related to their overall satisfaction with the crowns (Kupietzky et al., 2004). In 2005, the same authors published another retrospective study with clinical and radiographic data on strip crowns after 3 years of follow-up (Kupietzky et al., 2005). The study sample consisted of 145 composite resin strip crowns in 52 children and the results showed a 78% retention rate for a period of over 36 months (Kupietzky et al., 2005). Similar to the previous study, the crowns that were considered “lost” only exhibited partial loss of the composite resin material. Ram and Fuks found similar results for crown retention in a 2006 retrospective study (Ram et al., 2006). After a 2-year follow-up, 80% of the resin-bonded composite strip crowns were successful at the final examination (Ram et al., 2006).
The retrospective studies described above involved the restoration of primary anterior teeth under local anesthesia, with or without some form of conscious sedation. Several other retrospective studies have also investigated the longevity of composite resin strip crowns placed under general anesthesia. Eidelman et al. (2000) compared the durability of restorations placed in children under sedation to those placed under a general anesthetic (Eidelman et al., 2000). In a sample of 34 children followed between 6 and 24 months, successful marginal adaptation and anatomic form were found in 90% and 86%, respectively (Eidelman et al., 2000). In comparison, out of 31 children who were treated with sedation, marginal adaptation and anatomic form were considered successful in 63% and 65%, respectively (Eidelman et al., 2000). This difference between successful treatment under general anesthesia and conscious sedation was statistically significant. The results of this study suggested that strip crowns placed under general anesthesia may exhibit superior longevity (Eidelman et al., 2000).

O’Sullivan and Curzon (1991) reviewed 80 children who were treated under general anesthesia (O’Sullivan et al., 1991). Only 16 teeth received composite resin strip crowns and with a follow-up period of 2 years, the authors reported a 100% success rate. In 57 children followed for a minimum of 1 year, Su and colleagues (1992) found a 78% success rate for 50 teeth that had received composite resin strip crowns, with fracture of the composite resin being the main type of failure (Su et al., 1992). Tate et al. (2002) did a similar study and found a 49% success rate for composite resin strip crowns placed under general anesthesia in 63 patients who were followed for a minimum of 6 months (Tate et al., 2002). Finally, Al-Eheideb and Herman (2003) reported a 70% success rate for 23 teeth with composite resin strip crowns followed between 6 and 27 months (Al-Eheideb et al., 2003). Overall, from the above mentioned retrospective chart studies, the retention rate for composite resin strip crowns ranges from 49%
to 100% with follow-up periods from 6 months to 27 months (Al-Eheideb et al., 2003; Eidelman et al., 2000; O'Sullivan et al., 1991; Su et al., 1992; Tate et al., 2002).

Patient behavior is an important factor in deciding which treatment modality is best suited for a child and their parents. Information regarding patient behavior during the placement of the restorations was absent from many of the studies described above (Judd et al., 1990; Kenny et al., 1986; Kupietzky et al., 2005; Kupietzky et al., 2004; Kupietzky et al., 2003; Mortada et al., 2004), which precludes the analysis of the influence of child cooperation on the clinical performance of the crowns. A clinician must consider different dimensions of treatment such as ease of treatment, and without information on child cooperation it becomes impossible to separate technical difficulties associated with the type of restoration from behavioral complexities of the treated child. One group of authors recorded patient cooperation at the time of dental treatment as a secondary outcome measure and found that behavior had no significant influence on clinical and radiographic outcomes (Ram et al., 2006).

One study considered patient behavior as the primary determinant of the clinical success of composite resin strip crowns by comparing the success rate of treatment under conscious sedation with that under general anesthesia (Eidelman et al., 2000). Eidelman found that the performance of strip crowns placed under general anesthesia was superior to those placed under sedation. A few authors have also completely eliminated patient cooperation as a variable affecting treatment outcome by evaluating treatment success in patients having received anterior crown restorations under general anesthesia (Al-Eheideb et al., 2003; O'Sullivan et al., 1991; Su et al., 1992; Tate et al., 2002). Overall, the data suggests that treatment under general anesthesia may result in better quality of treatment due to the elimination of patient cooperation, which invariably affects the clinical conditions at the time.
of restoration. This is especially true for fearful young children where poor cooperation and a lack of good moisture control may interfere with the successful placement of composite resin strip crowns.

Retrospective data can provide useful information on any type of restoration, especially when the number of existing prospective clinical trials is limited. Some may argue that retrospective studies are more representative of the general population than prospective studies. However, the lack of treatment standardization and reliance on charting of uncertain accuracy are weaknesses inherent to the retrospective nature of such studies. The small sample sizes and short follow-up periods also restrict one’s ability to relate the study results to clinical decision-making and practice.

Even in the face of their superior esthetics, composite resin strip crowns present several disadvantages. They require a more delicate placement; proper moisture and hemorrhage control, appropriate patient selection, tooth preparation and application of adhesive and composite which can all lead to the failure of this type of restoration (Croll, 1995; Kupietzky, 2002; Lee, 2002; Ram et al., 2000; Waggoner, 2002). Therefore, a less technique-sensitive yet still esthetic full coronal coverage restoration is desirable.

2.1.6 Laboratory-Enhanced Composite Resin Crowns

The placement of direct composite resin for the restoration of carious or fractured primary maxillary incisors presents multiple challenges to the clinician and there are numerous limitations to the material and technique. For instance, lack of patient cooperation and difficulty in obtaining adequate isolation of the teeth leading to hemorrhage and salivary contamination of the working field greatly compromises successful of placement and longevity of composite resin strip crowns (Croll, 1995; Kupietzky, 2002; Lee, 2002; Ram et al., 2000;
Waggoner, 2002). Secondly, incomplete polymerization of the direct composite resin material may occur due to the presence of ambient oxygen (Ellis et al., 1992; Updyke et al., 2001). Placement of the composite resin material in small increments can help improve polymerization by increasing the depth of cure but it also increases chair-time and possibility of contamination, thus leading to increase risk of failure of the resin restoration (Ellis et al., 1992; Updyke et al., 2001).

Laboratory enhanced composite resin crowns entail a two-appointment procedure which involves caries removal and preparation of the affected tooth, followed by an impression with a polyvinylsiloxane material and temporization of the tooth on the first visit. Cementation of the final laboratory fabricated composite resin crown with a resin cement is then performed at the second visit. A few case reports in the literature describe the use of indirect composite resin for the restoration to help overcome the challenges mentioned above. Ellis et al. described a case report of a 3-year old girl with ectodermal dysplasia (Ellis et al., 1992). Indirect composite resin crowns for her primary maxillary incisors were fabricated in 2 dental appointments. A polyvinylsiloxane impression of the maxilla was taken on the first visit and the impression was sent to a laboratory for the fabrication of the crowns. Indirect composite resin crowns have the advantage of being light polymerized under a vacuum, thus eliminating the problem of oxygen inhibition of polymerization (Ellis et al., 1992). Another advantage of indirect composite resin is the improved abrasion and wear resistance over direct composite resin (Ellis et al., 1992; Gallegos et al., 1988).

The second dental visit involves the cementation and finishing of the composite resin crowns. Motisuki and colleagues (2005) describe a similar technique for the fabrication of indirect composite resin crowns with the addition of a fibreglass post to improve retention of
the restoration (Motisuki et al., 2005). The technique also involves 2 dental appointments for an impression and then insertion of the crowns. The authors claim that the 2 appointments minimize the time spent in the chair by a potentially uncooperative patient during each appointment, which in turn decreases operative complexities such as moisture contamination.

In summary, the few case reports on laboratory-enhanced composite resin crowns suggest that there may be several advantages to their use such as more complete resin polymerization, better wear resistance and decreased clinical chair time. Although the above mentioned authors did report satisfactory patient cooperation during dental treatment, it is difficult to extrapolate the relationship of patient behavior at the time of crown placement and the clinical success of the restorations from such case reports. Overall, there is insufficient evidence in the literature to be able to recommend these types of restorations over other more conventional preformed anterior crowns for primary teeth. High quality prospective clinical studies with large sample sizes and long-term follow-up are needed to validate the practicality and longevity of indirect composite resin crowns.

2.1.7 Zirconia Crowns

![Zirconia crowns by NuSmile, USA](image)

**Figure 8: Zirconia crowns by NuSmile, USA** (NuSmile, 2014).

A recent addition to the spectrum of choices for preformed primary anterior crowns is the zirconia crown (Figure 8). There are 3 different commercially available zirconia crowns:
EZ Pedo Zirconia Crowns (EZ Pedo Inc., El Dorado Hills, CA 95762 USA), NuSmile ZR Pediatric Crowns (NuSmile, LTD., Houston, Tx 77008, USA), and Zirconia Kinder Krown (Kinder Krown, St. Louis Park, MN 55426, USA). These crowns are believed to have superior strength in comparison to all other previously described preformed anterior crowns, including stainless steel crowns. They are tooth-colored and are usually available in two different light shades. Due to these qualities, zirconia crowns are becoming more attractive to clinicians. The indications for such crowns do not differ from the previously mentioned preformed primary crowns and the placement technique resembles that of pre-veneered stainless steel crowns.

Incisal, facial, lingual and interproximal reductions between 0.5 and 0.75 millimeter (facial-lingual surfaces) to 2 millimeter (incisal) are required to passively fit an adequately sized zirconia crown. A major difference from the other types of crowns is that the length of the zirconia crown cannot be adjusted with scissors but instead a rotary bur with water spray must be used. Occlusal and interproximal reductions are also contraindicated due to possible weakening and thinning of the ceramic.

Despite their increasing popularity, the clinical performance of these crowns has yet to be reported in the literature. There are a few clinical studies that are presently underway in the United States, but until the results of sufficiently large prospective clinical studies with long-term follow-ups are published in the literature, the evidence on the clinical success and longevity of the zirconia crowns remains insubstantial.
2.1.8 Pedo Jacket Crowns

An alternate crown form for grossly decayed or traumatized primary incisors that is commercially available is the Pedo Jacket (Figure 9). Pedo Jacket crowns are marketed by Success Essentials Space Maintainers Laboratory (Van Nuys, CA 91409-4184, USA). The “jacket” consists of a copolyester material in the natural primary tooth color shade A2. The crown is flexible and its length can be adjusted and trimmed with scissors. In contrast with all of the crowns discussed above, it is important to note that this is the only flexible or soft crown option available. This property allows for the Pedo Jacket crown to accommodate the great variability in tooth size and shape and to facilitate adaptation to the teeth, especially in a pre-cooperative child. The tooth preparation is similar to that of strip crowns but often requires less tooth reduction. It includes caries removal and preparation of the tooth to conform to the inner surface of the crown leaving undercuts or parallel surfaces. The crown is then fitted onto the tooth and trimmed with scissors to adjust the length as necessary. The copolyester crown shell must be primed with a plastic primer material provided by the manufacturer. The exact chemical composition of the Pedo Jacket crown or crown primer has not been made available by the manufacturer. The prepared tooth is then conditioned with acid etch and a bonding agent is recommended. The crown is then filled with composite resin or a resin-modified glass.
ionomer if moisture and hemorrhage control cannot be achieved. Once the crown is seated on the tooth, it is polymerized and the crown form is left on the tooth.

Pedo Jacket crowns are similar in cost to composite resin strip crowns ($403.85 Pedo Jacket Anterior Crown starter kit #450-200 by Success Essentials Space Maintainer Laboratory, Van Nuys, CA 91409-4184, USA, 2014), making them an affordable treatment choice. The Pedo Jacket possesses a few advantages that make it especially suitable for the pre-cooperative child. Firstly, it requires minimal tooth preparation. This property may make the Pedo Jacket a suitable provisional restoration until the child is old enough to receive other conventional treatment. In addition, when moisture and hemorrhage control cannot be achieved the crown form can be filled using a resin-modified glass ionomer instead of a composite resin material. It is not uncommon for parents to prefer “white crowns” for their child and the white color of the Pedo Jacket makes it esthetically acceptable. Another important advantage of the Pedo Jacket is that it is filled and left on the tooth and no “stripping” of the crown form is necessary. Polishing of the margins is also not required as the margins are finished prior to light curing of the restorative material by removing all excess with hand instruments. Elimination of these additional treatment steps results in decreased chair-time which can be crucial for young children in whom cooperation may be limited. Crown forms for maxillary and mandibular first primary molars are also commercially available. Hence, for esthetic reasons and ease of use, Pedo Jackets may present a viable treatment option for decayed or fractured primary anterior teeth.

Like all other restorations, Pedo Jacket crowns have their disadvantages. They tend to exhibit wear in areas of heavy occlusion and the crown margin can discolor over time. A common type of failure is the stripping of the Pedo Jacket crown from the filling material.
Often the remaining composite resin or resin-modified glass ionomer remains intact on the primary tooth. With the copolyester shell completely lost, the remaining restorative material appears as a strip crown, which can be left on the tooth without requiring additional treatment intervention. A brief summary of Pedo Jacket crowns, including their advantages and disadvantages are listed in Table 1.

**Table 1: Advantages and disadvantages of Pedo Jacket crowns.**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Good esthetics</td>
<td>1. Can tear margins with rotary instruments</td>
</tr>
<tr>
<td>2. Flexible and easy to adapt</td>
<td>2. Can wear</td>
</tr>
<tr>
<td>3. Clinically efficient as the crowns do not have to be stripped off at the end of the procedure</td>
<td>3. Crown can separate from cement</td>
</tr>
<tr>
<td>4. Can act as temporary restorations when used with RMGI</td>
<td>4. Difficult to place in crowded dentitions</td>
</tr>
<tr>
<td>5. If the crown debonds, the residual RMGI cement appears as a strip crown</td>
<td>5. Cannot heat sterilize crowns</td>
</tr>
<tr>
<td>6. Meant for maxillary anteriors but adaptable to other teeth (mandibular anteriors, cuspids)</td>
<td></td>
</tr>
<tr>
<td>7. Easy access to pulp chamber in case of later pulp involvement</td>
<td></td>
</tr>
<tr>
<td>8. Easy repair of defects</td>
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</tbody>
</table>

To date, reports on the risks and benefits of Pedo Jacket crowns in the restoration of carious or traumatized primary teeth remain anecdotal. There are no clinical studies to evaluate the durability and longevity of Pedo Jacket crowns. Pedo Jacket crowns may help overcome some of the shortcomings of the previously discussed crowns and prospective clinical data is necessary to investigate whether these crowns may be a practical alternative for the restoration
of primary anteriors. This research study describes the first prospective study on the clinical performance of Pedo Jacket crowns.

### 2.2. Resin-Modified Glass Ionomer for Crown Cementation

#### 2.2.1. Geristore Overview and Clinical Applications

Geristore (Den-Mat, Santa Maria, CA 93455 USA) is a dual-cure resin-modified glass ionomer with a hydrophilic Bis-GMA formulation. It is a radiopaque material filled with small composite particles and contains barium fluorosilicate, a fluoride-containing glass (Miller, 1993). It is a self adhesive material that can be used for a wide variety of clinical applications. Conventional uses for Geristore and other resin-modified glass ionomer (RMGI) cements include root caries, Class V restorations, small Class I and II restorations, subgingival restorations, repair of external root resorption and root perforations, root end fillings, cavity liner, base material, core material, porcelain repair, and cementation of fixed dental prostheses including metal and porcelain fused to metal (PFM) restorations (Breault et al., 2000; Dragoo, 1996; Galan, 1991; Greer et al., 2001; Miller, 1993).

Geristore, as its name implies, was initially indicated for the restoration of root caries in the geriatric population (Miller, 1993). It has since then been used in all populations including the geriatric, pediatric, and adult populations. It is especially advantageous in the pediatric population; firstly, Geristore is self-adhesive and bonds to enamel and dentin (Burgess et al., 1994; Dragoo, 1996). Although a bonding agent is not necessary, Tenure Quick Bond (Den-Mat, Santa Maria, CA 93455 USA) can be used to increase bond strength to these surfaces. Secondly, Geristore has dual cure properties that allow it to be placed and set with greater speed as compared to a traditional composite resin material. Its dual cure property allows the chemical setting reaction to initiate within 90 seconds of mixing the Geristore, which then
prevents shrinkage of the composite resin material away from the cavity preparation walls as light curing is performed (Miller, 1993). For these reasons and others to be discussed below, Geristore was selected as the restorative material for the cementation of Pedo Jacket crowns in this study.

2.2.2. Composition and Properties

Resin-modified glass ionomer (RMGI) cements were created to surmount some of the shortfalls of traditional glass ionomer (GIC) cements. They contain the same components as traditional GICs (polyalkenoic acid liquid and aluminum-fluorosilicate glass base powder) (Berg, 1998) but they also contain a small particle hydrophilic resin composite, which provides a dual cure capability to the material (Miller, 1993). RMGIs contain a hydrophilic resin monomer (hydroxyethylmethacrylate, HEMA) and a photoinitiator, which permit a light-initiated polymerization of methacrylate groups (Berg, 1998; Burgess et al., 1994; Kim et al., 1998; Mitra, 1991; Mount, 1994; Watson, 1990). A separate setting reaction occurs between the polyalkenoic acid and aluminum-fluorosilicate glass, which undergo the conventional GI chemical self-cure via an acid-base reaction and results in the release of fluoride ions (Berg, 1998; Burgess et al., 1994; Mitra, 1991; Mount, 1994; Watson, 1990). Geristore is radiopaque, filled 50% by weight with small composite particles, contains a barium fluorosilicate glass of 3-4 micron particle sizes, and is a dual-cured composite resin with a low fluoride-releasing ability (Burgess et al., 1994; Miller, 1993; Scherer et al., 1995).

There are many advantages offered by RMGIs compared to traditional GICs. For example, the resin component in RMGIs provides additional mechanical strength (i.e. resistance to fracture) as well as better esthetics than traditional GICs (Berg, 1998; Burgess et al., 1994; Croll, 1995). The GIC component of RMGIs, specifically the barium fluorosilicate
glass, maintains the ability to release fluoride (Berg, 1998; Burgess et al., 1994; Mitra, 1991; Watson, 1990), a property that is desirable in any caries-prone individual. RMGIs are less moisture sensitive than composite resins (Waggoner, 2002) and are also more resistant to damage from moisture and desiccation (Kim et al., 1998; Mount, 1994; Wilson, 1989), which are conditions that impede the setting reaction of traditional GIs and result in increased staining, abrasion and loss of translucency of the restorative material (Burgess et al., 1994; Mount et al., 1982; Walls, 1986; Wilson, 1989). In addition, RMGIs offer a smoother surface finish than conventional GIs (Berg, 1998; Burgess et al., 1994). Surface defects of RMGI restorations can be repaired by adding supplementary material, with the bond strength between the existing and added material being sufficiently strong (Burgess et al., 1994). Other advantages of RMGIs such as Geristore include adherence to tooth structure, insolubility in oral fluids, a low coefficient of thermal expansion, and biocompatibility (Burgess et al., 1994; Croll, 1995; Dragoo, 1996; Lin et al., 1992; Rusz et al., 1992; Sidhu et al., 1995; Wilder et al., 1996).

The disadvantages of RMGIs lie in their relatively more difficult handling properties compared to composite resins, and also in the existence of polymerization shrinkage by virtue of containing a resin component (Attin et al., 1995; Davidson et al., 1984; Kim et al., 1998). The wear resistance and physical strength of RMGIs, although substantially better than conventional GIs, are nonetheless weaker than that of composite resins (Mount, 1994; Waggoner, 2002). However, there are no studies that specifically compare the shear bond strength of Geristore and composite resin. Lastly, the surface finish and esthetics of RMGIs are inferior to that of composite resins and poly-acid modified resins; the large glass particles contained in RMGIs increase surface roughness (Kramer et al., 2007; Waggoner, 2002). Like all restorative materials, RMGIs are not ideal in all facets of desirable outcomes. However, the
benefits of an RMGI such as Geristore may make them a resilient and practical cementing material for Pedo Jacket crowns in pre-cooperative children with poor oral hygiene and a low level of cooperation.

2.2.3. Shear Bond Strength

The shear bond strength (SBS) of conventional glass ionomer cements is characteristically reported to be low, with a range between 3 and 7 Megapascals (MPa) (Aboush et al., 1986; Hotz et al., 1977; Powis et al., 1982). Failure of GI cements is due to the lack of cohesive strength of the material (Burgess et al., 1994; Mitra, 1991). In contrast, resin-modified glass ionomers have been shown to possess increased mechanical properties compared to conventional GI cements. The mean shear bond strength of RMGIs is generally higher than that of conventional GIs, with a bond strength varying between 6 to 12 MPa (Cortes et al., 1993; Garcia-Godoy, 1992; Hinoura et al., 1991; Lin et al., 1992; McCaghren et al., 1990; Mitra, 1991; Prati et al., 1991; Strickland et al., 1990). Swift et al. (1995) evaluated the shear dentin bond strengths of five different RMGIs in vitro, including Fuji II LC (GC America, Chicago, IL 60658), Geristore (Den-Mat Corp, Santa Maria, CA 93456), Photac-Fil Aplicap (ESPE-Premier Sales Corp, Norristown, PA 19404), VariGlass VLC (L.D. Caulk/Dentsply, Milford, DE 19963), Vitremer (3M Dental Products, St Paul, MN 55144), and Ketac-Fil Aplicap (ESPE-Premier) as the conventional GI control group. The authors found that the Fuji II LC had the highest mean shear bond strength (12.3 MPa), the control (Ketac-Fil) had the lowest (1.1 MPa) and Geristore was intermediate in value (8.6 MPa) (Swift et al., 1995). This increase in bond strength is largely due to the greater cohesive strength of the materials within the RMGI (Burgess et al., 1994; Mitra, 1991). The range of clinically acceptable SBS for anterior restorations in primary teeth is not known.
Although Geristore and other RMGIs are capable of adhering to tooth structure alone, it is recommended to use RGMI dentin primers or conditioners by the respective manufacturers. The conditioning of the dentin has been shown to improve the shear bond strength of the RMGI material (Burgess et al., 1994; Hinoura et al., 1991; Watson, 1990). In addition, the application of a light cure has also demonstrated increased RMGI shear bond strengths (Burgess et al., 1994; Hinoura et al., 1991). Dentin conditioning has also been reported to lead to a decrease in microleakage at the interface of the tooth and RMGI restoration (Crim, 1993). Therefore, both a dentin conditioner and light cure should be applied in order to maximize the success of an RMGI restoration. In the case of this clinical study and in vitro experiment, 38% phosphoric acid gel was used to acid etch the surface of the prepared teeth, a bonding agent was used prior to cementing the Pedo Jacket crowns with Geristore and the cemented crowns were light cured (see Materials and Methods for a more detailed description).

2.2.4. Biocompatibility

Historically, Geristore has been used in the treatment of subgingival defects (e.g. root perforations, external root resorption) due to its biocompatibility as a restorative material. There are few studies that have shown that Geristore can be successfully used in the management of subgingival and subosseous defects (Behnia et al., 2000; Dragoo, 1997; Resillez-Urioste et al., 1998; Roth, 1998; Scherer et al., 1995; Shuman, 1999), as well as guided tissue regeneration in permanent teeth (Abitbol et al., 1995; Abitbol et al., 1996). However, studies that evaluate the biocompatibility of Geristore are scarce and involve permanent teeth or adult tissue samples. For instance, one author showed that normal periodontal healing occurs with Geristore as evidenced by the induction of normal gingival and periodontal fibroblast attachment to Geristore as a root-end filling material in vitro (Camp et al., 2003). Another laboratory study showed that fibroblast viability and cell growth is not
affected by Geristore (Al-Sabek et al., 2005). In summary, a few laboratory studies have demonstrated the biocompatibility of Geristore and no adverse effects have been documented in the literature. Although direct evidence does not exist in primary teeth, it can be extrapolated from these studies that Geristore may also be biocompatible as a cement for Pedo Jacket crowns in children.

2.2.5. Fluoride Release and Cariostatic Mechanisms

Resin-modified glass ionomer cements, including Geristore, have been shown to leach small amounts of fluoride (Burgess et al., 1994; Miller, 1993), with levels comparable to the amount of fluoride released by glass ionomer cements (Robertello et al., 1999). The rate of fluoride release is greatest during the first 24 hours after insertion of the dental material (8 to 15 parts per million, ppm). The rate of fluoride ion release then tapers off on the seventh day (1 to 2 ppm) and stabilizes between the tenth day and third week thereafter (Attar et al., 2003; Creanor et al., 1994; Gao et al., 2000; Khoroushi et al., 2013; Yap et al., 2002).

Fluoride release from a restorative material may be of profound clinical importance when used in children with an elevated dental caries risk. It is a known fact that fluoride possesses antibacterial activity, including the inhibition of bacterial adhesion and colonization (Rolla, 1977; Rolla et al., 1975). Fluoride also inhibits carbohydrate metabolism and reduces bacterial acid production by acidifying the bacterial cytoplasm and inhibiting glycolysis (Eisenberg et al., 1980; Hamilton, 1977; Maltz et al., 1982). Other well-known beneficial activities of fluoride are the prevention of enamel demineralization and the promotion of remineralization (Levine, 1976; ten Cate et al., 1991; Wong et al., 1987).

The concentration of fluoride tends to be increased in plaque around GICs (Forss et al., 1995); there are a number of in vivo studies that demonstrate a significantly reduced level of
the cariogenic bacteria mutans streptococci in plaque surrounding glass ionomer and resin-modified glass ionomer restorations (Koch et al., 1990; Svanberg et al., 1990). Orthodontic brackets cemented with glass ionomer cements also reflect the benefit of fluoride release from GICs in that mutans streptococci and lactobacilli colonize more often around brackets with composite resins than with GICs (Hallgren et al., 1992). An in vivo study demonstrated that the resin modified glass ionomer Geristore also exhibited significantly reduced concentrations of mutans streptococci and lactobacilli 5 months after cementation of orthodontic brackets in comparison to brackets cemented with a composite resin (Wright et al., 1996).

Hence, Geristore as cement for Pedo Jacket crowns may exhibit caries-protective properties. The increased fluoride concentration in plaque and the associated reduction in cariogenic bacteria around the resin modified glass ionomer may be clinically beneficial to children with high caries susceptibility.

2.2.6. Pedo Jacket Crowns and Resin-Modified Glass Ionomer Cement as an Interim Therapeutic Restoration

The usefulness of RMGI materials for the restoration of primary teeth have been previously documented in the literature, especially for class I, II, III and V restorations (Croll et al., 2001; Croll et al., 1995; CrollKillian, 1993a, 1993b; CrollKillian et al., 1993; Donly et al., 1999). As summarized previously, RMGIs exhibit many properties that are beneficial to the rehabilitation of teeth with early childhood caries. Specifically, the fast dual cure, moisture tolerance, release of fluoride which aids in remineralization and cariostatic processes, and biocompatibility of RMGIs are advantageous to a young child with a high caries risk.

Nelson (2013) described two case reports whereby resin-modified glass ionomer strip crowns were used as interim restorations for carious primary anterior teeth (Nelson, 2013). The
two cases involved young children (a 3 year-old male and 4 year old female) with carious primary maxillary central incisors involving multiple surfaces. The children were unable to cooperate for conventional treatment with the use of local anesthesia and the parents had refused pharmacological behavior management techniques and general anesthesia. Instead, resin-modified glass ionomer strip crowns were placed to restore the maxillary primary central incisors. The technique involved minimal preparation of the teeth, including slicing of the interproximal surfaces with the use of a high-speed handpiece/bur only; the incisal edges were not reduced. Removal of gross caries, but not all caries, was done using rotary or hand instruments. Adequately-sized strip crowns were then filled with a RMGI (Fuji II LC RMGI, GC America, Alsip, Ill.; strip crown forms, 3M ESPE, St. Paul, Minn., USA), excess RMGI was removed, the crowns were light-cured, and minimal finishing of the incisal edge was required if any. The first case was followed up to 23 months after initial placement. The child had lost the crowns on the primary lateral incisors but although the crowns on the central incisors exhibited moderate wear, they were deemed clinically acceptable. The second patient was recalled at 9 months and the crowns were found to be intact. Therefore, this case report suggested that RMGI strip crowns may be successful as interim restorations in young, uncooperative children for whom sedation or general anesthesia is not possible.

The above case reports parallel the Hall technique principle introduced by Innes et al. (2006). This technique is an alternative approach to the traditional placement of stainless steel crowns on decayed primary molars which require local anesthesia, complete tooth reduction and caries removal. The Hall technique is minimally invasive; it does not require the use of local anesthesia, tooth preparation or removal of caries. A stainless steel crown of adequate size is simply selected, seated with finger pressure or biting force, and cemented with a glass ionomer cement onto the unprepared affected molar. The outcome of this unconventional
method was analyzed in a split mouth, randomized clinical trial by Innes et al. in 2007. The authors compared conventional restorations (mostly GI) in carious primary molars as control with Hall technique preformed metal crowns. Overall, the preformed metal crowns were well tolerated by the children and demonstrated a lower number of failures than the conventional group of restorations, with a failure rate of 8% and 61% respectively after a minimum follow-up period of 23 months and a sample of 128 restorations in each group (Innes et al., 2007).

Our research used a resin-modified glass ionomer, Geristore, for the cementation of the Pedo Jacket crowns in young children with early childhood caries affecting the maxillary primary anterior teeth. Similar to the concepts illustrated by the above case report and the Hall technique, one of the main indications for Pedo Jacket crowns in our study was for caries control and interim restorations for carious incisors in young children who lacked the ability to cooperate. The goal was to temporize and stabilize the teeth by arresting the progression of caries until the child becomes old enough to tolerate definitive restorations such as composite resin strip crowns or any of the metal variety of preformed metal crowns. Under certain circumstances the Pedo Jacket crowns can serve as definitive final restorations.

2.3. Past Study Designs on Anterior Full Coverage Restorations for ECC

The vast majority of studies on preformed primary anterior crowns that are available in the literature are retrospective studies, case reports, or descriptive articles that outline the clinical placement technique of the different crowns. What is lacking is good quality evidence in the form of prospective clinical trials that evaluate the clinical and radiographic performance of primary anterior crowns. Despite the long history of use of some of the aforementioned primary anterior crowns, the most ideal restoration for decayed or traumatized primary incisors remains subjective. The literature on how primary crowns perform in oral environments with
differing levels of oral hygiene is also sparse. Few clinical studies reported the oral hygiene of their study participants but no assessment was made to correlate the success of a crown with oral hygiene (MacLean et al., 2007; Shah et al., 2004). Therefore, there is a need for high quality prospective clinical studies to investigate the longevity of the available preformed primary anterior crowns including Pedo Jacket crowns.

3. STATEMENT OF THE PROBLEM

Although many of the available types of anterior preformed crowns are universally used by pediatric dentists, scientific evidence is presently lacking to corroborate the superiority of one type of crown over others. The flexible Pedo Jacket crowns are an alternate to rigid full coronal coverage restorations that can be used for primary incisors, canines and first molars. There is no clinical study evaluating their performance and durability in children.

One of the methods of clinical failure of Pedo Jacket crowns has been anecdotally reported to involve the separation of the Pedo Jacket crown form from the cement material. Information on the physical performance of these crowns under different conditions is unavailable and there is no laboratory study to characterize the retention of Pedo Jacket crowns.

4. AIMS AND OBJECTIVES

1. To evaluate the clinical performance of Pedo Jacket crowns in the restoration of carious primary maxillary anteriors prospectively and to determine if Pedo Jacket crowns are a viable interim treatment alternative in the management of early childhood caries in pre-cooperative children.
2. To characterize the shear bond strength of Pedo Jacket crowns and to determine the effect of different methods for increasing the shear bond strength of Pedo Jacket crowns in vitro.

5. MATERIALS AND METHODS

5.1. Study Design

This project was approved by the Research and Ethics Committees of the University of Toronto, conducted in compliance with the ethical principles of the Health Sciences Research Ethics Board (REB; Appendix 2). This was a 12-month prospective, longitudinal, multicentre clinical study design, conducted by four pediatric dentists (GK, JM, JO, and SB). The study participants had to return for 6-month and 12-month recall examinations.

5.1.1. Subject Selection

This study was designed to evaluate the clinical success of Pedo Jacket crowns that were placed in six different private dental practices with the above mentioned clinicians. The study subjects received one or more Pedo Jacket crowns placed by one of the four clinicians at their respective private practices. The children were treated for dental caries of the primary maxillary incisors and canines over a period of 12 months. Inclusion and exclusion criteria similar to those for trials of other types of preformed anterior crowns for primary teeth (Kupietzky et al., 2005; Kupietzky et al., 2003; MacLean et al., 2007; Shah et al., 2004) were used as outlined below:

- Inclusion criteria: healthy children between 1 and 5 years old, carious primary maxillary incisors and canines, compliant for recall visits and written informed consent.
- Exclusion criteria: non-restorable tooth, tooth near exfoliation.
5.1.2. Restorative Materials and Dental Cement

Pedo Jacket crowns (Success Essentials Space Maintainers Laboratory, Chatsworth, CA 91311 USA) were used to restore carious primary maxillary incisors and canines. A plastic primer provided by the same manufacturer was also used in conjunction with the Pedo Jacket crowns.

Geristore Syringeable (Den-Mat, Santa Maria, CA 93455 USA), a dual-cure resin-modified glass ionomer, was used in this study as the cement material in the Pedo Jacket crown (Figure 10c). Geristore was chosen for compatibility with the crown, ease of use and good esthetics.

A Geristore bonding agent (Figure 10d) was used to increase the bond strength of the Geristore to the enamel and dentin surfaces. Tenure Quik Bond with Fluoride (Den-Mat, Santa Maria, CA 93455 USA) was chosen for this experiment due to its ease of use (single step application, no mixing required). The restorative materials used in the clinical study are listed in Table 2 below.

Figure 10: Restorative materials. (a) Pedo Jacket Crowns; (b) Plastic Primer for Pedo Jacket Crowns; (c) Geristore Syringeable; (d) Tenure Quik Bond with Fluoride.
<table>
<thead>
<tr>
<th>Materials</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pedo Jacket Crown</td>
<td>Success Essentials Space Maintainers Laboratory, Van Nuys, CA 91409-4184 USA</td>
</tr>
<tr>
<td>Pedo Jacket plastic primer</td>
<td>Success Essentials Space Maintainers Laboratory, Van Nuys, CA 91409-4184 USA</td>
</tr>
<tr>
<td>Geristore Syringeable</td>
<td>Den-Mat, Santa Maria, CA 93455 USA</td>
</tr>
<tr>
<td>Tenure Quik with Fluoride</td>
<td>Den-Mat, Santa Maria, CA 93455 USA</td>
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</table>

Table 2: Restorative materials and adhesive system used in the clinical study.

5.1.3. Procedures

Four pediatric dentists were trained and calibrated on the use of the Pedo Jacket crowns as well as the assessment criteria through a calibration exercise conducted by the study investigator under the supervision of the Principal Investigator (PI). The calibration exercise involved a training session that described the standardized operative protocol and instructions in carrying out the preparation of carious teeth and placement of the Pedo Jacket crowns.

Each dentist was asked to recruit patients from their private dental offices. Subjects in this convenience sample were approached at their scheduled preventive care appointment and invited to participate. Following consent, a standard examination was performed with a mouth mirror and explorer. The oral hygiene of every child was recorded using the Debris (Greene et al., 1964) and Modified Gingival Indices (Loe, 1967). A periapical radiograph of the carious primary maxillary incisors or canines was taken either at the examination appointment or at the beginning of the restorative appointment. A total of 60 children were eligible for inclusion in the study and were treated with Pedo Jacket crowns. The crowns were placed either under general anesthesia or local anesthesia. The treated teeth had multiple carious surfaces. A detailed description of the clinical technique is illustrated in Figure 11 below. Briefly, after
local anesthesia and rubber dam placement, caries were excavated, the teeth were minimally reduced from all surfaces to preserve maximum enamel and Pedo Jacket crowns were fitted. If necessary, the length of the Pedo Jacket crowns were adjusted and trimmed with scissors. A gel etching agent (Etch Rite, 38% phosphoric acid gel, Pulpdent Corporation, Watertown, MA, 02471 USA) was applied for 15 seconds and was rinsed off thoroughly. Tenure Quik Bond with Fluoride (Den-Mat, Santa Maria, CA 93455 USA) was used according to the manufacturer’s instructions. The crowns were cemented with a resin-modified glass ionomer cement (Geristore Syringeable, Den-Mat, Santa Maria, CA 93455 USA).
Figure 11: Clinical technique for the placement of a Pedo Jacket crown. a) Local anesthesia and rubber dam placement. b) Caries removal. c) Tooth reduction using a fine diamond bur and high speed handpiece until sufficient reduction achieved to fit Pedo Jacket; effort made to preserve maximal amount of enamel. d) Dry fitting of adequately-sized Pedo Jacket. e) Trimming of the crown to achieve adequate length with crown margin at cervical junction of tooth. f) Dry fitting of the crown after length adjustment. g) Two single layers of primer applied to inner surface of crown; first layer applied 2 minutes before filling crown with cement; second layer applied just prior to filling with cement. h) Etching of the tooth for 15 seconds, followed by thorough rinsing. i) Bonding agent placement on the tooth; 3 consecutive coats applied to tooth and allowed to sit for 15 seconds, followed by air spray, then 30 second light cure. j) Filling the crown with Geristore and seating of the crown. k) Removal of all excess cement. l) Light curing of the seated crown for 40 seconds per surface (facial and lingual).
5.1.4. Clinical and Radiographic Assessment of Pedo Jacket Crowns

Five non-blinded, calibrated examiners (GK, JM, JO, SB, and AC, the study investigator) completed all clinical and radiographic evaluations of the crowns with the chairside assessment criteria outlined below and recorded the data. When possible, digital intraoral photographs were taken of the teeth pre- and post-treatment. The clinical data collected included the patient’s gender, age and date of restoration placement.

Clinical and radiographic examinations were performed for evaluation of the Pedo Jacket crowns (Table 3). Criteria selected for this study reflect those used in similar studies and considered important in the clinical and radiographic acceptance of preformed primary anterior crowns (Kupietzky et al., 2005; Kupietzky et al., 2003; MacLean et al., 2007; Shah et al., 2004). Calibration sessions were held prior to data collection, including the identification and scoring of the variables. The assessment parameters and the scoring system used are shown in Table 3 below; they include the ease of use of the Pedo Jacket crowns, presence of recurrent caries, retention of the crown, marginal integrity, fracture, wear, color stability, soft-tissue associated pathology, cost of placement/repair, as well as overall clinical outcome of the crowns. The radiographic criteria were defined as: (0) healthy (no pulp pathology); (1) pulpal changes evident but no treatment is required, only observation (e.g. pulp calcification); (2) pulp changes evident and treatment such as endodontic therapy or extraction is required (e.g. external root resorption, internal root resorption, periapical bone destruction). Clinical and radiographic success was defined as crowns that were completely intact or had minor defects that did not require treatment (equivalent to scores of 0 or 1). Clinical and radiographic failures included crowns that demonstrated extensive defects requiring repair/extraction of the tooth or loss of the crown (equivalent to scores of 2 or 3). The child’s oral hygiene was recorded using the Debris (Greene et al., 1964) and Modified Gingival Indices (Loe, 1967).
Table 3: Clinical and Radiographic Assessment of Pedo Jacket Crowns

**Immediate Post-Placement**

<table>
<thead>
<tr>
<th>1. Ease of use</th>
<th>0 = Easy</th>
<th>1 = Moderately Easy</th>
<th>2 = Difficult</th>
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**6 and 12 Months Post-Placement**

<table>
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<tr>
<th>2. Presence of recurrent caries</th>
<th>0 = No</th>
<th>2 = Yes</th>
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<table>
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<tr>
<th>3. Presence of crown</th>
<th>0 = Present</th>
<th>1 = Partial loss</th>
<th>2 = Complete loss</th>
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| 4. Marginal integrity/gingival margin discoloration | 0 = None: No chipping, No discoloration | 1 = Minor-Moderate chipping and discoloration (≤2 surfaces affected) | 2 = Severe chipping and discoloration (>2 surfaces affected) |
|-----------------------------------------------------|----------------------------------------|---------------------------------------------------------------|
|                                                     |                                        |                                                               |

<table>
<thead>
<tr>
<th>5. Presence of fractures/chipping</th>
<th>0 = None</th>
<th>1 = Mild-Moderate (≤2 surfaces affected)</th>
<th>2 = Severe (&gt;2 surfaces affected)</th>
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<tr>
<th>6. Presence of incisal/lingual wear</th>
<th>0 = None</th>
<th>1 = Mild-Moderate (≤1/3 of the crown)</th>
<th>2 = Severe (&gt;1/3 of the crown)</th>
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<table>
<thead>
<tr>
<th>7. Color stability</th>
<th>0 = No discoloration</th>
<th>1 = Minor-Moderate discoloration (≤2 surfaces affected)</th>
<th>2 = Severe discoloration (&gt;2 surfaces affected)</th>
</tr>
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<table>
<thead>
<tr>
<th>8. Radiographic pulpal health</th>
<th>0 = Healthy</th>
<th>1 = Changes visible but no treatment required</th>
<th>2 = Changes visible and treatment is required</th>
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<table>
<thead>
<tr>
<th>9. Presence of tooth-associated pathology</th>
<th>0 = None</th>
<th>2 = Yes, gingival abscess</th>
<th>3 = Yes, periapical abscess</th>
</tr>
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<table>
<thead>
<tr>
<th>10. Cost of placement/replacement</th>
<th>0 = Affordable: Similar to cost of strip crowns</th>
<th>1 = Expensive: Similar to cost of preveneered stainless steel crowns</th>
<th>2 = Very Expensive: More expensive than the cost of preveneered stainless steel crowns</th>
</tr>
</thead>
</table>
The child’s behavior was recorded at each of the dental appointments using the Frankl behavior rating scale (Frankl et al., 1962) in Table 4. This behavior rating scale was not applicable for treatment under general anesthesia.

**Table 4: Frankl Behavioral Rating Scale** (Frankl et al., 1962)

<table>
<thead>
<tr>
<th>1.</th>
<th>- -</th>
<th>Definitely negative. Refusal of treatment, forceful crying, fearfulness, or any other overt evidence of extreme negativism.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>-</td>
<td>Negative. Reluctance to accept treatment, uncooperative, some evidence of negative attitude but not pronounced (sullen, withdrawn).</td>
</tr>
<tr>
<td>3.</td>
<td>+</td>
<td>Positive. Acceptance of treatment; cautious behavior at times; willingness to comply with the dentist, at times with reservation, but patient follows the dentist's directions cooperatively.</td>
</tr>
<tr>
<td>4.</td>
<td>+ +</td>
<td>Definitely positive. Good rapport with the dentist, interested in the dental procedures, laughter and enjoyment.</td>
</tr>
</tbody>
</table>

### 5.2. Statistical Analyses

The clinical data were compiled, and descriptive statistics were generated for each of the clinical and radiographic parameters used to evaluate crown longevity. Chi Square or Fisher’s Exact tests were used to examine the possible relationship between oral hygiene and crown failure. Data were entered into an Excel spreadsheet (Microsoft Corp, Redmond, Wash)
and imported into IBM SPSS Statistics 21.0 software (SPSS, Inc, Chicago, Ill) for statistical analysis. Descriptive statistics were used to describe the demographic information. A P-value of less than 0.05 was considered significant.

5.3. In Vitro Study

5.3.1. Sample Preparation

**Tooth preparation**

The *in vitro* experiment was conducted by the study investigator. Forty human permanent teeth (incisors, canines, premolars) extracted due to root caries, periodontal disease or for orthodontic purposes were obtained. The teeth were thoroughly cleaned and stored in closed bottles containing distilled water and thymol as a disinfectant. The teeth were removed from the thymol solution and stored in distilled water at 37 degrees Celsius in the dark, for at least 24 hours before beginning the experiment.

The teeth were prepared using a high speed handpiece and a fine diamond bur. The teeth were prepared minimally on the interproximal (0.5 – 1 mm), facial/buccal (0.25 - 0.5 mm), lingual (0.25 - 0.5 mm) and incisal (1 - 1.5 mm) surfaces until sufficient reduction was obtained to fit a Pedo Jacket crown (Figure 12). Effort was made to preserve as much enamel as possible. Etch Rite (38% phosphoric acid gel; Pulpdent Corporation, Watertown, MA, 02471 USA) was applied to all surfaces of the teeth for 15 seconds. The etchant was thoroughly rinsed with water spray. The teeth were dried using air spray to reveal a chalky white appearance of the enamel.
The specimens were randomly assigned to one of the four treatment groups (N=10) for bonding with a resin-modified glass ionomer cement. The RMGI cement was bonded according to the manufacturer’s instructions.

**Fitting of the Pedo Jacket Crown**

Pedo Jacket crowns were fitted to the prepared teeth and trimmed with curved scissors as necessary until the crown margins were at the cervical margins of the teeth. Geristore Syringeable (Den-Mat, Santa Maria, CA 93455 USA) was used as cement. The Geristore was refrigerated for storage prior to use in the experiment. The Geristore was brought to room temperature at least 30 minutes before beginning the experiment.
**Bonding system**

![Tenure Quik bonding agent by Den-Mat, USA.](image)

A Geristore bonding agent (Figure 13) was used to increase the bond strength of the Geristore to the enamel and dentin surfaces. Tenure Quik Bond with Fluoride (Den-Mat, Santa Maria, CA 93455 USA) was chosen for the experiment due to its ease of use (single step application, no mixing required). The bonding agent Tenure Quik with Fluoride was stored at room temperature prior to use in the experiment. A microbrush was completely immersed in Tenure Quik with Fluoride. Using a fully saturated brush tip, 3 consecutive coats were applied to the prepared teeth. The bonding agent was allowed to sit on the teeth for 15 seconds. The teeth were then air-dried gently with air spray, leaving a glossy appearance on the tooth surface. If the surface was not glossy after drying, the Tenure Quik with Fluoride was reapplied and gently re-dried. The bonding agent was then light cured for 30 seconds using a conventional halogen curing light.
Treatment Group Procedure

Group 1: Pedo Jacket crowns with primer only (Control)

The plastic primer provided for the Pedo Jacket crowns (Figure 14) was placed on the inner surface of the crowns using a microbrush. The Pedo Jacket crowns were primed twice with the plastic primer: a single layer was placed and allowed to sit for 2 minutes, and then another single layer of primer was placed just prior to filling the crowns with Geristore.

![Figure 14: Crown primer and brush applicators by Space Maintainers Laboratory, USA.](image)

Crown cementation

![Figure 15: Geristore crown cement by Den-Mat, USA.](image)

A syringe tip was placed on the Geristore syringe (Den-Mat, Santa Maria, CA 93455 USA) to dispense the material into and to fill the crowns (Figure 15). The Pedo Jacket crowns were seated onto the prepared teeth with finger pressure and all excess Geristore was expressed and removed with a hand instrument. The facial/buccal and lingual surfaces of the restored teeth were then cured with a conventional halogen light for 40 seconds per surface. A dental probe was used to check for completeness of cure. When necessary, the curing cycle was
repeated until complete cure of the material was achieved. No finishing of the restored teeth was done.

**Group 2: Pedo Jacket crowns with mechanical retention**

![Figure 16: Pedo Jacket with mechanical retention](image)

A single perforation on the facial/buccal surface 2 mm above the cemento-enamel junction of each Pedo Jacket crown was placed using a high speed handpiece and a tapered fine diamond bur (Figure 16). The teeth were then restored as per the steps outlined in group 1.

**Group 3: Pedo Jacket crown with glass ionomer inorganic particles added to the plastic primer; moderate concentration GIC particles (GIC 1)**

The tooth preparation and application of the Tenure Quik bonding agent were done according to the same steps outlined in group 1, with the exception of the primer application. The inner surfaces of the Pedo Jacket crowns were primed once with a single layer of plastic primer and allowed to sit for 2 minutes. Then glass ionomer inorganic particles (Ketac Cem powder, 3M ESPE, St. Paul, MN 55144-100 USA) of moderate concentration (0.305 g GIC/150 µL primer, equivalent to 1 scoop of GIC powder and 8 drops of plastic primer) were incorporated into the plastic primer liquid by metal spatula. These glass ionomer particles were
added to help create a rough surface on the inner surface of the crown and to embed into the Geristore surface. This mixture of glass ionomer inorganic particles and plastic primer was applied in a thin layer using a microbrush to prime the inner surface of the crowns just prior to filling the crowns with Geristore. The Pedo Jacket crowns were then cemented as per the steps outlined in group 1.

**Group 4: Pedo Jacket crown with GIC inorganic particles added to the plastic primer:**

**Low concentration GIC particles (GIC 2)**

The tooth preparation and application of the Tenure Quik bonding agent were done according to the same steps outlined above. As in group 3, the inner surfaces of the Pedo Jacket crowns were primed once with a single layer of plastic primer and allowed to sit for 2 minutes. Then GIC inorganic particles (Ketac Cem powder, 3M ESPE, St. Paul, MN 55144-1000 USA) of lower concentration (0.1525 g GIC/150 µL primer, equivalent to 1/2 scoop of GIC powder and 8 drops of plastic primer) were incorporated into the plastic primer liquid by metal spatula. This mixture of glass ionomer inorganic particles and plastic primer was applied in a thin layer using a microbrush to prime the inner surface of the crowns just prior to filling the crowns with Geristore. The Pedo Jacket crowns were then cemented as per the steps outlined in group 1. Table 5 summarizes the restorative materials used.
Table 5: Restorative materials and adhesive system used for the in vitro study.

<table>
<thead>
<tr>
<th>Materials</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pedo Jacket Crown</td>
<td>Success Essentials Space Maintainers Laboratory, Van Nuys, CA 91409-4184 USA</td>
</tr>
<tr>
<td>Pedo Jacket plastic primer</td>
<td>Success Essentials Space Maintainers Laboratory, Van Nuys, CA 91409-4184 USA</td>
</tr>
<tr>
<td>Geristore Syringeable</td>
<td>Den-Mat, Santa Maria, CA 93455 USA</td>
</tr>
<tr>
<td>Tenure Quik with Fluoride</td>
<td>Den-Mat, Santa Maria, CA 93455 USA</td>
</tr>
<tr>
<td>Ketac Cem Easymix powder</td>
<td>3M ESPE, St. Paul, MN, 55144-1000 USA</td>
</tr>
</tbody>
</table>

5.3.2. Thermocycling

Thermocycling is a commonly used method for artificial aging. The ISO TR 11 450 standard indicates that a thermocycling regimen comprising 500 cycles in water between 5 and 55 °C is an appropriate artificial aging method (ISO, 1994). The restorations were finished and stored in distilled water at 37 °C for 24 h and then subjected to thermocycling. The specimens were thermocycled 500 times between water baths held at 5 °C and 55 °C with 30 seconds of dwell time.

5.3.3. Mounting of Specimens

The teeth were mounted in cylindrical cold-cure acrylic resin blocks of 2.54 centimeters (1 inch) in diameter and 1.5 centimeters (cm) in height. The lingual surface of the teeth were embedded into the acrylic with the long axis of the tooth specimens parallel to the flat surface of the acrylic blocks, exposing 2 mm of the facial/buccal surface of the teeth above the acrylic (Figure 17). The facial/buccal surface of the teeth was selected for testing because this surface is more flat and even than the lingual surface of the teeth, which allows for a more homogeneous application of the shear force by the Instron Testing Machine.
5.3.4. **Instron Testing for Shear Bond Strength**

A Universal Testing Machine or Instron Materials Testing Machine (Instron model 8501) was used to test the maximum shear bond strength of the Pedo Jacket crowns in each of the four groups. The specimens were fixed with a steel vice and were transferred to a testing holder which could be approximated to the moving cross-head of the Instron testing machine (Figure 18). Prior to mounting the teeth, the facial/buccal root surfaces were cut with a high speed carbide bur to a depth of 1 mm to provide room for the cross-head. The cross-head was then positioned parallel to the gingival margin of the crown and would contact the facial/buccal surface of the teeth at the inferior margin of the Pedo Jacket crown. The maximum shear bond strength required to debond the Pedo Jacket crown from the tooth was recorded in Newtons (N), at a cross-head speed of 1 mm/minute and load cell of 10,000 N. Since the area at the point of force application varied from specimen to specimen, it was not possible to convert the force units from Newton and express them as Pascal units.
5.3.5. Assessment of Fracture Failure

5.3.5.1. Scanning Electron Microscopy (SEM)

A Hitachi S-2500 scanning electron microscope was used for examination of the interfacial structure between the Pedo Jacket crown (PJ) and the RMGI cement (RMGIC), as well as that of the RMGI cement and dentin. This was carried out on two different groups of teeth. The first group was Pedo Jacket crowns restored in vitro according to the methods described below (Pedo Jacket crowns). The second group of teeth consisted of a select number of teeth that underwent mechanical testing in vitro (Shear-Tested Pedo Jacket crowns). Prior to SEM analysis, all samples were critical point dried (Anderson, 1951) and sputter-coated with a 9 nanometer thick layer of platinum particles.

**Group A: Pedo Jacket crowns**

The purpose of viewing the Pedo Jacket crowns under SEM was to qualitatively analyze the interface between the crown and the cement in specimens restored with different
conditioning systems. Three different specimens were imaged in this group; the first was a Pedo Jacket crown cemented according to the manufacturer’s instructions (as outlined above in Treatment Group 1); the other two specimens consisted of Pedo Jacket crowns in which glass ionomer inorganic particles were mixed in with the crown primer (Treatment Groups 3 and 4). The aim was to determine whether the chemical addition of glass ionomer particles to the crown primer enhanced the adhesion of the Pedo Jacket crown to the resin-modified glass ionomer cement.

Each specimen was sliced along the long axis of the tooth just lateral to the midline using a diamond wafer blade (Electron Microscopy Sciences, Hatfield, PA 19940 USA) and low speed saw. This slice was made to allow for the visualization of the internal surfaces of the tooth and the boundaries between the crown, Geristore cement and dentin (Figure 19) under SEM. The smaller sections of the teeth were discarded and the larger sections were used for SEM analysis.

![Figure 19: Sectioned tooth showing the Pedo Jacket crown, RMGI cement and dentin; PJ = Pedo Jacket crown; RMGiC = Resin-modified glass ionomer cement.](image)
Group B: Shear-Tested Pedo Jacket crowns

The second group of specimens for SEM analysis included Pedo Jacket crowns that underwent Instron testing for shear bond strength. Once maximum shear bond strength was attained and debonding of the Pedo Jacket occurred, the debonded surface was examined under SEM at different magnifications. The objective of viewing the shear-tested specimens was to examine the failed surfaces and determine the interface at which the crown had failed for qualitative analysis (crown-cement interface vs. cement-dentin interface).

5.3.5.2. Microscopy

Imaging of specimens was also undertaken at a magnification of 10X to 30X to supplement the qualitative analysis of crown failure subsequent to shear bond strength testing. Representative specimens were selected for imaging in order to further describe the surface at which debonding of the crown occurred.

5.4. Statistical Analysis

The data were analyzed by ANOVA and post-hoc multiple pairwise comparisons using the Tukey and Bonferroni’s tests. The data were entered into an Excel spreadsheet (Microsoft Corp, Redmond, Wash) and imported into IBM SPSS Statistics 21.0 software (SPSS, Inc, Chicago, Ill) for statistical analysis.
6. RESULTS

6.1 Prospective Clinical Study

6.1.1. Patient Characteristics

Sixty children who met the inclusion criteria and provided consent to participate in the study were enrolled in this prospective clinical trial (33 males, 27 females). Among the 60 participating children, 161 primary maxillary anterior teeth had received Pedo Jacket crowns (90 central incisors, 69 lateral incisors, 2 canines). Of the 60 children, 6 children were lost to follow-up. The reasons for the loss to follow-up included inability to contact families of participants due to moved, altered or lost telephone services, or because the families were not interested in continuing in the study. Fifty-four children with 142 treated teeth (31 males, 23 females) remained with the study. Of these 54, 50 were available at the 6-month follow-up and 48 were available at the 12 month follow-up. The children were seen as close to the 6 and 12-month intervals as possible, however, the time interval was longer in some cases due to the varying compliance of the study participants with their recall visits. The average age of the children was 42.5 months (S.D. ± 13.0, range 13.4 to 71.1 months) at the time of crown placement, 51.6 months (S.D. ± 13.1, range 19.5 to 83.3 months) at 6 months, and 65.5 months (S.D. ± 14.4, range 41.1-95.1 months) at 12 months. Thirty-eight children were treated under local anesthesia and 16 children under general anesthesia. At the last follow-up visit, the oral hygiene level was good (scores 0 or 1 on Debris and Modified Gingival Indices) in 85.2% of children (46 out of 54), and poor (scores 2 or 3 on Debris and Modified Gingival Indices) in 15.8% (8 out of 54). Table 6 shows the summary statistics of the study sample described.
Table 6: Summary statistics of study participants at the last follow-up visit.

<table>
<thead>
<tr>
<th>Number of</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>54</td>
</tr>
<tr>
<td>Teeth</td>
<td>142</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>31</td>
</tr>
<tr>
<td>Female</td>
<td>23</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean age at (months)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of placement</td>
<td>42.5</td>
</tr>
<tr>
<td>6 month follow-up</td>
<td>51.6</td>
</tr>
<tr>
<td>12 month follow-up</td>
<td>65.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment modality (children)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Local anesthesia</td>
<td>38</td>
</tr>
<tr>
<td>General anesthesia</td>
<td>16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oral Hygiene</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>46</td>
</tr>
<tr>
<td>Poor</td>
<td>8</td>
</tr>
</tbody>
</table>

The distribution of teeth included in the study is shown in Table 7. Of the 161 teeth restored with Pedo Jacket crowns, 90 were primary maxillary central incisors, 69 were lateral incisors, and 2 were canines. At 6 months, 128 primary teeth (72 primary central incisors, 54 lateral incisors, 2 canines) were available for analysis. At 12 months, 129 primary teeth (71 central incisors, 56 lateral incisors, 2 canines) were available for analysis. One primary lateral incisor received a pulpotomy and 14 primary incisors (10 centrals, 4 laterals) received primary root canal therapy at the time of placement of the Pedo Jacket crowns. Of these, 8 incisors and the single pulpotomized tooth were available for analysis.
Table 7: Distribution of teeth included in the study including the 6 and 12-month follow-ups.

<table>
<thead>
<tr>
<th>Tooth distribution</th>
<th>Other variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central incisors (teeth)</td>
<td>Lateral incisors (teeth)</td>
</tr>
<tr>
<td>Pulpotomy</td>
<td>RCT</td>
</tr>
<tr>
<td>Time of placement</td>
<td>6 months</td>
</tr>
<tr>
<td>Teeth (Proportion of children)</td>
<td>82 (31)</td>
</tr>
<tr>
<td>6 Months Post-Placement</td>
<td></td>
</tr>
<tr>
<td>Teeth (Proportion of children)</td>
<td>122 (48.5)</td>
</tr>
<tr>
<td>3. Presence of crown</td>
<td>0 = Present</td>
</tr>
<tr>
<td>Teeth (Proportion of children)</td>
<td>126 (49.42)</td>
</tr>
</tbody>
</table>

6.1.2. Clinical and Radiographic Assessment of Pedo Jacket Crowns

Clinical and radiographic examination results for all 13 crown assessment criteria are listed in Table 8.

Table 8: Results of clinical and radiographic assessment at 6 and 12 months

Immediate Post-Placement

<table>
<thead>
<tr>
<th>1. Ease of use</th>
<th>0 = Easy</th>
<th>1 = Moderately Easy</th>
<th>2 = Difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth (Proportion of children)</td>
<td>82 (31)</td>
<td>46 (18.5)</td>
<td>14 (4.5)</td>
</tr>
</tbody>
</table>

6 Months Post-Placement

<table>
<thead>
<tr>
<th>2. Presence of recurrent caries</th>
<th>0 = No</th>
<th>2 = Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth (Proportion of children)</td>
<td>122 (48.5)</td>
<td>6 (1.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Presence of crown</th>
<th>0 = Present</th>
<th>1 = Partial loss</th>
<th>2 = Complete loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth (Proportion of children)</td>
<td>126 (49.42)</td>
<td>0</td>
<td>2 (0.58)</td>
</tr>
<tr>
<td>4. Marginal integrity/gingival margin discoloration</td>
<td>0  =  None: No chipping, No discoloration</td>
<td>1  =  Minor- Moderate chipping and discoloration (≤2 surfaces affected)</td>
<td>2  =  Severe chipping and discoloration (&gt;2 surfaces affected)</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>------------------------------------------</td>
<td>-------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>123 (48.25)</td>
<td>5 (1.75)</td>
<td>0</td>
</tr>
</tbody>
</table>

| 5. Presence of fractures/chipping                 | 0  =  None                               | 1  =  Mild-Moderate (≤2 surfaces affected)     | 2  =  Severe (>2 surfaces affected)            |
| **Teeth (Proportion of children)**               | 116 (47)                                 | 12 (3)                                        | 0                                             |

| 6. Presence of incisal/lingual wear              | 0  =  None                               | 1  =  Mild-Moderate (≤1/3 of the crown)       | 2  =  Severe (>1/3 of the crown)              |
| **Teeth (Proportion of children)**               | 105 (42)                                 | 23 (8)                                        | 0                                             |

| 7. Color stability                                | 0  =  No discoloration                   | 1  =  Minor-Moderate discoloration (≤2 surfaces affected) | 2  =  Severe discoloration (>2 surfaces affected) |
| **Teeth (Proportion of children)**               | 79 (33.25)                               | 49 (16.75)                                    | 0                                             |

| 8. Radiographic pulpal health                     | 0  =  Healthy                            | 1  =  Changes visible but no treatment required | 2  =  Changes visible and treatment is required |
| **Teeth (Proportion of children)**               | 106 (41.75)                              | 0                                              | 1 (0.25)                                      |

| 9. Presence of tooth-associated pathology         | 0  =  None                               | 2  =  Yes, gingival abscess                     | 3  =  Yes, periapical abscess                 |
| **Teeth (Proportion of children)**               | 127 (49.75)                              | 0                                              | 1 (0.25)                                      |

| 10. Cost of placement/replacement                | 0  =  Affordable: Similar to cost of strip crowns | 1  =  Expensive: Similar to cost of preveneered stainless steel crowns | 2  =  Very Expensive: More expensive than the cost of preveneered stainless steel crowns |
| **Teeth (Proportion of children)**               | 117 (46)                                 | 0                                              | 0                                             |
11. Overall clinical outcome

<table>
<thead>
<tr>
<th>Teeth (Proportion of children)</th>
<th>0 = Crown intact</th>
<th>1 = mild defect that requires only monitoring</th>
<th>2 = Moderate defects that require repair or replacement</th>
<th>3 = Crown failure requiring extraction of tooth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>83 (36.25)</td>
<td>39 (11.92)</td>
<td>4 (1.25)</td>
<td>2 (0.58)</td>
</tr>
</tbody>
</table>

12. Debris index (Greene et al., 1964)

<table>
<thead>
<tr>
<th>Teeth (Proportion of children)</th>
<th>0 = No plaque</th>
<th>1 = Plaque covering 1/3 of the crown</th>
<th>2 = Plaque covering 2/3 of the crown</th>
<th>3 = Plaque completely covering the crown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>48 (19.5)</td>
<td>58 (23.17)</td>
<td>18 (6.33)</td>
<td>4 (1)</td>
</tr>
</tbody>
</table>

13. Modified gingival index (Loe, 1967)

<table>
<thead>
<tr>
<th>Teeth (Proportion of children)</th>
<th>0 = Normal gingiva</th>
<th>1 = Mild inflammation, slight change in color, slight edema, no bleeding on probing</th>
<th>2 = Moderate inflammation, redness, edema, and glazing, bleeding on probing</th>
<th>3 = Severe inflammation, marked redness and edema, ulceration, spontaneous bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>75 (32)</td>
<td>37 (12.5)</td>
<td>16 (5.5)</td>
<td>0</td>
</tr>
</tbody>
</table>

12 Months Post-Placement

<table>
<thead>
<tr>
<th>2. Presence of recurrent caries</th>
<th>0 = No</th>
<th>2 = Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth (Proportion of children)</td>
<td>117 (44.5)</td>
<td>7 (1.75)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Presence of crown</th>
<th>0 = Present</th>
<th>1 = Partial loss</th>
<th>2 = Complete loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth (Proportion of children)</td>
<td>114 (42.75)</td>
<td>0</td>
<td>10 (3.5)</td>
</tr>
</tbody>
</table>

<p>| 4. Marginal integrity/gingival margin discoloration | 0 = None: No chipping, No discoloration | 1 = Minor- Moderate chipping and discoloration (≤2 surfaces affected) | 2 = Severe chipping and discoloration (&gt;2 surfaces affected) |
|---------------------------------------------------|-----------------------------------------|---------------------------------------------------------------------|
| Teeth (Proportion of children)                     | 102 (38.75)                             | 11 (4.67)                                                           | 11 (2.83)                                |</p>
<table>
<thead>
<tr>
<th>5. Presence of fractures/chipping</th>
<th>0 = None</th>
<th>1 = Mild-Moderate (≤2 surfaces affected)</th>
<th>2 = Severe (&gt;2 surfaces affected)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>91 (34.92)</td>
<td>25 (9.33)</td>
<td>8 (2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Presence of incisal/lingual wear</th>
<th>0 = None</th>
<th>1 = Mild-Moderate (≤1/3 of the crown)</th>
<th>2 = Severe (&gt;1/3 of the crown)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>46 (17.17)</td>
<td>68 (26.58)</td>
<td>10 (2.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Color stability</th>
<th>0 = No discoloration</th>
<th>1 = Minor-Moderate discoloration (≤2 surfaces affected)</th>
<th>2 = Severe discoloration (&gt;2 surfaces affected)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>17 (6.5)</td>
<td>85 (33.67)</td>
<td>22 (6.08)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. Radiographic pulpal health</th>
<th>0 = Healthy</th>
<th>1 = Changes visible but no treatment required</th>
<th>2 = Changes visible and treatment is required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>115 (43)</td>
<td>2 (1)</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Presence of tooth-associated pathology</th>
<th>0 = None</th>
<th>2 = Yes, gingival abscess</th>
<th>3 = Yes, periapical abscess</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>121 (45.25)</td>
<td>2 (0.5)</td>
<td>1 (0.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. Cost of placement/replacement</th>
<th>0 = Affordable: Similar to cost of strip crowns</th>
<th>1 = Expensive: Similar to cost of preveneered stainless steel crowns</th>
<th>2 = Very Expensive: More expensive than the cost of preveneered stainless steel crowns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>112 (73.25)</td>
<td>4 (1)</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. Overall clinical outcome</th>
<th>0 = Crown intact</th>
<th>1 = mild defect that requires only monitoring</th>
<th>2 = Moderate defects that require repair or replacement</th>
<th>3 = Crown failure requiring extraction of tooth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth (Proportion of children)</strong></td>
<td>12 (4.5)</td>
<td>99 (37.42)</td>
<td>8 (2.58)</td>
<td>10 (3.5)</td>
</tr>
<tr>
<td>12. Debris index (Greene et al., 1964)</td>
<td>0 = No plaque</td>
<td>1 = Plaque covering 1/3 of the crown</td>
<td>2 = Plaque covering 2/3 of the crown</td>
<td>3 = Plaque completely covering the crown</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------------</td>
<td>--------------------------------------</td>
<td>--------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Teeth (Proportion of children)</td>
<td>60 (23)</td>
<td>48 (19.17)</td>
<td>15 (4.33)</td>
<td>6 (1.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>13. Modified gingival index (Loe, 1967)</th>
<th>0 = Normal gingiva</th>
<th>1 = Mild inflammation, slight change in color, slight edema, no bleeding on probing</th>
<th>2 = Moderate inflammation, redness, edema, and glazing, bleeding on probing</th>
<th>3 = Severe inflammation, marked redness and edema, ulceration, spontaneous bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth (Proportion of children)</td>
<td>76 (31.67)</td>
<td>43 (13.33)</td>
<td>6 (2)</td>
<td>4 (1)</td>
</tr>
</tbody>
</table>

In summary, 86.0% (111 out of 129 teeth) of the crowns were clinically and radiographically successful during the 12-month study period. These successful crowns were present in 87.3% of the children (41.92 out of 48 children). The children in Figure 20 (right) is expressed as a fraction due to the fact that certain children had both successful and failed crowns. Figure 20 illustrates these overall successes (as defined earlier to mean an intact crown or a mild defect that did not require intervention) and failures (moderate defect requiring repair or complete loss of the crown).
Of the 111 successful crowns, 9.3% (12 teeth) were completely intact; 76.7% (99 teeth) exhibited mild defects that did not require further treatment; 6.2% (8 teeth) had more moderate defects that necessitated repair of the Pedo Jacket crowns, which were considered as failures; 7.8% (10 teeth) of the crowns were also failures due to the complete loss of the crown. One central incisor was extracted due to the presence of internal root resorption, which was likely the consequence of trauma during a fall reported by the parent of the affected child. Figure 21 illustrates the teeth and proportion of children with teeth that were intact, with mild to moderate defects, and lost crowns. The number of children was reported as a fraction when a child had multiple restored teeth with different clinical outcomes for individual teeth.

Figure 20: Overall successes vs. failures at 12 months.
Figure 21: Overall clinical outcome of Pedo Jacket crowns at 12 months.

Pedo Jacket crowns were successfully retained after at least 6 months. Two crowns (1.6%) in the same child had fallen off at 6 months. At 12 months, 15 crowns were lost in 7 children. Of these 15 crowns, 4 crowns had exfoliated naturally; 1 primary central incisor was lost due to trauma from a fall. The remaining 10 crowns constituted clinical failures, which represented 8.1% of the study sample. Thus, the overall retention of Pedo Jacket crowns after 12 months was high (91.9% or 114 teeth). Figure 22 summarizes the 12-month results in terms of teeth and proportion of children with retained versus lost Pedo Jacket crowns.
Figure 22: Proportion of retained vs. lost Pedo Jacket crowns at 12 months.

The majority of Pedo Jacket crowns exhibited some degree of wear, as illustrated in Figure 23. Fifty-five percent (68 teeth) had minor lingual or incisal wear limited to less than the incisal third of the crown and 8.1% (10 teeth) had severe lingual or incisal wear affecting more than the incisal third of the crown. Thirty-seven percent of crowns (46 teeth) did not show any wear.

Figure 23: Presence of incisal and lingual wear at 12 months.
Clinical examinations revealed discoloration of the Pedo Jacket crowns to varying degrees within the same patient and at varying time points. The 12-month results are shown in Figure 24. Thirteen percent of crowns (17 teeth) had no discoloration, whereas minor discoloration involving 2 or less surfaces and severe discoloration of 3 or more surfaces were present in 68.5% (85 teeth) and 17.7% (22 teeth), respectively.

<table>
<thead>
<tr>
<th>Teeth</th>
<th>Proportion of children</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.7% (22)</td>
<td>13.7% (17)</td>
</tr>
<tr>
<td>68.5% (85)</td>
<td>13.1% (6.08)</td>
</tr>
<tr>
<td>Major &gt; 2 surfaces</td>
<td>None</td>
</tr>
</tbody>
</table>

Figure 24: Presence of crown discoloration at 12 months.

The Debris and Modified Gingival Indices revealed that most participating children had good oral hygiene levels (Scores of 0 or 1). The results are shown in Figure 25. At 12 months, 47.9% of children (23 children) had no visible plaque, 39.9% (19.17 children) had plaque covering a third of the crown, 9% (4.33 children) had plaque covering two-thirds of the crown, and 3.1% (1.5 children) had crowns completely covered in plaque. Gingival health was optimal in 66% (31.67 children) of the study sample. Twenty-eight percent of children (13.33 children) had only mild gingival inflammation, whereas 4.2% (2 children) and 2.1% (1 child) exhibited moderate to severe gingival inflammation, respectively. Again, the results for the number of
children are reported as a fraction due to the fact that some children had multiple Pedo Jacket crowns with different score categories for the individual teeth.

![Debris Index and Modified Gingival Index](image)

**Figure 25:** Oral hygiene at 12 months. a) Debris Index. b) Modified Gingival Index.

The overall clinical success rate and results from the other assessment parameters revealed a progressive decline in the clinical outcome of the crowns over time (95.3% success at 6 months versus 86.0% success at 12 months).

**6.1.3. Associations between Crown Function and Selected Variables**

Treatment under local anesthesia or general anesthesia did not show a significant association with crown success of failure in the treated children (Table 9). 81.0% of children with successful Pedo Jacket crowns received treatment under local anesthesia, and 19.0% received treatment under general anesthesia. Of the children with failed crowns, 66.7% were treated under local anesthesia, and the remaining 33.3% were treated under general anesthesia.
Table 9: Relationship between crown success or failure in children by treatment under local anesthesia or general anesthesia at 12 months.

<table>
<thead>
<tr>
<th>Children N = 48</th>
<th>Treatment Modality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local Anesthesia</td>
</tr>
<tr>
<td>Success</td>
<td>34</td>
</tr>
<tr>
<td>Failure</td>
<td>4</td>
</tr>
</tbody>
</table>

Fisher’s Exact Test; P > 0.05.

As indicated by the Debris and Modified Gingival Indices, our study showed that the oral hygiene level of the child was not significantly related to crown success or failure (Table 10). 87.8% of successes were associated with good oral hygiene, whereas 12.2% of successes were found in children with poor oral hygiene. Conversely, 71.4% of failed crowns were found in children with good oral hygiene, and 28.6% in children with poor oral hygiene.

Table 10: Relationship between crown success or failure in children by level of oral hygiene.

<table>
<thead>
<tr>
<th>Children N = 48</th>
<th>Oral Hygiene Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good</td>
</tr>
<tr>
<td>Success</td>
<td>36</td>
</tr>
<tr>
<td>Failure</td>
<td>5</td>
</tr>
</tbody>
</table>

Fisher’s Exact Test; P > 0.05.

Similar to oral hygiene, crown success was not significantly related to the amount of crown discoloration (Table 11). 16.2% of successful crowns had no color change, 68.6% had mild color change, and 15.2% had severe discoloration. In contrast, all failed crowns exhibited
some degree of discoloration. Sixty-eight percent of failed crowns had mild color change, and 31.5% had severe color change.

**Table 11: Relationship between crown success or failure and discoloration in teeth.**

<table>
<thead>
<tr>
<th>Teeth N = 124</th>
<th>Discoloration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Success</td>
<td>17</td>
</tr>
<tr>
<td>Failure</td>
<td>0</td>
</tr>
</tbody>
</table>

Chi Square Test; P > 0.05.

6.2 **In Vitro Study**

6.2.1. **Shear Bond Strength**

A total of 40 teeth included in the analysis (N = 10 in each group). The shear bond strengths in Newtons (mean ± S.E.M.) of the four Pedo Jacket groups are reported in Table 12 and Figure 26. Analysis of the data revealed that the shear bond strengths were not significantly different (P > 0.05). The shear bond strength of the GIC 2 group (258.0 ± 43.14) was the greatest among all groups, followed by the Mechanical Retention (237.99 ± 26.91), GIC 1 (226.52 ± 29.79) and Control (186.22 ± 27.98) groups in descending order of magnitude. Although not statistically significant, the percentage increase in SBS ranged from 22% for the mechanical retention group, to 39% for the GIC 2 group, with a mean of 29%. Therefore based on our findings, adding either chemical retention or mechanical retention to the Pedo Jacket crowns may exert a slight effect on overall crown retention as demonstrated by the increasing trend in shear bond strengths in the three treatment groups compared to control.
Table 12: Shear bond strengths (N) for the four Pedo Jacket groups.

<table>
<thead>
<tr>
<th>Group Number</th>
<th>Group Name</th>
<th>Number of Specimens</th>
<th>Mean</th>
<th>S.D.</th>
<th>S.E.M.</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Control</td>
<td>10</td>
<td>186.22</td>
<td>88.48</td>
<td>27.98</td>
<td>93.09-326.08</td>
</tr>
<tr>
<td>2</td>
<td>Mechanical Retention</td>
<td>10</td>
<td>237.99</td>
<td>85.09</td>
<td>26.91</td>
<td>115.87-420.85</td>
</tr>
<tr>
<td>3</td>
<td>GIC 1</td>
<td>10</td>
<td>226.52</td>
<td>94.20</td>
<td>29.79</td>
<td>117.53-426.65</td>
</tr>
<tr>
<td>4</td>
<td>GIC 2</td>
<td>10</td>
<td>258.00</td>
<td>136.40</td>
<td>43.14</td>
<td>130.56-575.81</td>
</tr>
</tbody>
</table>

Standard deviation = S.D.; Standard error of the mean = S.E.M.

Figure 26: Shear bond strengths of the Pedo Jacket crowns for the Control, Mechanical Retention, GIC 1 and GIC 2 groups, showing means and standard error of the means; results were not statistically significant, ANOVA, P > 0.05.
6.2.2. Scanning Electron Microscopy

**Group A: Pedo Jacket crowns**

Analysis of scanning electron micrographs of Pedo Jacket crown sections from different groups revealed dissimilarities in the quality of interfacial structures between the Pedo Jacket crown and the resin-modified glass ionomer cement. The control specimen demonstrated a more ragged crown-cement interface (PJ-RMGIC) with linear structural defects extending from the junction towards the inner third of the cement layer (Figure 27a). In contrast, the specimens from both GIC 1 and GIC 2 groups showed a smoother surface and closer approximation of the two surfaces at the PJ-RMGIC junction (Figure 27b and c). This may be due to the mixture of glass ionomer particles within the crown primer, which may have led to better adhesion of the crown to the RMGI cement.

![Figure 27: Scanning electron micrograph of Pedo Jacket crowns from three different treatment groups at 100X magnification. a) Control. b) GIC 1; 0.30 g GI particles/150 µL primer. c) GIC 2; 0.15 g GI particles/150 µL primer.](image)
Group B: Shear-Tested Pedo Jacket crowns

Scanning electron microscopy examination of the sheared site of the Pedo Jacket crown suggested a bonding mechanism for the nature of the bond failure. SEM images showed adhesive failure of the crown with debonding of the Pedo Jacket crown at the crown-cement interface (PJ-RMGIC), as seen in Figure 28. However, a fracture line was also observed at the boundary between the RMGI cement and dentin surface of the tooth, suggesting that adhesive failure may also occur between the tooth-cement surfaces.

Figure 28: Scanning electron micrograph of fracture surface after shear bond strength testing, at 50X magnification.

6.2.3. Microscopy

The figure below shows two specimens in which the Pedo Jacket crowns had peeled off the cement once maximum shear force was attained. The Instron-tested crowns consistently showed failure of adhesion at the crown-cement interface (Figure 29a), however, a minority of teeth also showed fracture occurring variably at the cement-dentin junction (Figure 29b).
7. DISCUSSION

7.1 Prospective Clinical Study

Crown success and retention

This is the first study reporting the clinical performance of Pedo Jacket crowns in the restoration of primary maxillary anteriors affected by early childhood caries. Pedo Jacket crowns are unique in that they are the only esthetic flexible preformed crowns, a property that allows them to easily adapt to teeth. The first objective of the study was to prospectively evaluate the clinical performance of Pedo Jacket crowns. Our 12-month results showed that the retention of Pedo Jacket crowns was high (91.9%). Overall, 86% (111 out of 129 teeth) of the crowns were clinically and radiographically successful during the 12-month study period. A few of the children in the study were found to have both successful and failed crowns. Although the exact explanation cannot be determined based on the study results, some reasons for children having both intact and failed crowns include incisor crowding, damage to the existing crowns during the preparation of adjacent teeth, a deep overbite or an anterior edge-to-edge contact.
edge occlusion. Our study also revealed that the child’s oral hygiene was not significantly related to crown success.

These results can be compared to only two other prospective studies available in the literature, which pertain to the retention of composite resin strip crowns. The first study found a retention rate of 100% after 12 months, and out of 92 teeth, only 4 teeth had recurrent decay (Judd et al., 1990). The second prospective study showed partial or complete retention in 81.2% of 96 composite resin strip crowns at 18 months (Mortada et al., 2004). The majority of other studies in the literature are retrospective, with reports of composite resin strip crown success ranging from 49% to 100% with follow-up periods from 6 to 36 months (Al-Eheideb et al., 2003; Eidelman et al., 2000; Kupietzky et al., 2005; Kupietzky et al., 2003; O'Sullivan et al., 1991; Ram et al., 2006; Su et al., 1992; Tate et al., 2002). On the other hand, preveneered stainless steel crowns have been shown to have a success range of 61% to 99% with similar follow-ups of 6 to 32 months (MacLean et al., 2007; Roberts et al., 2001; Shah et al., 2004).

By and large, the clinical and radiographic performance of the Pedo Jacket crowns in this prospective clinical study was satisfactory, with the success of Pedo Jacket crowns lying within the reported ranges of other conventional preformed anterior crowns. Even in cases where the Pedo Jacket crown shell was lost, the restorative material remained intact; the restored tooth continued to be esthetic as it appeared similar to a strip crown (Figure 30). In such cases, the restored teeth can be left as `strip crowns` and require only monitoring until normal exfoliation. A study with a longer time interval for follow-up of Pedo Jacket crowns, however, is warranted to strengthen the current evidence from this study.
Figure 30: Clinical example of a child with 2 primary maxillary central incisors (51 and 61) restored with Pedo Jacket crowns showing lost Pedo Jacket crowns on both teeth but the cement material appears intact and similar to strip crowns. Note: crowns 51 and 61 were lost after the second recall visit (12 months) but the underlying restorative material remained intact for a total duration of 3 years 2.7 months. (Images courtesy of Dr. G. Kulkarni)

The relatively good success rate of the Pedo Jacket crowns over the one year study period is important in one other respect. In children who, due to their age or emotional immaturity, are unable to cooperate for conventional treatments that require a greater degree of cooperation, Pedo Jacket crowns may provide an esthetic interim option. Significant positive behavior changes may be seen in children in as short a period as six months to a year, especially with careful behavior shaping by the clinician. Since Pedo Jacket crowns are easier to place in pre-cooperative children, they may serve to arrest the progression of caries, improve the child's appearance and afford another opportunity for definitive treatment with conventional or newer esthetic crowns at a subsequent time, if necessary. From the results of our study with follow-up periods longer than one year in some cases, it was also evident that in many children, Pedo Jacket crowns could last the entire lifespan of the primary teeth until natural exfoliation providing not just an interim solution but a definitive treatment option.

Color stability

In the present study, the majority of crowns (82.3% or 102 teeth) had no or mild discoloration (affecting 2 surfaces or less) which did not require intervention and were considered esthetically acceptable after 12 months. The remaining 17.7% (22 teeth) of crowns
had suboptimal appearance and displayed severe discoloration (affecting more than 2 surfaces of the crown). Although not formally recorded for the study participants, the crown discoloration was more of a concern for the clinician and rarely if ever did the parent or the child complain about the color. Moreover, crown discoloration was never a reason for the crown to be redone.

In comparison, composite resin strip crowns showed a similar amount of discoloration. In a 2003 study, 74% of composite resin strip crowns (83 teeth) showed a good color match relative to adjacent teeth over a mean period of 18 months (Kupietzky et al., 2003). In 2005, 88% of composite resin strip crowns (127 teeth) also did not show noticeable difference in color match over a period of 3 years (Kupietzky et al., 2005). However, the same primary author in the 2003 and 2005 studies reported above evaluated parental satisfaction with regards to the composite resin strip crowns and found that parents were least satisfied with the color of the crowns (Kupietzky et al., 2004). Similar results are reported for preveneered stainless steel crowns. One study showed that 24% (7 out of 29 teeth) had color mismatch with adjacent teeth after a mean period of 20 months (Roberts et al., 2001). Another study on Kinder Krows found that 20% of crowns had minor color changes compared to the original crowns (Shah et al., 2004). In contrast, only 3 teeth out of 226 NuSmile crowns (1%) exhibited color change after at least 6 months (MacLean et al., 2007). Parental satisfaction with the color of preveneered stainless steel crowns was 89%, which was the lowest rating related to crown features due to its overly white color (Champagne et al., 2007). Although parental satisfaction was not recorded in our study, the esthetic aspect of color of Pedo Jacket crowns is largely clinically acceptable and has overall color stability that is comparable to other crowns reported in the literature.
Another component of the clinical assessment was the amount of crown wear. The vast majority of Pedo Jacket crowns was either intact (37.1% or 46 teeth) or showed a mild degree of wear (54.8% or 68 teeth) at 12 months after crown placement. The greater proportion of crowns with only slight incisal (limited to incisal third; Figure 31 and 32) or lingual wear were clinically stable and did not require further treatment. A small number of crowns exhibited severe wear (8.1%) and were judged to be clinically unacceptable. These results can be compared to that of another study on preveneered stainless steel crowns; the authors found that 15% of crowns (7 teeth) lost resin in the incisal third due to wear over an average period of 17.5 months (Shah et al., 2004). Another report on preveneered stainless steel crowns found that 20 out of 26 crowns (77%) had incisal wear after a mean of 20.7 months (Roberts et al., 2001). Both these studies showed a positive relationship, though weak, between increased overbite and incisal wear/facing fracture of the crowns. Maclean et al. (2007) found a lower rate of incisal wear/attrition in NuSmile preveneered stainless steel crowns, with 71% of crowns resisting attrition after at least 6 months (MacLean et al., 2007). This present study did not evaluate the association between crown wear and occlusion and therefore no inferences can be made. In the future, occlusion and parafunctional habits such as bruxism should be recorded and analyzed in relation to crown wear and overall clinical success, especially if the crown was deemed by the clinician to require clinical intervention for that reason. The degree of wear of the Pedo Jacket crowns demonstrated in this study, however, is consistent with that of preveneered crowns, which have been reported to be the most durable types of crowns to date. This finding suggests that, with proper case selection, Pedo Jacket crowns may also be a robust restoration in young children.
The good overall clinical success of the crowns and its ease of use in combination with resin-modified glass ionomer cement make this treatment option desirable in the management of anterior caries in pre-cooperative children, especially as interim restorations. The restoration of carious primary teeth is technically demanding and in such young children, uncooperative behavior may negatively impact on the quality of treatment delivered or make it impossible. Many children may require pharmacological aids or even treatment under general anesthetic in order to improve child cooperation and tooth isolation. Although these advanced behavior management techniques may be warranted in some cases, they may not be feasible for certain families due to limited financial resources. In addition, due to the inherent risks of all types of
sedation, some parents may be adamant and simply prefer non-pharmacological methods of treatment for their child. Therefore, a crown option with less-technique sensitivity is preferable in these children.

This study showed that the ease of use of Pedo Jacket crowns reported by the clinicians was high. This was true for the treatment of cases conducted either under local anesthesia or general anesthesia, with local anesthesia accounting for the majority of cases (70.4%, or 38 out of 54 children). Based on the results of this study, there were no significant differences between the success of Pedo Jacket crowns placed under local anesthesia or general anesthesia. Similarly, a retrospective study evaluating the longevity of composite resin strip crowns placed under oral sedation, found that behavior had no influence on the clinical and radiographic findings of the crowns (Ram et al., 2006). This contrasts with another retrospective study that showed that composite resin strip crowns placed in children under general anesthesia had better clinical outcomes than those placed under local anesthesia, and this difference was statistically significant (Eidelman et al., 2000). Although the evidence in the literature is mixed, child behavior may negatively affect the performance of anterior crowns. Thus, the level of skill required for the placement of a restoration is an important consideration in treating a young child with anterior caries and the ease of use of Pedo Jacket crowns makes them a suitable treatment option. While Pedo Jacket crowns were generally found to be easy to use in the dentitions that were spaced or well-aligned, in dentitions with minimal spacing or crowding they were difficult to use. However, crowded dentitions with significant amounts of tooth overlap would be difficult to restore regardless of the modality.

The reported rate of recurrent caries in this study was shown to be low (5.6% after 12 months), which may be attributable to the anti-cariogenic fluoride releasing property of the
resin-modified glass ionomer cement used or the relatively short study period. In comparison, the rate of secondary caries associated with composite resin strip crowns ranges from 14% to 26% in the literature, with study periods ranging from 6 to 24 months. (Eidelman et al., 2000; Ram et al., 2006). Though there are no existing studies that directly compare Pedo Jacket crowns to composite resin strip crowns, the lower incidence of secondary caries in teeth restored with Pedo Jacket crowns is encouraging. This would especially be of benefit to children with a high caries risk, such as those in this study with severe early childhood caries-affected primary anterior teeth.

The combination of both superior ease of placement and cariostatic effect of the RMGI cement make the Pedo Jacket crown an advantageous type primary anterior crown. It provides a means to treat and limit the progression of caries in a very young child until the child reaches an emotional maturity level that is more permissive to conventional treatment with composite resin strip crowns or other types of preformed anterior crowns at a later date when the child is older and therefore behavior is likely more conducive to alternative treatments if necessary. In certain cases the crowns may not only function as an interim therapeutic option but also a definitive restoration. Indeed, a majority of the Pedo Jacket crowns in this study were maintained until natural exfoliation of the teeth. This observation needs to be verified in longer term study.

7.2 In Vitro Study

This study is also the first to assess the shear bond strength of Pedo Jacket crowns in vitro. Pedo Jacket crowns offer advantages over other anterior restorations as they are esthetic, easily adaptable, and the resin-modified glass ionomer cement has simple handling properties and cariostatic activity attributed to fluoride release. However, the bond of the Pedo Jacket
crown is important to its success. The first objective of this *in vitro* study was to characterize the shear bond strength of Pedo Jacket crowns. A baseline shear bond strength of 186.22 ± 27.98 (N ± S.E.M.) was established for Pedo Jacket crowns restored as per the manufacturer’s instructions.

This baseline value can be compared to that of various preveneered stainless steel crowns: Kinder Krowns 397.2 ± 53.0 (N ± S.D.), NuSmile 447.2 ± 78.5, Cheng Crowns 511.9 ± 83.4, and Whiter Biter Crown II 686.5 ± 181.4 (Waggoner *et al.*, 1995). Another laboratory study revealed shear bond strengths of preveneered stainless steel crowns that more closely approximated the results from our study: Unitek 111 N, Dura Crown 154 N, Kinder Krown 228 N, NuSmile 172 N (Guelmann *et al.*, 2003).

Based on our results, the SBS of Pedo Jacket crowns was lower or within the range of SBS reported for preveneered stainless steel crowns in the literature. However, failure of Pedo Jacket crowns differ from resin veneer loss in that the shell debonds entirely and uniformly from the cement; this cement usually remains intact and still appear as an esthetic crown consisting of the resin-modified glass ionomer cement. Fracture of resin facings on a preveneered stainless steel crown cannot be repaired and occurs non-uniformly, which renders the crown unesthetic. In contrast, if a defect develops in the Pedo Jacket crown it is restorable. The best type crown should combine both durability and esthetics; perhaps with further research and improved bonding of the crown, Pedo Jacket crowns may approach this ideal.

As alluded to previously, a method of failure of Pedo Jacket crowns involves the separation of the crown shell from the cement. This type of failure prompted our *in vitro* experiments. In this study, the teeth were prepared using three different conditioning systems with the aim of improving the bond of the Pedo Jacket tooth to the RMGI cement. The first
group tested involved the addition of mechanical retention (hole through the facial/buccal surface of the Pedo Jacket crown); the second and third groups were physico-chemically-modified to enhance the bond between the crown and cement. The findings from our study revealed that although not statistically significant, the mean shear bond strength of the three different Pedo Jacket test groups increased. The GIC 2 group (addition of glass ionomer inorganic particles to crown primer) had the highest SBS, which may suggest that the addition of glass ionomer inorganic particles to the crown primer may have improved the adhesion of the crown to the RMGI cement. The Pedo Jacket group with mechanical retention had the second greatest SBS value. It is conceivable that combining both chemical and mechanical means of retention can further enhance the strength of the bond of the crown. However, that combination was not tested in this study. Statistical significance may be seen with larger sized sample and more uniform samples. The addition of GIC particles either by the clinician or preferably the manufacturer is a relatively easy modification that is likely to improve clinical performance of the Pedo Jacket crowns. The other possible reason for statistical non-significance was the inability to standardize the area of shear force application and obtain results in Megapascals instead of Newtons.

Case studies

Individual cases from our clinical study on Pedo Jacket crowns highlighted key commonalities. One such finding was the relationship between oral hygiene and the clinical outcome of the crowns. A few existing clinical studies on other preformed crowns have recorded the oral hygiene of the study participants but no analysis was done to confirm the effect of different oral environments on crown success or failure. Children with poor oral hygiene have a more elevated risk of developing new and recurrent decay. Intuitively, in such
cases one would expect more restoration failures and a higher need for re-treatment. Children with excellent oral hygiene, on the other hand, should be better able to maintain their restorations indefinitely (Figure 33). Clinicians involved with the study perceived this to be true, however, this hypothesis was not validated by our statistical analysis. Although no statistical association was found between oral hygiene levels and the clinical outcome of the Pedo Jacket crowns, worse clinical crown outcomes were found in children with poorer oral hygiene levels. There were some exceptions in children that, in spite of poor oral hygiene, the Pedo Jacket crowns were successful and were maintained until normal exfoliation. This attests to the clinical durability of the Pedo Jacket crowns. Figure 34 is an example of an uncooperative young female with poor oral hygiene and despite multiple treatment visits for recurrent decay on her posterior teeth, her anterior Pedo Jacket crowns were maintained until natural exfoliation.

![Figure 33: Clinical example of Pedo Jacket crowns with excellent oral hygiene.](Images courtesy of Dr. G. Kulkarni)
Figure 34: Young female with poor oral hygiene and high caries risk. a) Pre-treatment. b) Pre-operative occlusal radiograph showing extensive decay of maxillary anterior dentition. c) Restored maxillary incisors with Pedo Jacket crowns; plaque and gingivitis and marginal discoloration of the crowns is evident. d) Physiological root resorption of primary maxillary central incisors with intact crowns. (Images courtesy of Dr. G. Kulkarni)

Endodontic treatment

An advantage of Pedo Jacket crowns is that if a tooth develops pulpal pathology after the initial placement of the crown, endodontic treatment can be performed without having to redo the crown completely. Endodontic access can be easily made through the lingual surface of the crown with a high speed handpiece, and a composite resin or resin-modified glass ionomer can be used to seal the access. Figure 35 is an example of such a case. This feature makes the Pedo Jacket crown a versatile restorative option.
Figure 35: Clinical example of endodontic treatment performed through the Pedo Jacket crown of right primary maxillary central incisor. a) Abscessed right primary maxillary central incisor. b) Endodontic access done through lingual surface of crown. c) Occlusal radiograph. d) Endodontic access sealed with composite resin. (Images courtesy of Dr. S. Badr)

Limitations

While this research showed promising results, there were limitations to this clinical and in vitro study. In our clinical study, there was no control group consisting of more conventional preformed primary anterior crowns such as composite resin strip crowns. Therefore no direct comparisons of Pedo Jacket crown success could be made. Ideally, a longer follow-up period than 12 months is desirable in order to assess the long-term outcome of Pedo Jacket crowns and compare them to the available studies. Examiner bias may have been introduced since the examiners were also the clinicians who restored the decayed primary incisors with Pedo Jacket crowns. To rule out examiner bias, the reliability of the crown assessment tool was assessed by an independent examiner. Agreement between scores was found to be high (91.4%). Finally, due to clinician preference, a rubber dam was not consistently used during the preparation and
placement of the crowns. This could have negatively affected the outcome of the crowns and the overall success of the crowns may have been underestimated in this study.

Despite the limitations, the present in vitro study provides baseline shear bond strength for planning future studies and a value for comparison with other crown forms, thus establishing a good foundation for similar studies. The number of samples tested was small and may have precluded the ability of the study to detect statistical significance. Another limitation was the non-uniformity of the extracted teeth that were restored with Pedo Jacket crowns. Teeth selected had an intact crown portion but the teeth were all different sizes and shapes, and the thickness of cement used was variable between specimens. This could have affected the placement of the cross-head of the Instron machine thereby affecting the results of the shear testing. Though a single skilled and experienced laboratory technician conducted the mechanical testing, the sharpness and the distance at which the chisel of the cross-head was placed against the tooth and the area over which the shear force was applied, could also have influenced the values of the maximum shear bond strength of the crowns. Lastly, the results from this laboratory study were based on permanent teeth, which are anatomically and physically different from teeth of the primary dentition. Clinical extrapolation of the in vitro results should therefore be done with the above caveat.

Significance of study

This is the first clinical and laboratory study on Pedo Jacket crowns. Overall, the findings of this clinical study show that Pedo Jacket crowns are a practical and esthetic full coverage restoration for severely decayed primary maxillary anteriors. This is especially true in the very young child of pre-cooperative age, in whom ideal treatment is compromised by uncooperative behavior in the dental chair. When proposing this treatment option with the
parents of an affected child, however, the possibility of crown loss should be discussed. The successful outcomes of Pedo Jacket crowns, including their ease of placement, good retention, resistance to severe discoloration and wear, all lie well within the range of reported success for the different types of primary anterior crowns described in the literature. These findings suggest that Pedo Jacket crowns should be considered as a viable treatment option for the anterior primary dentition.

The *in vitro* portion of the study established the baseline shear bond strength of Pedo Jacket crowns. It also showed that there may be simple and practical methods for improving the retention of the Pedo Jacket crowns.

This study also provides a good template for future studies. The crown assessment tool used in the study can be easily adapted for similar studies on more recently available crowns.
8. CONCLUSIONS

1. This prospective clinical study demonstrated that Pedo Jacket crowns are a viable and esthetic primary anterior crown option, especially in pre-cooperative children with early childhood caries affecting the anterior dentition. The crowns performed well over a period of 12 months. Despite some negative clinical changes, the majority of Pedo Jacket crowns were successful, with good to excellent esthetic appearance. A drawback of Pedo Jacket crown was the separation of the crown from the cement. There was also increased incidence of discoloration and wear of the crowns with time.

2. Within the limitations of the in vitro study, the results suggested that mechanical or chemical methods can be incorporated for increasing crown retention.
APPENDIX 1

Faculty of Dentistry
University of Toronto

RESEARCH CONSENT FORM

Patient Name: _______________________________________

DOB: ____________________________________________________________________

Clinical Investigation:
A prospective longitudinal clinical trial study to investigate the success of Pedo Jacket crowns compared to composite resin strip crowns.

Principal Investigator:
Dr Gajanan Kulkarni, Associate Professor, Pediatric and Preventive Dentistry. Tel: 416-979-4929 ext. 4460

Student Investigator:
Dr. Aimee Andres Castro, M.Sc.- Pediatric Dentistry candidate. Tel: 647-465-5778

Purpose:
To investigate the success of Pedo Jacket crowns in restoring decayed primary anterior teeth compared composite resin strip crowns.

Description:
Participants will receive Pedo Jacket crowns for the restoration of upper primary anterior teeth. A dental examination similar to a regular check-up at the dentist will be conducted at 6 months and 1 year after the crowns are placed. We will examine your teeth, do a cleaning for you, take 2-4 radiographs (X-rays) and digital photographs.

Potential harms, injuries or inconvenience
Potential harms and injuries as a result of participating in this study are the same as the risks of receiving any dental procedures in the clinical setting. The inconvenience lies in having to come to the Faculty of Dentistry for the examination to be conducted and the time spent in collecting the needed information.

Potential benefits:
A dental examination has the potential benefit of early detection of dental disease which may be managed thereafter at the Faculty of Dentistry or any other dental clinic. You will get copies of the X-rays if you wish. Should any oral or dental problems be identified by the examiner, you will be notified of your options regarding follow up and treatments.

Duration of study:
The placement of the crown(s) will be done in 1 visit at the dental office, which will take approximately 30 minutes. Two follow-up examinations (at 6 months and 1 year after) are required to complete the clinical examination, which will again be approximately 30 minutes each.

Confidentiality:
Confidentiality will be respected and no information that discloses your identity will be released or published without consent unless required by law. For your information, the research consent form will be inserted in the patient health record.

Participation:
Participation in this study is completely voluntary. You may choose to withdraw from this study at any point of time without provision of a reason.
Consent:

I acknowledge that the research procedures described above have been explained to me and that any questions that I have asked have been answered to my satisfaction.

I have been informed of the right not to participate and the right to withdraw from this study at any given point of time without provision of a reason.

The potential harms and discomforts have been explained to me. I understand the benefits (if any) of participating in the research study. I know that I may ask now, or in the future, any questions I have about the study or the research procedures.

I have been assured that records collected in this study will be kept confidential and that no information will be released or printed that would disclose personal identity without my permission unless required by law.

I, ________________________________ hereby consent to participate in the above mentioned study

_______________________________________
Signature / Date

_______________________________________
Name / Signature of person who obtained consent
APPENDIX 2

UNIVERSITY OF TORONTO

PROTOCOL REFERENCE # 27380

March 20, 2012

Dr. Gajanan Kulkarni                                    Dr. Aimee Andres Castro
FACULTY OF DENTISTRY                                      FACULTY OF DENTISTRY

Dear Dr. Kulkarni, Dr. Aimee Andres Castro,

Re: Your research protocol entitled, “Comparison of pedo jacket crowns to strip crowns in the treatment of early childhood caries: A clinical trial”

ETHICS APPROVAL

| Original Approval Date: March 20, 2012 |
| Expiry Date: March 19, 2013 |
| Continuing Review Level: 1 |

We are writing to advise you that the Health Sciences Research Ethics Board (REB) has granted approval to the above-named research protocol under the REB’s delegated review process. Your protocol has been approved for a period of one year and ongoing research under this protocol must be renewed prior to the expiry date.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events in the research should be reported to the Office of Research Ethics as soon as possible.

Please ensure that you submit an Annual Renewal Form or a Study Completion Report 15 to 30 days prior to the expiry date of your current ethics approval. Note that annual renewals for studies cannot be accepted more than 30 days prior to the date of expiry.

If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

Yours sincerely,

Judith Friedland, Ph.D.
REB Chair

Daniel Gyewu
REB Manager

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REFERENCES


