Clinical and Experimental Health Sciences

Randomized Clinical Trial of Heated HighViscosity Glass Ionomer Class II Restorations in Deciduous Molars: 12 Months Follow Up

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Received: 18.09.2021 **Accepted:** 27.01.2022

ABSTRACT

Objective: New generation High Viscosity Glass Ionomer Cements (HVGICs) have enhanced physical and mechanical properties. By effectively closing the restoration margin, it ensures that the restorations will last longer. The aim of this study was to investigate the clinical performances of heat-cured versus non heated HVGIC in class II restorations of deciduous molars.

Methods: This randomized, split mouth, multicentre study was performed in four different centres. A total of 250 deciduous molars from 88 individuals were randomly allocated to one of the following groups: 1) non-heated (*n* = 125) 2) heated (*n* = 125) and restored with a HVGIC using LED light for heat application. Restorations were clinically evaluated according to the modified USPHS at the baseline, 6 months and 12 months. The survival analysis was performed by Kaplan Meier and Life Tables. This study was retrospectively registered to the ClinicalTrials.gov with the ID number of NCT04291872 at 2nd March 2020.

Results: No statistically significant differences were found between the groups regarding to modified USPHS criteria ($p>0.05$). Success rate in retention criteria was 94.1% of the heat-cured and 92.6% of the non-heated restorations after 12 months. The mean survival time was 11.8 ±0.1 months in the heated group, while 11.9±0.1 months in the non-heated group.

Conclusion: The heat treated HVGIC for Class II restorations did not show any significant differences in 12 months' follow-up compared with the conventional technique.

Keywords: Dental caries, Glass ionomer cement, Deciduous tooth

1. INTRODUCTION

The conventional Glass Ionomer Cements (GICs) have numerous useful characteristics. For instance; chemical adhesion to structure of the tooth, a slow fluoride releasing, acceptable biocompatibility, good compressive (1, 2). On the other hand, the material is sensitive to water uptake within first 10 min after mixing which affect low wear resistance of GIC restorations (3).

Considering these disadvantages, manufacturers have developed new generation High Viscosity Glass Ionomer Cements HVGICs to improve physical and mechanical properties, as well as effectively seal the cavity restoration margin, resulting in higher longevity of restorations (4). Currently, the material of choice is HVGICs, due to its satisfactory survival in Class II restorations deciduous and permanent teeth (5, 6). Although HVGICs have certain advantages that present improved mechanical properties when compared to the earlier generation of conventional restorative GICs, some undesirable features limit to its clinical use. The major vulnerable feature of GICs is their poor fracture resistance. It is thought that this feature can improve with the process of the material maturation (7). In the previous research has shown that there are phrasal maturation processes in GICs. It takes over from the 4 to 6th weeks of settings (8). If dehydration occurs during the reaction, the GIC may present low surface strength, leading to have wear values lower and poor flexural and compressive strength at the early stage of setting (9).

Thermal-cured application to GIC was introduced to improve physical properties in recent studies (3, 10). It was thought that the change in temperature do not directly change the

DOI: 10.33808/clinexphealthsci.997219

mechanic properties of the material and but increase the molecular kinetic energy to ensure adequate adhesion to dental tissues (11). Adding external energy through heat application, the setting of traditional GIC is needed to obtain improved initial mechanical features and marginal adaptation (12). The idea was tested to get shorter initial stage to improve the hardness of GIC that could increase physical-mechanical strength and decrease microleakage values. Heat application in order to setting the material faster and reach sufficient maturation can positively affect the mechanical properties, especially in encapsulated glass ionomer cements (10).

Dental setting lamps can be used as a source of heat for GIC (13). The newest LED light have higher power density and hence higher thermal emission (14, 15).

The objective of the current research was to compare the clinical success rates of heated versus non heated HVGIC in class II restorations of deciduous molars.

2. METHODS

The study reviewed and approved by The Human Research Ethics Committee of Yeditepe University, School of Medicine with the protocol number of 37068.608.6100-15-1081 (Date: 25.06.2015). This study was retrospectively registered to the ClinicalTrials.gov with the ID number of NCT04291872.

2.1. Study Design and Selection of Participants.

This randomized controlled, split–mouth multicentre study was carried out in Marmara University, Faculty of Dentistry, Department of Pediatric Dentistry, Istanbul University, Faculty of Dentistry, Department of Pediatric Dentistry, Karadeniz Technical University, Faculty of Dentistry, Department of Pediatric Dentistry, and Ege University, Faculty of Dentistry, Department of Pediatric Dentistry between December 2015 – September 2017. A total of 275 children who came to these centres' clinics were assessed for the eligibility of the study. According to inclusion and exclusion criteria 88 children with 250 teeth were included in the study (Figure1). Informed consent forms were obtained from parents/caregiver before their participation in the study. No children were excluded based on sex, social or economic status. The consort principles for Randomised Control Trials (RCTs) were used (16).

The inclusion criteria were:

- healthy children aged between 5-7 years old
- has at least two approximal carious in deciduous posterior teeth
- has an appropriate interdigital occlusal relationship
- has at least one adjacent contact tooth

The exclusion criteria were:

- non-cooperative children
- children with special needs
- cavity with restorations
- developmental and acquired defects due to teeth,
- abscess, pain, pulp exposure
- has Class III occlusal relationship, cross bite, occlusal interference

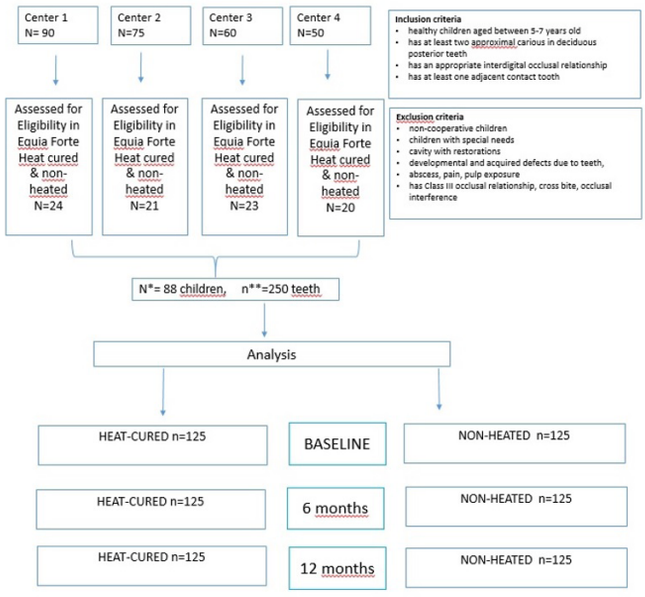

Figure 1. *Flow diagram of reporting trials of patient randomization*

2.2. Calibration

This randomized controlled, multicentre study was performed in four different centres. All pediatric dentists who took part in the study participated in the lecture and hands on course. Each pediatric dentist was educated and were familiar according to *Good Clinical Practise* (17). In each centre, one calibrated pediatric dentist made all the restorations accompanying with chairside assistant.

2.3. Sample Size Calculation

The sample size of this research was calculated according to previous study by Hubel et al. (18). The minimum sample size for the study was calculated as 78 participants at alpha error of 0.05 and beta error of 0.20. With possible drop outs 88 patients were included in the study.

2.4. Treatment Procedure

For randomisation, a lottery method used to distribute the groups (heated or non-heated) used for each patient's first restoration. Topical (10%Lidocaine – VEMCAINE, VEM İlaç San. Ankara/Turkey) and infiltrative local anaesthesia (Articaine Hydrocloride with epinephrine 0,01mg, VEM İlaç San. Ankara/Turkey) was applied respectively. To prepare the access cavity for proximal surface, a high-speed 801-012 diamond bur (FG Diamond-ADIA Dental Burs, Turkey) was used with under an air–water coolant. After obtaining access of the proximal site, Class II cavity was prepared using low speed considering the preparation of cavity according to non-selective caries removal technique.

Cavity was isolated by using cotton rolls and the sectional contoured metal matrices band (TOR VM, Russia) was placed interproximal and secured with a wooden wedge.

For split mouth study design, each restoration was randomly distributed to one proximal lesions until two treatment options were placed in each child with in equal number.

Non-Heated: Class II cavities were restored with Equia Forte (GC Corporation, Europe) according to manufacturer's instruction. For mixing the encapsulated Equia Forte Bulk Fill Glass Hybrid, Capsule Mixer CM-II (GC Europe) was used for 10 sec under +/ – 4000 rpm. The automatically mixed study material (10 s) was slowly injected into the cavity. The overflowing excesses were cleaned by hand tools. The restoration material was formed into shape after 45 sec.

Heated: Teeth were restored with the same protocol with non-Heated Group. LED light (GC – D-Light DUO) was used at standard mode 1200 m W /cm^2, at 50-60 ºC, for 60 sec. Immediately after heat application, occlusal interferences were checked. All the restorations both heated and non-heated were trimmed and polished after setting time (estimated setting time; net setting time=2 minute, total time (Average)= 3 minute, 25 seconds).

2.5. Clinical Evaluation and Follow-up

All restorations were evaluated by two calibrated examiners.

Marginal Integrity (MI), Marginal Discoloration (MD), Secondary Caries (SC), Anatomic Form (AF), and retention (R) were examined according to the modified USPHS at baseline and 6, 12 months. For each scale, there is an evaluation range from Alpha (perfect) to Delta (unsuccessful). Alpha (A) and Bravo (B) were used for clinically satisfying restorations (successful), while the Charlie (C) and Delta (D) scores were used to score clinically failures (unsuccessful) (19). The baseline evaluated initially after completing the restoration.

2.6. Statistical Methods

IBM SPSS Statistics 22 (SPSS IBM, Turkey) programs were used. Fisher's Exact Chi-square, Continuity (Yates) correction, Fisher Freeman Halton test and Mc Nemar test were used to compare the data with descriptive statistical methods (frequency). Survival analysis were evaluated using Kaplan Meier and Life Tables. Additionally, effects of selected such factors (heating condition: heated/ nonheated, jaw: maxilla/ mandibula, deciduous molar teeth: first/second molar, location: left/right,) were used to test their main effects on the dependent variable scores of 12 months' retention were redefined as binary variables (Alpha and Beta=Success and Charlie=Failure)) by using binary logistic regression enter method and $p<0.05$ was considered statistically significant.

3. RESULTS

3.1. Demographic Characteristics

The research was completed with 88 patients (boy=40, girl=48) with 250 teeth at the end of 12 months. The children's age ranged between 5–7 years (mean age=6.79±0.9). The distribution of the teeth according to the localization was described in Table 1.

Table 1. *The distribution of the treated teeth*

		N*	%
Molar type (N=250)	First Deciduous molar	134	53.6
	Second Deciduous molar	116	46.4
Jaws (N=250)	Upper jaw	111	44.4
	Lower jaw	139	55.6
Location (N=250)	Right side	126	50.4
	Left side	124	49.6

**indicates N= Number of teeth*

3.2. Clinical success

According to the Fisher Freeman Halton Test, the marginal integrity (p=0.007), marginal discoloration (p=0.027) and the retention criteria (p=0.001) showed significant differences for heat-cured and non-heated restorations in 6 months follow up period (Table 2).

While the success rates of anatomic form did not display any statistical significant differences between two groups, the heated group showed more acceptable success rates for 6 and 12 months' controls (Tables 2 and 3).

According to the retention criteria; the heat-cured was 94.1 % and the non-heated restoration was 92.6 % judged clinically as successful after 12 months (Table 3). The anatomical form and secondary caries showed no significant changes for both groups in one-year follow-up (Table 3).

The mean survival time in the heat-cured was 11.8±0.1 months and non-heated group was 11.9±0.1 months (Figure 2).

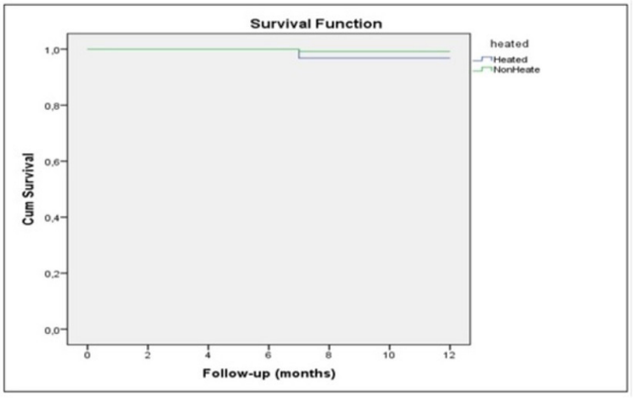

Figure 2. *Estimated cumulative survival curves of the restorations according to the retention codes*

The redefined ratios of success and failure were calculated as 89.2% (Success) and 7.2% (Failure), respectively. Also, the missing sample ratio was obtained as 3.6%. The binary logistic regression model revealed that any factors did not have significantly effects on the outcomes of 12 months retention (heating condition: p=0.307, jaw: p=0.620, deciduous molar: p=0.483, location: p=0.975, p>0.05 for all) (Table 4).

Table 2. *Comparison of baseline, 6 months and 12 months successes of groups*

		Baseline			6 months			12 months		
		Heatcured	NonHeated	p	Heatcured	NonHeated	p	Heatcured	NonHeated	p
Marginal Integrity	A	125 (100%)	125 (100%)		107 (86.3%)	93 (75%)		90 (75.6%)	77 (63.1%)	
	B	———-	———-	___	12 (9.7%)	24 (19.4%)	[1]0.007*	21 (17.6%)	27 (22.1%)	[1]0.087
	C	———-	———-		0 (0%)	5 (4%)		1 (0.8%)	6 (4.9%)	
	D	———-	———		5 (4%)	2 (1.6%)		7 (5.9%)	12 (9.8%)	
Marginal Discoloration	A	125 (100%)	125 (100%)		111 (89.5%)	102 (82.3%)		84 (70.6%)	73(59.8%)	
	B	———-	———-	___	9 (7.3%)	21 (16.9%)	[1]0.027*	26 (21.8%)	34 (27.6%)	[3]0.196
	C	———-	———-		4 (3.2%)	1 (0.8%)		9 (7.6%)	15 (12.3%)	
Seconder Caries	A	125 (100%)	125 (100%)		122 (98.4%)	118(95.2%)	[2]0.281	112 (94.1%)	108 (88.5%)	[4]0.147
	B	———	———	___	2 (1.6%)	6 (4.8%)		7 (5.9%)	14 (11.5%)	
Anatomic Form	A	125 (100%)	124 (99.2%)		109 (88%)	99 (79.8%)		88 (74%)	84 (68.9%)	
	B	———-	1 (0.8%)	1.000	11 (8.8%)	19 (15.3%)	[1]0.219	21 (17.6%)	25 (20.5%)	[3]0.665
	C	———-	———-		4 (3.2%)	6 (4.8%)		10 (8.4%)	13 (10.6%)	
Retantion	A	125 (100%)	125 (100%)		120 (96.8%)	112(90.3%)		105 (88.2%)	94 (77%)	
	B	———-	———-	___	1 (0.8%)	12 (9.7%)	[1]0.001*	7 (5.9%)	19 (15.6%)	[3]0.079
	C	———-	———-		3 (2.4%)	0 (0%)		7 (5.9%)	9 (7.4%)	

*[1]Fisher Freeman Halton Test, [2]Fisher's Exact Test, [3]Chi-Square, [4]Continuity (yates) test, *indicates p<0.05. A: Alpha, B:Bravo, C:Charlie, D:Delta.*

Table 3. *Clinical evaluation of heated and non-heated glass ionomer restorations with percentages values of clinically acceptable ratings (Alpha and Bravo) at baseline, 6 months and 12 months.*

		Baseline	6 months	12 months
		A+B	A+B	A+B
Marginal Integrity	H	100% (125/125)	95.2% (119/125)	88.8% (111/125)
	NH	100% (125/125)	93.6% (117/125)	83.2% (104/125)
	p	-	[a]0.767	[a]0.072
Marginal Discoloration	H	100% (125/125)	96% (120/125)	88% (110/125)
	NH	100% (125/125)	98.4% (123/125)	85.6% (107/125)
	p	-	0.370	[a]0.312
Anatomic Form	H	100% (125/125)	96% (120/125)	87.2% (109/125)
	NH	100% (125/125)	94.4% (118/125)	87.2% (109/125)
	p	-	0.540	[a]0.616
Retention	H	100% (125/125)	96.8% (121/125)	89.6% (112/125)
	NH	100% (125/125)	99.2% (124/125)	90.4% (113/125)
	p	-	0.370	[a]0.190

[a]Continuity (yates) correction A: Alpha, B: Bravo, C: Charlie, D: Delta; H: Heated, NH: Non-Heated

Table 4. *Binary logistic regression outcomes of the 12 months retention*

Factors	Std Error	Wald	p	Exp(B) – CI95% (Lower-Upper)
Heating condition (Heated/Non-Heated)	0.503	1.043	0.307	1.671 (0.624-4.48)
Jaw (Maxilla/Mandibula)	0.504	0.246	0.620	0.779 (0.29-2.092)
Deciduous molar (First/Second deciduous molar)	0.504	0.492	0.483	0.703 (0.262-1.885)
Location (Left/Right)	0.493	0.001	0.975	0.984 (0.375-2.586)
Consant	0.263	97.039	0	0.075

4. DISCUSSION

Glass-ionomer cements have been the subject of numerous studies regarding their clinical performance. Some researchers have tried to accelerate GIC setting reaction using ultrasonic waves, heat application with warm metal plates or heat application using Light / LED Cure dental devices in in-vitro studies (13, 20, 21).The efficacy of heat application deals with the thermal features of GICs. One of the favourable characteristics of the GICs is acceptable thermal properties, and these properties have not been studied many. Heat application is assumed to quicken the matrix-forming response of the cement and so at starting organize, the setting response will result in a more progressed and more noteworthy surface hardness. Applying heat moves forward the early properties of the GICs at a time when they are most vulnerable to harm (22). In this study, it was aimed to examine whether the durability of the material can be increased by heat application or not. Heat cure has been applied for different periods in different studies (10, 23). We applied 60 seconds in our study.

According to the conclusion of this research display that LED curing achieved significantly lower temperature rise than halogen lights for all test conditions (15). Clearly sufficient heat was not emitted from all LED curing lights. Thus, a special "heat application" LED light-curing unit has been manufactured. Its output temperature reaches 60 C in less than 60 seconds. The heat source is the LED light source also using for the polymerization of the composite resin material. Led cure dental devices can heat up to 50-60 degrees to a certain depth (3).

Molina et al. (2013) (24) compared Biaxial Flexural Strength (BFS) of different HVGICs after heat application with LED. They found that heating the GICs with an LED curing light 1400 Mw/cm2 during for setting for 30sec increased the BFS value for all GICs. In another in-vitro study; heating glass-ionomer restorative cements with an LED light-curing unit of 1200 mW/cm2 during 40 s improved marginal adaptation to enamel (13). However, there have been concerns that exposure to heat from these sources could lead to damage to tooth pulp. Van-Duinen et al. (2016) (25) concluded in their in-vitro study that heated GIC restoration setting does not have any harmful effect on pulp tissue and any pathological conditions. Gavic et al. (2015) (14) explained that glass-ionomer cements are capable of protecting the pulp for thermal damage. This issue cannot be concluded with just a few studies but more clinical studies are needed.

The recently introduced thermal-cured GIC have been used in restorative clinical studies. Skrinjaric et al. (2008) (23) evaluated the retention rate of heated GI sealant material for 1-year clinical follow up and concluded that heat treatment of GIC have had no effect on retention rate. In another clinical study, the success of light cured ART conventional HVGI fissure sealants were evaluated. Light cured conventional ART HVGI displayed more acceptable results in compared to those sealed with resin-composite and glass-carbomer (26). Tal et al. (2017) (3) concluded that heated HVGIC may be a better alternative restorative material for Class II restorations in deciduous molar.

Based on our 6 months' results, the retention of the restoration was more successful in the non-heated group, whereas in the 12-month follow-up, the heated group was more successful. While there was no significant difference between the groups according to the retention criteria, there was less loss of restoration in the heated group in 12 months. Within the statistical confines of survival analysis, although there was no statistically significant difference, heat application on GIC restoration had more successful results. According to the 6-month results, the marginal discoloration in the non-heated group was less observed than the heated group, whereas in the 12-month data, the number of the fail of restorations in the non-heated group was higher.

Although, we did not any obtain significant differences for all measurements during the study period, we have decided to clarify whether 12 months of retention outcomes would be affected by any other factors. The study focused on the deciduous and the young permanent dentition associated unsuccessful restorations with some variables such as patients' age (27). But the present clinical trial fulfilled this requirement since it evaluated the survival rates of restorations in only deciduous dentition. Also the split mouth design was followed so as to compare the two methods in the same child, in such a way so that all parameters and environment are kept constant (28). With respect to the potential data to obtain the main effects of such other factors (heating condition, jaws, deciduous molars and location of teeth), the binary logistic regression model (scores of 12 months were redefined as binary variables: Alpha and Beta=Success and Charlie=Failure) was used. Our regression model indicated neither factors revealed significant effects on the survival rates in 12 months' retention. Even though, this redefined variable is not much more clinically realistic, one year results might be promising regarding heat application for HVGIC. The heating condition (heated or unheated) of GICs could have an action on the retention of material if they could be tested in longer periods with more samples in later studies.

Although there are studies including CIS for one year follow up period (29-31), short follow up period is the limitation of our study as well. However, we first aimed to evaluate the efficiency of the heat application, and we focused on the success of the restorations. Eventually, we can suggest that this technique should be further investigated.

5. CONCLUSION

Our 12 months' findings suggested that the clinical success of HVGICs in class II cavity in posterior teeth are independent from the heat application. This study presents valuable results regarding the clinical application of GICs restoration in class II restorations in deciduous teeth.

Conflict of interests: All authors declare that they have no conflict of interest.

Funding Sources: This study was not supported by any grant or company.

Acknowledgements: The authors would like to thank the Phd Students; Elif Kanberoglu and Beril Muratoglu for the contribution of the study.

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How to cite this article: Yilmaz MA, Eren Giray F, Tuna Ince EB, Tuzuner T, Yetkiner AA, Ersin N, Kargul B. Randomized Clinical Trial of Heated HighViscosity Glass Ionomer Class II Restorations in Deciduous Molars: 12 Months Follow Up. Clin Exp Health Sci 2022; 12: 514-520. DOI: 10.33808/clinexphealthsci.997219