Clinical Performance of High Viscosity Glass Ionomer Restorations In Pulp Treated Primary Molars: 12-Month Results

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Abstract

This study aims to investigate the clinical performance and the survival time of pulp-treated primary molars followed by high viscosity glass ionomer (HVGIC) restoration. A total of 39 children with a total of 42 primary molars that needed to receive pulp therapy were included. All pulp-treated primary molars were immediately restored with HVGIC restoration (Fuji IX GP EXTRA™) and evaluated using the modified Ryge's criteria. The prepared cavities of studied teeth were classified into two groups, the cavities that did not extend beyond the line angles and cavities that extend beyond line angles were defined as the ideal-cavity and the less ideal-cavity restorations, respectively. The overall success rates of the studied teeth at baseline, 6-month, and 12-month follow-up periods were 97.6%, 97.6%, and 90.5% respectively. The overall success rate was statistically different between baseline and 12-month follow-up period (p=0.018), using Friedman's test. At a 12-month follow-up period, the success rate of ideal-cavity restoration was statistically higher than less-ideal cavity restorations (p=0.035), using Fisher's exact test. A statistically significant difference, regarding marginal integrity, were found between both groups (p=0.035) while the difference in tooth integrity was not found between both groups (p=0.084). Secondary caries were not found in all studied teeth. The mean survival time for the ideal cavity group and less-ideal cavity group was 12 months and 11.6 months, respectively, using Kaplan-Meier analysis. The results after 1 year suggest that the HVGIC may be recommended as an alternative for restoring pulp-treated primary molar when a stainless steel crown is not indicated.

Keywords: *High Viscosity Glass Ionomer Cement, Primary Teeth, Pulpotomy, Pulpectomy.*

1. Introduction

The restoration of severely broken-down primary molars is often a clinical challenge. The requirements for an acceptable restoration include durability, sealing efficacy, natural color, and easy and rapid placement. The pulp-treated primary tooth should be restored with a restoration that seals the tooth from microleakage. According to the American Academy of Pediatric Dentistry (AAPD, 2017a) restorative guidelines after pulpotomies, the following statement is found: "The most effective long-term restoration after pulpotomies in primary molars is a stainless steel crown (SSC), which protects the weakened cavity walls and prevents marginal microleakage. However, if there is sufficient supporting enamel remaining, amalgam or composite resin can provide a functional alternative when the primary tooth has a life span of 2 years or less." (M. Guelmann, Fair, & Bimstein, 2005; G. Holan, Fuks, & Ketlz, 2002; Huth et al., 2005). Similarly, a systematic review concluded that either intra-coronal restoration or an SSC may be adequate to achieve a good marginal seal for single surface (occlusal) restorations on a primary tooth with a life span of two years or less; whereas for multi-surface restorations, SSCs are the treatment of choice (Seale & Randall, 2015).

After pulpotomy or pulpectomy therapy in primary teeth, glass ionomers are useful in a type of sandwich technique. The pulp space is filled with zinc oxide eugenol cement and lost dentine is entirely replaced with resin-modified glass ionomer cement (RMGIC), and the surface above it is restored with resin-based composite (RBC) (Berg & Donly, 1988). A conference paper in 2015 stated that "although there is not a good long term clinical trial reporting on the outcomes of this technique, there is much anecdotal information reported by practitioners, seemingly all favorable. Logically, the key to success is completely sealing off access of salivary-borne bacteria to the pulp space. It requires the complete seal of cavosurface margins, which is probably achievable" (Berg & Croll, 2015). However, It has been recommended that this conservative restoration (sandwich technique) is indicated for selected cases only: when significant tooth structure has remained when at least 2 complete walls of tooth structure are left, and when only one proximal surface is involved, having its gingival margin still in enamel(M Guelmann, Shapira, Silva, & Fuks, 2011).

A two-year randomized control trial regarding restoration of primary molars that had to undergo a pulpotomy procedure found that a non-significant difference in survival rate for teeth restored with stainless steel crowns (95 %) versus modified open-sandwich (RMGIC/RBC) restorations (92.5%). Meanwhile, this study showed more gingival bleeding for stainless steel crowns versus modified open-sandwich restorations (M Atieh, 2008). Likewise, a systematic review did not show strong evidence that stainless steel crowns were superior to other restorations for pulpotomized teeth (Bazargan, Chopra, Gatonye, Jones, & Kaur, 2007). Thus, the stainless steel crown restoration may not always be necessary for pulp-treated primary molars. Moreover, SSC restorations always require a significant amount of tooth preparation, and maybe the risks of restorative therapy including iatrogenic damage to adjacent teeth (AAPD, 2017b; Lenters, vanAmerongen, & Mandari, 2006).

As mentioned above, 2-year-results indicated that the modified open-sandwich restoration is an appropriate alternative to SSC in pulpotomized primary molars. This restorative technique takes advantage of all the positive properties of RMGIC and RBC including its adhesive and fluoride-releasing. However, this study has discussed that the modified open-sandwich restoration has some considerations such as highly technique sensitive, requiring patient compliance and adequate moisture isolation and, increased expense in time and material (M Atieh, 2008). Besides, the coronal pulp space of the pulpotomized tooth of this study was filled with reinforced zinc oxide eugenol cement. Zinc oxide eugenol cement remains the material of choice for pulp chamber filling material following pulpotomies or pulpectomies in the primary dentition. It should be used with caution under RBC restorations because the eugenol can inhibit the polymerization of the resin (Nowak, Christensen, Mabry, Townsend, & Wells, 2019). Similarly, RMGICs are cooperated with the photopolymerized resins and should be concerned, when they are used with zinc oxide eugenol cement.

New reinforced glass ionomer materials as high viscosity glass ionomer cement have been indicated as long-term temporary restorations and have been utilized for atraumatic restorative techniques (ART). The high viscosity glass ionomer cement (HVGICs) are high powder/liquid ratio traditional glass ionomer materials, enhanced physical properties developed by manipulation of glass particle size and distribution and content of polyacid component (Cole & Welbury, 2000; J E Frencken, Songpaisan, Phantumvanit, & Pilot, 1994; Raggio, Hesse, Lenzi, Guglielmi, & Braga, 2013).

A prospective clinical study has recommended that an encapsulated HVGIC (KetacMolarEasymixTM) in conjunction with the ART was a viable option for restoring carious dentine lesions in single surfaces in vital primary molars and shown that the cumulative survival rate over 3 years was 66.8%, 90.1% and 56.4% for all, single- and multiple-surface, respectively. These survival rates were not different from the comparative conventional amalgam restorations (Hilgert et al., 2014). Subsequently, a systematic review concluded that The ART restorations performed with HVGICs have a similar survival rate compared with conventional amalgam restorations and can be considered an option to restore occlusoproximal cavities in primary molars (Tedesco et al., 2017).

Thus, improved high viscosity glass ionomer cement especially in encapsulated type has gained much interest internationally and was useful for the restorative treatment in children (Croll & Nicholson, 2002). As of today, there has no clinical study about using HVGIC restoration in pulpotomized or pulpectomized primary molars.

Restorative dentistry for children is always looking for an alternative to restore primary teeth that have had a pulp procedure performed. Although an SSC is a gold standard for these teeth, the use of the improved high viscosity glass ionomer restorative cement may be an alternative. So, in this study, the researchers have been interested in: Can high viscosity glass ionomer restorative cement be used as the final restoration in pulpotomy or pulpectomy treated primary molar without compromising the long-term success of the treatment?

2. Objectives

This research is a prospective clinical study that aims to investigate the clinical performance and the survival time of the intra-coronal restorative technique using high viscosity glass ionomer restorative cement (HVGIC) in pulpotomy or pulpectomy treated primary molars.

3. Materials and Methods

This research was approved by the Research Ethics Committee, Research Institute of Rangsit University, Thailand. At the baseline visit, the objective, the possible treatment outcomes, and the research methodology were explained and clarified to the parents. Informed consent was obtained from them prior to the study.

3.1 Sample selection

Healthy children aged 3-11 years who were receiving comprehensive treatment in pediatric dental clinic, with least one primary molar that needed pulpotomy or pulpectomy, or an emergency pulp treatment in primary molars were selected.

The remaining tooth structure must be restorable with an intra-coronal restoration. After completely removed dental caries, the cavities with single-surface occlusal cavities and two-surface cavities (occlusal-mesial, OM or occlusal-distal, OD), with or without buccal /lingual extension, were included. Multi-surface (more than two surfaces) cavities or the extension of caries beyond its gingival margin (is not still in enamel) were excluded.

The teeth that presented absence of permanent tooth germ, excessive tooth mobility, advanced internal/external root resorption, periapical infection involved the crypt of the successor's tooth, calcific metamorphosis, unrestorable crown due to extensive destruction, and were difficult to obtain moisture control were also excluded.

The sample size will be calculated based on a review indicated that the mean survival time in months of glass ionomer cement restorations in posterior primary teeth and restoration in pulp treated primary molars is 12 months (Papathanasiou et al., 1994) and 23.7 months (M Atieh, 2008), respectively.

3.2 Intervention regarding the technique of pulp therapy

Both pulpotomy and pulpectomy were performed by one experienced pediatric dentist. Following standard clinical practice, a periapical radiograph of the subject tooth was taken at the baseline. Administration of local anesthesia and isolation with rubber dam was performed. Then, carious lesions were completely removed before pulpal exposure to minimize bacterial contamination following exposure.

3.2.1 Pulpotomy technique

The roof of the pulp chamber was removed by joining the pulpal horns with bur cuts. This procedure was performed by using a no.330 carbide dental bur mounted in a water-cooled high-speed turbine. The coronal pulp was amputated using a sterile slow-speed round steel bur (no.016 or no.018)

Following coronal amputation, bleeding was controlled by placing sterile, saline-wetted cotton wool pellets on the pulp stump under slight pressure for a few minutes. When the cotton pellets were removed, hemostasis should be apparent. Excessive bleeding, which persists despite cotton pellet pressure and the deep purple color of the tissue, is shown. Such signs indicated that the tooth was not a candidate for formorcresol pulpotomy, and pulpectomy was performed.

Following the hemostasis, cotton pellets soaked with dilute formorcresol (1:5 Buckley's solution) were placed on the radicular pulp stumps for 5 min, after which the coronal pulp space was filled with a reinforced zinc oxide eugenol base (IRMTM, Caulk-Dentsply, USA).

3.2.2 Pulpectomy technique

Upon removal of the roof of the pulp chamber to gain access to the root canals, the pulp tissue was removed with barbed broaches. Working length was set at approximately 1 mm short of the apical foramen. All pulpectomies were performed using a conventional technique in which mechanical hand filing was performed in a step-back manner with K-file up to size no. 25 or 30. Irrigation was performed with 2.5% sodium hypochlorite solution (NaOCl) after each instrument. The root canals were finally irrigated with sterile normal saline to neutralize the effect of NaOCl and dried with paper points. The root canals were filled with Vitapex, calcium hydroxide paste with iodoform, (J Morita Cooperation, Tokyo, Japan) by injecting into each canal gradually until they were filled. The coronal pulp space was filled with a reinforced zinc oxide eugenol base, approximately 1mm in thickness (IRMTM, Caulk-Dentsply, USA).

All subject teeth were further prepared and immediately restored with intra-coronal restoration with high viscosity glass ionomer restorative cement (GC Fuji IX GP Extra TM, GC America Cooperation, and the USA)

3.3 Intervention regarding the technique of restoration

After the coronal pulp space-filling, the conservative cavity preparation was performed and the cavosurface margins were not beveled (AlvesdosSantos, Luiz, & Maia, 2010). Finally, the internal cavity walls must be smooth, clean, and sound surfaces.

After the cavities of pulp-treated teeth were completely prepared, if the prepared cavities did not extend beyond the line angles, such cavities were defined as the ideal-cavity HVGIC restorations. Besides, those cavities that extend beyond the line angles were defined as the less ideal-cavity HVGIC restorations. The T-band and wedge were applied before starting the restoration procedure.

According to the manufacturer's recommendations, the prepared cavities were applied with a dentine conditioner, 20% polyacrylic acid (GC Cavity Conditioner, GC America, USA) by using a micro brush for 10 seconds and then rinsing thoroughly with water. The excess water was dried by gently blowing with an air syringe. The prepared cavity surfaces appeared moist and glistening.

Fuji IX GP Extra encapsulated glass ionomer restorative cement was mixed for 10 seconds in an amalgamator. The mixed capsule was removed from the mixer and loaded into the GC Capsule Applier. The mixed HVGIC was load into the prepared cavity in one layer with the bulk-fill technique and adapted to the cavity walls with a plugger. At least 5 minutes later, the visible overhangs and anatomical contouring were adjusted and removed by superfine diamond finishing burs mounted in a water-cooled high-speed turbine. Contacts in centric and eccentric occlusion were checked with articulating paper and adjusted with the same finishing burs. Final finishing was performed underwater spray using EnchanceTM Finishers. The restorations were protected with GC Fuji Varnish^{TM}. The protective coating was applied with a micro brush and dry by gentle blowing with an air syringe.

The periapical radiographs of all pulp-treated teeth were taken immediately following the procedure to document the quality of root canal filling and coronal restoration and to help determine the teeth' prognosis. Post-operative clinical and radiographic assessments were performed every 6-month-recall period.

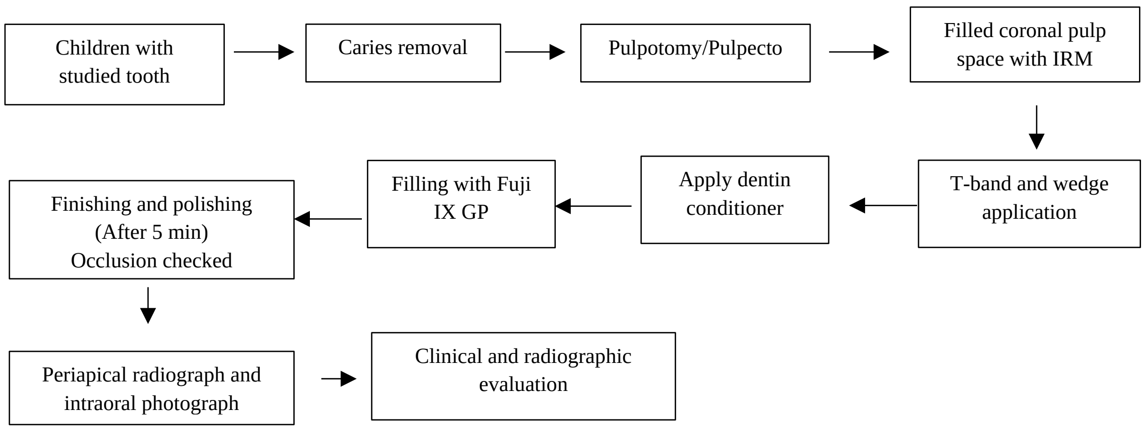

Figure 1 flowchart of the methodology

3.4 Outcome measures and clinical evaluation

The clinical outcome of HVGIC restoration in pulp-treated primary molars was assessed at the baseline (or within 1 month after treatment), 6 months, and 12 months or until tooth exfoliation or patient dropout. The primary endpoints were satisfactory retentions and pathologically free, 1 year after baseline. The clinical failure parameters of pulpotomy or pulpectomy treatments were defined as spontaneous pain, soft tissue swelling or fistula, pathological tooth mobility, or the radiographically pathological process that does not resolve in 6 months. The clinical failure parameters of restorations were defined as partial or tooth fracture, which needs to receive a replacement or total loss of restorations. The subject teeth that present at least one of those parameters were recorded as unfavorable outcomes or failures.

The performance of the restorations was evaluated by using the modified Ryge's criteria (Table 1), which was based on USPHS criteria, following the previous studies (M Atieh, 2008; B T Zulfikaroglu et al., 2008), in terms of marginal discoloration, marginal adaptation, wear/anatomical form, teeth integrity (tooth loss or enamel loss), and, secondary caries. The clinical evaluation was performed by two independent evaluators using visual examination with a mouth mirror and dental probe. The inter-rater reliability was measured using Cohen's Kappa Test (κ >0.8). The two independent evaluators measured the sample teeth in 5 different categories using modified Ryge's Criteria.

Table 1 Modified Ryge's Criteria for direct evaluation of restorations

Category	**Characteristic**	**Method**
Marginal discoloration		
Alpha	No visual evidence of discoloration	VI
Bravo	Slight staining which can be polished away	VI
Charlie	Discoloration has penetrated in the pulpal direction	VI
Marginal adaptation		
Alpha	Restoration is fully intact. No explore catch evident.	VI/E
Bravo	Slight explorer catches in no more than 1/3 of margins	VI/E
Charlie	Explore catch and/or penetration is evident in more than 1/3 of restoration margins	VI/E
Wear/Anatomical form		
Alpha	Restoration is continuous within its anatomical form	VI/E
Bravo	Restoration is slightly flattened or discontinuous within its anatomical form, but missing material does not expose dentin or base	VI/E
Charlie	Sufficient material is lost to expose dentine or base	VI/E
Enamel loss		
Alpha	Enamel is free from any visible crack, fracture, or loss	VI/E
Bravo	Cracking or chipping of enamel along restoration margins	VI/E
Charlie	Loss of cusp of supporting cavity wall	VI
Secondary caries		
Alpha	No caries presents	VI
Bravo	Caries present associated with the restoration	VI
Charlie	Restoration is replaced because of caries	VI

*VI = Visual Inspection; E = Explorer

Also, the follow-up periapical radiographs were assessed by the same evaluators. When disagreement occurs during evaluation, discrepancies were discussed until consensus will be obtained.

3.5 Statistical analysis

Descriptive statistics were used to describe the frequency distributions of evaluated criteria (i.e., the mean age of subject, % of clinically unfavorable outcome, and percentage of categorized clinical performance in each parameter). The data was calculated using SPSS program version 26.

The comparison in the clinical performance of HVGIC restorations in pulp-treated molars regarding modified Ryge's criteria between baseline and recall periods were performed by using the Friedman test with the level of significance (p=0.05). The comparison of clinical performance between the ideal and less-ideal groups was performed using Fisher's exact test with the level of significance (p=0.05).

The analysis in survival time between the ideal cavity-HVGIC restorations and the less ideal cavity-HVGI restorations in pulp treated primary molars was carried out by using the Kaplan-Meier analysis; the subject teeth that have dropout, natural exfoliation, and other reasons for replacement of the restorations (e.g.

new proximal lesion independent of evaluated restoration) were estimated as censored. The date, which data was censored, was taken to be the last time at which the subject tooth was seen.

Besides, the mean survival time in months over 2 years and the annual failure rate of overall HVGIC restorations, the ideal cavity-HVGIC restorations, and the less ideal cavity-HVGI restorations in pulp treated primary molars were calculated, respectively.

4. Results and Discussion

4.1 Result

A total of 39 3- to 11-year-old boys and girls (mean age=7 years 8 months, SD=19.6 months) participated in the study (boy/girl ratio=1.67). Of 39 children, thirty-six children had one studied primary molar corresponding to the inclusion criteria of the study. Three children had two studied teeth. A total of 42 primary molars (35-second primary molars and 7 first primary molars) were evaluated. Thirty-four and eight of these studied teeth were in mixed dentition with erupted first permanent molars and primary dentition, respectively. Out of 42 studied teeth, 37 teeth received pulpectomy treatment. Five teeth received pulpotomy treatment.

Table 2 The overall outcome of pulp treated primary molars followed by HVGIC restorations (n = 42) at baseline, 6-month, and 12-month follow-up periods

	Baseline	**6-month recall**	**12-month recall**
Number of restorations	n = 42	n = 42	n = 42
Favorable / total	42^/42	42^/42	38/42
% success	100%	100%	90.5%

^ One of 1st primary molar showed radiographically defective restoration.

The overall success rates of pulp-treated primary molars followed by HVGIC restorations (n=42) at the baseline (evaluating within 1 month after receiving the treatment), 6-month, and 12-month follow-up periods were 97.6%, 97.6%, and 90.5% respectively, (Table 2). There was no difference in overall success rate between baseline and 6-month follow-up period (p=1.00). However, the overall success rate was statistically different between the baseline and the 12-month follow-up period (p=0.018). Pulp treatment failures were not found, clinically and radiographically, at follow-up periods of all studied teeth. At baseline, there was only one tooth that was classified as defective restoration because there was a radiographic marginal gap at the gingival margin of the proximally involved cavity. However, such radiographically defective restoration could not be detected clinically and was not judged as a failure. This tooth was planned for monitoring. At the end of a 12-month follow-up period, 4 (9.5%) of 42 studied teeth were classified as restorative failures. Out of 4 failures, 3 teeth presented obviously unfavorable marginal integrities with loss of supporting cavity walls and needed to receive a replacement or restoration. At 9 months, two of these three failures were detected and another one showed unfavorable marginal integrities within 10 months. These teeth were replaced by SSC restorations, (Figure 2). the one failure tooth was the radiographically defective restoration that was mentioned at the baseline follow-up period. The marginal gap of such tooth could be detected clinically at 12th month and then this failure tooth needed to replace with SSC restoration. Despite the existence of restorative failures, none of the teeth presented pulp treatment failures.

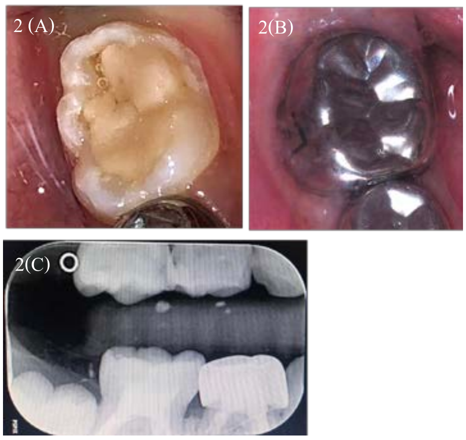

Figure 2 The pulpectomized secondary primary molar followed by HVGIC restoration in the group of less-ideal HVGIC restorations which was in the primary dentition. Figure 2 (A), showed an obvious unfavorable marginal integrity and tooth integrity. Figure 2 (B), showed the replacement with SSC restoration. Figure 2(C), showed bitewing radiograph before SSC restoration replacement.

Table 3 Restorative success rates of the pulp treated primary molars followed by HVGIC restorations (n = 42) at baseline, 6-month, and 12-month follow-up periods regarding the cavity type (Ideal vs. Less-ideal cavity restorations) *

	Baseline		**6-month recall**		**12-month recall**	
Cavity type	Ideal	Less-ideal	Ideal	Less-ideal	Ideal	Less-ideal
Favorable / total	23/23	19^/19	23/23	19^/19	23/23	15/19
% success	100%	100%	100%	100%	100%	78.9%

* Values are expressed as favorable / total (% successfully treated teeth).
^ One of 1st primary molar showed radiographically defective restoration.

42 of the pulp-treated primary molars followed by HVGIC restorations, 23 (54.8%) and 19 (45.2%) studied teeth were defined as the ideal-cavity HVGIC and the less-ideal cavity HVGIC restorations, respectively. At the baseline, one tooth was classified as radiographically defective restoration. Such tooth was in the group of less-ideal cavity HVGIC restorations. At the end of a 12-month follow-up period, out of 19 in the group of less ideal-cavity HVGIC restorations, 15 (78.9%) and 4 (21.1%) were judged as favorable restorations (Figure 3) and restorative failures, respectively. Meanwhile, all 23 (100%) teeth in the group of ideal-cavity HVGIC restorations were judged as favorable restorations (Figure 4). There was a statistical difference between ideal-cavity and less-ideal cavity restorations in restorative success at the end of a 12-month follow-up period (p=0.035), Table 3.

As mentioned above, the overall success rate (n=42) was different between the baseline and 12-month follow-up periods. However, the difference in restorative success rate was significantly found only in the group of the less ideal cavity (p=0.018). Conversely, there was no difference in the group of the ideal cavity in the same follow-up period.

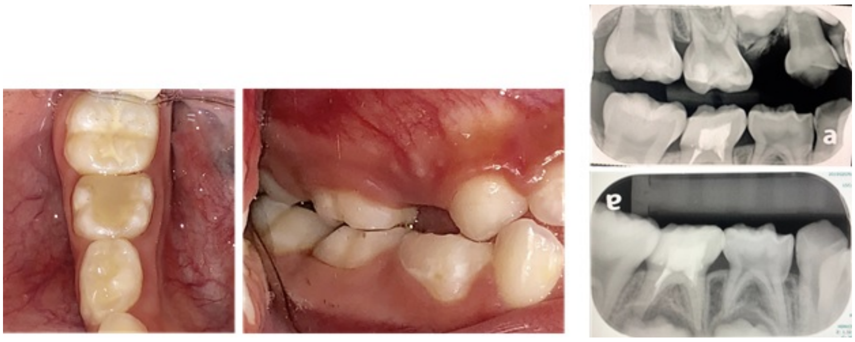

Figure 3 The pulpectomized secondary primary molar followed by HVGIC restoration in the group of less-ideal HVGIC restorations which was in mixed dentition

Figure 4 The pulpectomized primary secondary molar followed by HVGIC restoration in the group of ideal HVGIC restorations which was in mixed dentition

Clinical performances of HVGIC restorations in pulp-treated primary molars according to the modified Ryge's criteria were presented in Table 4. At the end of the 12 month follow-up period, there was a difference between ideal and less-ideal cavity HVGIC restorations regarding marginal integrity, (p=0.035), for both marginal adaptation and discoloration. The difference in tooth integrity was not found between both groups (p=0.084). Secondary caries were not found in both favorable and unfavorable restorations. Similarly, the difference in restorative wear/anatomical form was not statistically significant (p=1.000).

Table 4 Summary of HVGIC restorative performance according to the modified Ryge's Criteria

Criteria	**Group**	**Score**	**Control periods**	
			Baseline	**12-month**
Marginal integrity (Marginal adaptation)	**Ideal cavity**	Favorable (Score A+B)	23/23 (100%)	23/23 (100%)
		Unfavorable (Score C)	0/23 (0)	0/23 (0)
	Less ideal cavity	Favorable (Score A+B)	19/19 (100%)	15/19 (78.9%)
		Unfavorable (Score C)	0/19 (0)	4/19 21.1%
Marginal integrity (Marginal discoloration)	**Ideal cavity**	Favorable (Score A+B)	23/23 (100%)	23/23 (100%)
		Unfavorable (Score C)	0/23 (0)	0/23 (0)
	Less ideal cavity	Favorable (Score A+B)	19/19 (100%)	16/19 (84.2%)
		Unfavorable (Score C)	0/19 (0)	3/19 (15.8%)
Tooth integrity (Enamel loss)	**Ideal cavity**	Favorable (Score A+B)	23/23 (100%)	23/23 (100%)
		Unfavorable (Score C)	0/23 (0)	0/23 (0)
	Less ideal cavity	Favorable (Score A+B)	19/19 (100%)	16/19 (84.2%)
		Unfavorable (Score C)	0/19 (0)	3/19 (15.8%)
Secondary caries	**Ideal cavity**	Favorable (Score A+B)	23/23 (100%)	23/23 (100%)
		Unfavorable (Score C)	0/23 (0)	0/23 (0)
	Less ideal cavity	Favorable (Score A+B)	19/19 (100%)	19/19 (100%)
		Unfavorable (Score C)	0/19 (0)	0/19 (0)
Wear/anatomical form	**Ideal cavity**	Favorable (Score A+B)	23/23 (100%)	23/23 (100%)
		Unfavorable (Score C)	0/23 (0)	0/23 (0)
	Less ideal cavity	Favorable (Score A+B)	19/19 (100%)	19/19 (100%)
		Unfavorable (Score C)	0/19 (0)	0/19 (0)

Table 5 Distribution of 38 favorable restorative teeth regarding the tooth, cavity, and dentition type at 12 months*

Type of tooth	**1st primary molar**		**2nd primary molar**		**Total**
	6/38 (15.8%)		32/38 (84.2%)		**38**
Type of cavity	**Ideal**	**Less-ideal**	**Ideal**	**Less-ideal**	Total
Primary dentition	2/38 (5.26%)	n/a	3/38 (7.9%)	0/38 (0)	5/38 (13.2%)
Mixed dentition	1/38 (2.6%)	3/38 (7.9%)	17/38 (44.7%)	12/38 (31.6%)	33/38 (86.8%)
Total	3 /38 (7.9%)	3/38 (7.9%)	20/38 (52.6%)	12/38 (31.6%)	**38**

* Values are expressed as favorable / total of 38 favorable restorations (%)
* n/a means not available due to no studied teeth were classified into the specific group.

From Table 5, the distribution of favorable restorative teeth at 12-month follow-up period regarding tooth, dentition, and cavity type. 38 teeth were judged as favorable restorations, 33 teeth (86.8%) were in mixed dentition. Out of such 33 favorable restorative teeth, the majority of these teeth were secondary primary molars (29 teeth, 84.2%). Of such 29 secondary primary molars, 17 teeth (58.6%) and 12 teeth (41.4%) were in the group of ideal and the group less-ideal cavity restorations, respectively (shown in Figures 4 and 3).

Table 6 Distribution of 4 unfavorable restorative teeth regarding the tooth, cavity, and dentition type at 12 months *

Type of tooth	**1st primary molar**		**2nd primary molar**		**Total**
	1/4 (25%)		3/4 (75%)		**4**
Type of cavity	**Ideal**	**Less-ideal**	**Ideal**	**Less-ideal**	Total
Primary dentition	0/4 (0%)	n/a	0/4 (0%)	3/4 (75%)	3/4 (75%)
Mixed dentition	0/4 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
Total	0/4 (0%)	1/4 (25%)	0/4 (0%)	3/4 (75%)	4

* Values are expressed as unfavorable / total of 4 unfavorable restorations (%)
* n/a means not available due to no studied teeth were classified into the specific group.

Meanwhile, of 4 teeth were judged as unfavorable restorations, 3 teeth (75%) were the secondary primary molars that were in the primary dentition (shown in Figure 2). One tooth (25%) was the first primary molar that was in mixed dentition. The majority of all restorative failure teeth (100%) were in the group of less ideal cavity restorations (Table 6).

As seen in Figure 5, the cumulative survival curves for the ideal cavities group and less-ideal cavity group. After 1 year, the survival rate for the ideal cavity group was 100%, and for the less-ideal cavity group, a survival rate of 78.9% was computed. Over the whole clinically observed period of 12.0 months, the Kaplan–Meier algorithm showed a mean survival time for the ideal cavity group of 12.0 months with a 95% confidence interval between 12.0 months and 12.0 months. For the less-ideal cavity group, the mean survival time was 11.6 months with a 95% confidence interval between 11.2 months and 12.0 months (Table 7).

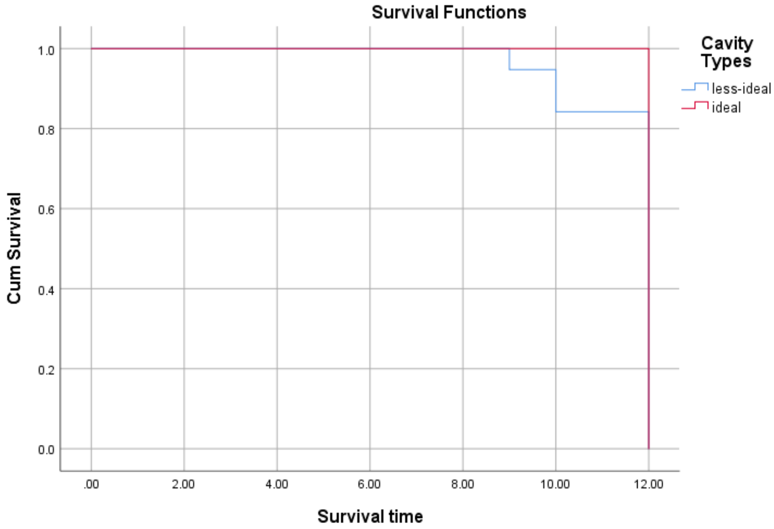

Figure 5 Kaplan-Meier Chart

Table 7 Survival characteristics of HVGIC restorations at 12 months

Cavity types	Number of case	Number of events	Number of Survived case	Mean survival time in months (95% confidence interval)
Ideal cavity group	23	0	23(100%)	12.0 (12.0, 12.0)
Less-ideal cavity group	19	4	15(78.9%)	11.6 (11.2, 12.0)

4.2 Discussion

The restoration of severely damaged primary molars is clinically challenging. Severely damaged primary molars are often detected with pulpal involvement, followed by pulp treatment. Regardless of the medicament being used, restoration of pulp treated (pulpotomized or pulpectomized) primary molars consists of filling up the empty pulp chamber with a zinc oxide eugenol-based material followed by a well-sealed restoration. The "gold standard" and most widely recommended type of restoration to meet that purpose has been a stainless steel crown that protects the weakened cavity walls and prevents marginal microleakage (A. Fuks et al., 2013; A. B. Fuks, 2002; Manual, 2010; Randall, Vrijhoef, & Wilson, 2000; Seale & Randall, 2015). SSCs have been recommended as ideal restoration for severely broken teeth and are considered to be superior to large multi-surface amalgam restorations (Randall, 2002; Randall et al., 2000; Roberts & Sherriff, 1990; Wong & Day, 1990). A systematic review showed placing preformed crowns as SSCs on primary molars with carious lesions, or following pulp treatment, is likely to reduce the risk of major failure or pain in the long term compared with conventional filling materials (Innes et al., 2015).

Nevertheless, there are still some disadvantages of SSCs restoration that are concerned. SSCs restoration takes a risk of a higher degree of gingivitis if there is improperly placed together with poorly maintained oral hygiene. It was probable that bulky SSC with poorly finished margins would act as secondary plaque retention. This result agrees with the previous study that showed a significant difference in the assessment of the gingival health, as evidenced by the higher percentage of SSCs causing spontaneous bleeding at the 24-month recall visit compared with the modified sandwich technique (M. Atieh, 2008). The influence of the skill of the clinician in placing stainless steel crowns has been emphasized by the previous study as being an important factor in minimizing defects in stainless steel crowns. The study reported a high percentage (42.5%) of defective and opened margins in crowns, which were placed in different health centers by various dentists with various degrees of knowledge, skill, and experience (Salama, 1996). On the contrary, it was also mentioned by another study that reported a low percentage (10%) of radiographically inadequate placement of SSCs. However, the study explained that these crowns were placed by students under close supervision in dental school where defective crowns were not approved (Sharaf & Farsi, 2004).

Meanwhile, adhesive restorations have several potential advantages over SSCs in primary teeth, including preservation of sound tooth tissue and normal contact area, and enhanced resistance to microleakage (el-Kalla & García-Godoy, 1999). Several studies tried to compare different types of restoration in pulp-treated primary molars. A randomized clinical trial assessed the survival rates of SSCs and sandwich restorations (RMGIC /a composite resin-based material) in primary molars after receiving diluted formocresol pulpotomy. This study revealed that the success rate of both materials over two years was considered excellent (>90%). The authors concluded that the sandwich restoration can be considered a reasonable alternative for SSC (M. Atieh, 2008). An earlier study in 2006 has evaluated the performance of mainly Class II restorations where pulpotomized primary molars received either a resin-based composite restoration or a polyacid modified resin composite (compomer). Each patient received at least 1 pair of restoration with both materials. At 24 month-recall, the authors revealed that significantly more radiographically pulp treatment failures were found with compomer restorations (17%), compared with composite (2%). The reasons for failure were attributed to coronal microleakage. Compomer restorations showed significantly more marginal discoloration (P= 0.001) and marginal disintegration (P= 0.001) than did the resin composite (Cehreli, Cetinguc, Cengiz, & Altay, 2006). Another study in 2008 used resin-based materials (compomers and hybrid resin) and amalgam to restore the 75 pulpectomized primary molars for a period of 12 months. Several bonding agent combinations were used. All restorations were performed over Class II preparations with no teeth needing a mesio-occluso-distal restoration or an SSC. After 1 year, 61 restorations (81%) were considered successful. The group of the hybrid resin-based composite together with dentin bonding agent performed best (with 93% success) (B. T. Zulfikaroglu, A. S. Atac, & Z. C. Cehreli, 2008). The present study revealed that the restorative success rate of HVGIC restorations in primary molars after receiving pulp treatment (pulpotomy or pulpectomy) was 90.5 % within a 1-year follow up period.

In this study, the restorative failures were found more common in the less-ideal cavities of second primary molars that were in the primary dentition. There were 4 restoration failures detected in the first 12-month follow-up period. Three of the failures, which were second primary molars in primary dentition, were found after the 6-month follow-up period. Accordingly, it might be assumed that it was because the second primary molars of primary dentition were the main functional teeth to support the occlusal force. Besides, the first permanent molar can support primary molars in bearing the occlusal force and can improve the survival time of the restoration in mixed dentition. Therefore, restorative failures were found more common in the primary dentition. While in mixed dentition, only one tooth was found as a failure at the 12-month follow-up period. From this data, it showed that the HVGIC restoration in pulp-treated primary molars might have a longer survival time and higher success rate when being restored in mixed dentition than in primary dentition.

The less-ideal cavities of pulp-treated primary molars have a weak, unsupported crown that is liable to fracture and therefore requires a restoration material that is capable of strengthening the weakened crown. The high success rate of HVGIC restorations in pulp-treated primary molars was frequently found in the second primary molars that were in mixed dentition, there was no difference between ideal cavities compared with less ideal cavities type. It may be explained that, in the mixed dentition, erupted first permanent molars are the main functional teeth to support the chewing force and there is an adequate crown structure of the second primary molars to support the restorative materials.

Interestingly, pulp treatment failure was not detected in this study. According to the well-known recommendation for pulp therapy, the major factor affecting the success of pulp treatment is the prevention of microleakage, thus a permanent restoration should be placed as soon as possible after the completion of the pulp treatment (Moskovitz, Sammara, & Holan, 2005). In this study, the primary molars were immediately restored after receiving pulp treatments. As a result, the success rate of pulp treatment in this study had a favorable outcome. So, this result was an affirmation that immediate restoration after receiving pulp treatment can improve success. The success rate of pulp treatment followed by immediately HVGIC restoration, obtained at 12 months (100%) was in line with those of previous clinical studies. The study of pulpectomized primary molars followed by adhesive restorations reported that the overall success rate of pulp treatment was 81 % (B. T. Zulfikaroglu et al., 2008). Similarly, in a randomized clinical trial of effectiveness in pulpotomized primary molars with MTA and Portland cement reported that no pulp failure was found in both group after immediately restored with resin-modified glass ionomer cement at the 1-year follow up period

(Sakai et al., 2009). Furthermore, a randomized clinical trial about clinical performance of SSCs and modified open-sandwich restoration in pulpotomized primary molar also reported that no pulp failure was detected over 1 year in both teeth that immediately restored with SSCs and modified open-sandwich restoration (M. Atieh, 2008)

Among the studied teeth found as restorative failures in this study, the pulp treatment of those teeth remained successful. This result agreed with a previous study that compared amalgam and SSC restorations of the pulpectomized primary molars, pulp treatment was found to be successful in 41.7% and unsuccessful in 58.3%. This difference was not statistically significant ($p > 0.05$). In teeth restored with amalgam, the micro-organisms could reach the cavity floor through micro-leakage. However, the underlying presence of ZOE, which has bactericidal properties minimized the survival chance of the micro-organisms. They concluded that restoration failure had no effect on treatment outcome and explained that the failure of restoration allows bacteria to penetrate the pulp and cause pulpal inflammation in pulpotomized teeth. However, before the invading microorganisms can reach the pulp, they must cross the barrier of ZOE cement used as a base material beneath the restoration. ZOE cement has a good sealing ability and antibacterial properties. Therefore, it may be suggested that ZOE used under restorations may prevent bacterial contamination either through its sealing ability and/or its antibacterial properties (Sonmez & Duruturk, 2010). The present study used reinforced ZOE cement (IRM TM) as pulp chamber filling material. Thus, it could be the preventive barrier of bacterial contamination in those restorative failure teeth.

Only one studied tooth (the first maxillary primary molar) of the present study has shown radiographically defective HVGIC restoration at the baseline evaluation. It might be explained that, in the conventional procedure, restoration in cavities with deep gingival margin can be clinically challenging. Such defective restorative tooth presented deep proximal caries lesion having its proximal gingival margin extended below the cement-enamel junction; the insertion of matrix band could not cover the distal gingival margin of the preparation, thus the distal marginal gap was existed after receiving the restoration.

A study in 2002 discussed the result of the study that the improvement of success rate in class I and class II primary molar restorations with glass ionomer cement is probably due to the interesting factor. Fuji IX GP TM is a high powder: liquid ratio GIC, with higher compressive strength (182 MPa) compared with the earlier Fuji II LC TM (154 MPa), it is intuitive that higher compressive strength material may clinically perform better (Rutar, McAllan, & tyas, 2002). A similar trend is the appearance of Fuji IX GP Extra TM that was used in the present study, it was improved in its higher compressive strength (255 MPa) and higher than Fuji IX GPTM

However, this study will require longer follow-up results and a significantly sufficient sample size to obtain a more accurate outcome about the clinical performance of high viscosity glass-ionomer restorations in pulp-treated primary molars.

5. Conclusion

In conclusion, under the condition of this study, HVGIC may be recommended as the material of choice for restoring pulp-treated primary molar when a stainless steel crown is not indicated. For instance, HVGIC can be either used as the final restoration on a pulp treated primary molar with sufficient remaining tooth structure when the tooth is in mixed dentition and has a life span of one year or less or a long term intermediate restoration in a primary molar with a questionable prognosis of pulp therapy.

6. References

AAPD. (2017a). Pulp therapy for primary and immature permanent teeth. *Pediatr Dent, 39*(6), 325-333.

AAPD. (2017b). Pediatric restorative dentistry. *Pediatr Dent*, 230-241.

AlvesdosSantos, M. P., Luiz, R. R., & Maia, L. C. (2010). Randomised trial of resin-based restorations in Class I and Class II beveled preparations in primary molars: 48-month results. *J Dent, 38*(6), 451-459.

Atieh, M. (2008). Stainless steel crown versus modified open-sandwich restorations for primary molars: a 2-year randomized clinical trial. *Int J Paediatr Dent, 18*(5), 325-332. doi:10.1111/j.1365-263X.2007.00900.x

Bazargan, H., Chopra, S., Gatonye, L., Jones, H., & Kaur, T. (2007). Permanent restorations on pulpotomized primary molars: An evidence-based review of the literature. Retrieved from http.//www.dentistry.utoronto.ca/system/files/pulpotomized primarymolars.PDF website:
Berg, J. H., & Croll, T. P. (2015). Glass ionomer restorative cement systems: an update. *Pediatr Dent, 37*(2), 116-114.
Berg, J. H., & Donly, K. J. (1988). Conservative technique for restoring primary molars after pulpotomy treatment. *ASDC J Dent Child 55*(6), 463-464.
Cehreli, Z. C., Cetinguc, A., Cengiz, S. B., & Altay, A. N. (2006). Clinical performance of pulpotomized primary molars restored with resin-based materials. 24-month results. *Am J Dent, 19*(5), 262-266.
Cole, B. O., & Welbury, R. R. (2000). The atraumatic restorative treatment (ART) technique: does it have a place in everyday practice? *Dent Update, 27*(3), 118-123.
Croll, T. P., & Nicholson, J. W. (2002). Glass ionomer cements in pediatric dentistry: review of the literature. *Pediatr Dent, 24(5),* 423-429.
el-Kalla, I. H., & García-Godoy, F. (1999). Fracture strength of adhesively restored pulpotomized primary molars. *ASDC J Dent Child, 66*(4), 238-242, 228.
Frencken, J. E., Songpaisan, Y., Phantumvanit, P., & Pilot, T. (1994). An atraumatic restorative treatment (ART) technique: evaluation after one year. *Int Dent J, 44*(5), 460-464.
Fuks, A., Pinkham, J., Casamassimo, P., Fields, H. J., McTigue, D., & Nowak, A. (2013). Pulp therapy for the primary dentition (5th ed.). St. Louis, Mo: Elsevier Saunders Co.
Fuks, A. B. (2002). Current concepts in vital primary pulp therapy. *Eur J Paediatr Dent, 3*(3), 115-120.
Guelmann, M., Shapira, J., Silva, D. R., & Fuks, A. B. (2011). Esthetic restorative options for pulpotomized primary molars: a review of literature. *J Clin Pediatr Dent, 36*(2), 123-126.
Hilgert, L. A., deAmorim, R. G., Leal, S. C., Mulder, J., Creugers, N. H., & Frencken, J. E. (2014). Is high-viscosity glass-ionomer-cement a successor to amalgam for treating primary molars? *Dent Mater, 30*(10), 1172-1178.
Holan, G., Fuks, A. B., & Ketlz, N. (2002). Success rate of formocresol pulpotomy in primary molars restored with stainless steel crown vs amalga. *Pediatr Dent, 24*(3), 212-216.
Huth, K. C., Paschos, E., Hajek-Al-Khatar, N., Hollweck, R., Crispin, A., Hickel, R., & Folwaczny, M. (2005). Effectiveness of 4 pulpotomy techniques--randomized controlled trial. *J Dent Res, 84*(12), 1144-1148. doi:10.1177/154405910508401210
Innes, N. P., Ricketts, D., Chong, L. Y., Keightley, A. J., Lamont, T., & Santamaria, R. M. (2015). Preformed crowns for decayed primary molar teeth. *Cochrane Database Syst Rev, 2015*(12), Cd005512. doi:10.1002/14651858.CD005512.pub3
Lenters, M., vanAmerongen, W. E., & Mandari, G. J. (2006). Iatrogenic damage to the adjacent surfaces of primary molars, in three different ways of cavity preparation. *Eur Arch Paediatr Dent, 7*(1), 6-10.
Manual, A. A. o. P. D. R. (2010). Guidelines on pulp therapy for primary and immature permanent teeth. *Pediatr Dent, 32,* 194-201.
Moskovitz, M., Sammara, E., & Holan, G. (2005). Success rate of root canal treatment in primary molars. *J Dent, 33*(1), 41-47. doi:10.1016/j.jdent.2004.07.009
Nowak, A. J., Christensen, J. R., Mabry, T. R., Townsend, J. A., & Wells, M. H. (2019). Pediatric Dentistry: Infancy through Adolescence (6th ed.). US: Elsevier.
Papathanasiou, A. G., Curzon, M. E., & Fairpo, C. G. (1994). The influence of restorative material on the survival rate of restorations in primary molars. *Pediatr Dent, 16*(4), 282-288.
Raggio, D. P., Hesse, D., Lenzi, T. L., Guglielmi, C. A., & Braga, M. M. (2013). Is Atraumatic restorative treatment an option for restoring occlusoproximal caries lesions in primary teeth? A systematic review and meta-analysis. *Int J Paediatr Dent, 23*(6), 435-443. doi:10.1111/ipd.12013
Randall, R. C. (2002). Preformed metal crowns for primary and permanent molar teeth: review of the literature. *Pediatr Dent, 24*(5), 489-500.

Randall, R. C., Vrijhoef, M. M., & Wilson, N. H. (2000). Efficacy of preformed metal crowns vs. amalgam restorations in primary molars: a systematic review. *J Am Dent Assoc*, *131*(3), 337-343. doi:10.14219/jada.archive.2000.0177

Roberts, J. F., & Sherriff, M. (1990). The fate and survival of amalgam and preformed crown molar restorations placed in a specialist paediatric dental practice. *Br Dent J*, *169*(8), 237-244. doi:10.1038/sj.bdj.4807333

Rutar, J., McAllan, L., & tyas, M. J. (2002). Three-year clinical performance of glass ionomer cement in primary molars. Int J Paediatr Dent, 12(2), 146-147. doi:10.1046/j.1365-263x.2002.00339.x

Sakai, V. T., Moretti, A. B., Oliveira, T. M., Fornetti, A. P., Santos, C. F., Machado, M. A., & Abdo, R. C. (2009). Pulpotomy of human primary molars with MTA and Portland cement: a randomised controlled trial. *Br Dent J*, *207*(3), E5; discussion 128-129. doi:10.1038/sj.bdj.2009.665

Salama, F. (1996). A study of the stainless steel crown errors: a suggestion for the modification of crown margins extension. *Cairo Dental Journal, 12*, 153-161

Seale, N. S., & Randall, R. (2015). The use of stainless steel crowns: a systematic literature review. *Pediatr Dent*, *37*(2), 145-160.

Sharaf, A. A., & Farsi, N. M. (2004). A clinical and radiographic evaluation of stainless steel crowns for primary molars. *J Dent*, *32*(1), 27-33. doi:10.1016/s0300-5712(03)00136-2

Sonmez, D., & Duruturk, L. (2010). Success rate of calcium hydroxide pulpotomy in primary molars restored with amalgam and stainless steel crowns. *Br Dent J*, *208*(9), E18; discussion 408-409. doi:10.1038/sj.bdj.2010.446

Tedesco, T. K., Calvo, A. F., Lenzi, T. L., Hesse, D., Guglielmi, C. A., Camargo, L. B., . . . Raggio, D. P. (2017). ART is an alternative for restoring occlusoproximal cavities in primary teeth - evidence from an updated systematic review and meta-analysis. *Int J Paediatr Dent*, *27*(3), 201-209.

Thabane, L. (2005). Sample Size Determnation in Clinical Trials. Retrieved from http://www.lebanathabane.com

Wong, F. S., & Day, S. J. (1990). An investigation of factors influencing the longevity of restorations in primary molars. *J Int Assoc Dent Child*, *20*(1), 11-16.

Zulfikaroglu, B. T., Atac, A. S., & Cehreli, Z. C. (2008). Clinical performance of Class II adhesive restorations in pulpectomized primary molars: 12-month results. *J Dent Child (Chic)*, *75*(1), 33-43