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COMPARISON OF HIGH VISCOSITY GLASS IONOMER CEMENT AND ALKASITE AS RESTORATIVE MATERIAL FOR ATRAUMATIC RESTORATIVE TREATMENT- A RANDOMIZED CONTROLLED TRIAL WITH SPLIT MOUTH DESIGN

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ABSTRACT

AIM: To assess and compare the clinical performance of High Viscosity Glass Ionomer Cement (HV-GIC) and Alkasite as a restorative material for Atraumatic Restorative Treatment in primary molars. **MATERIALS AND METHODS**: Thirty children with

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bilateral class I cavities (n- 60) were selected and randomly allocated to Group- 1 Alkasite and Group- 2 High Viscosity-Glass Ionomer Cement (HV-GIC). Restoration were evaluated at the 3rd and 6th months through Modified USPHS criteria (1980) and Modified Clinical criteria (1996). Statistical analysis was performed using Fisher's exact test and Kaplan-Meier survival analysis with IBM SPSS Statistics for Windows, Version 26.0. **RESULTS:** Restorations evaluated using modified USPHS criteria scored either Alpha (successful) or Bravo (clinically acceptable). At the 6th month follow-up 100% (n = 30) alpha score was obtained in criteria like Fracture, Secondary Caries, Post-operative sensitivity, Surface roughness, and Retention. Under Anatomic form and Marginal adaptation categories, the HV-GIC group scored 100% (n= 30) alpha and the Alkasite group scored 90% (n= 27) alpha at both 3rd and 6th month follow-up but this difference was statistically insignificant ($p > 0.05$). Additionally, score 0 (restorations present and good) was obtained in Modified Clinical Criteria for Evaluations of ART for all 30 (100%) restorations in HV-GIC group and 27 restorations (90%) in the Alkasite group at the end of 6 months ($p> 0.05$). **CONCLUSION:** This study demonstrated that both HV-GIC and Alkasite had clinically acceptable outcomes in restoring dental cavities using Atraumatic Restorative Treatment for primary molars.

KEYWORDS: Glass Ionomer Cement; Alkasite; Atraumatic Restorative Treatment; Dental Caries; Primary molars.

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COMPARACIÓN DE CEMENTO DE IONÓMERO DE VIDRIO DE ALTA VISCOSIDAD Y ALCASITA COMO MATERIAL RESTAURADOR PARA EL TRATAMIENTO RESTAURADOR ATRAUMÁTICO: UN ENSAYO CONTROLADO ALEATORIO CON DISEÑO DE BOCA DIVIDIDA

RESUMEN

OBJETIVO: Evaluar y comparar el desempeño clínico del cemento de ionómero de vidrio de alta viscosidad (HV-GIC) y Alkasite como material de restauración para el tratamiento de restauración atraumático en molares primarios. **MATERIALES Y MÉTODOS**: Se seleccionaron treinta niños con caries bilaterales de clase I (n-60) y se asignaron aleatoriamente al Grupo 1 Alkasite y al Grupo 2 Cemento de ionómero de vidrio de alta viscosidad (HV-GIC). La restauración se evaluó al tercer y sexto mes mediante los criterios modificados del USPHS (1980) y los criterios clínicos modificados (1996). El análisis estadístico se realizó mediante la prueba exacta de Fisher y el análisis de supervivencia de Kaplan-Meier con IBM SPSS Statistics para Windows, versión 26.0. **RESULTADOS**:

Las restauraciones evaluadas utilizando los criterios modificados del USPHS obtuvieron una puntuación Alfa (exitosa) o Bravo (clínicamente aceptable). Al sexto mes de seguimiento se obtuvo una puntuación alfa del 100% (n = 30) en criterios como fractura, caries secundaria, sensibilidad posoperatoria, rugosidad de la superficie y retención. En las categorías Forma anatómica y Adaptación marginal, el grupo HV-GIC obtuvo una

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puntuación alfa del 100 % (n = 30) y el grupo Alkasite obtuvo una puntuación alfa del 90 % (n = 27) al tercer y sexto mes de seguimiento, pero esta diferencia fue estadísticamente insignificante. (p > 0,05). Además, se obtuvo una puntuación de 0 (restauraciones presentes y buenas) en los Criterios clínicos modificados para evaluaciones de ART para las 30 restauraciones (100 %) en el grupo HV-GIC y 27 restauraciones (90 %) en el grupo Alkasite al final de los 6 meses. (p>0,05). **CONCLUSIÓN:** Este estudio demostró que tanto HV-GIC como Alkasite tuvieron resultados clínicamente aceptables en la restauración de caries dentales utilizando el tratamiento restaurador atraumático para molares primarios..

PALABRAS CLAVE: Cemento de Ionómero de Vidrio; Alcasita; Tratamiento Restaurador Atraumático; Caries Dental; Molares primarios.

INTRODUCTION

Dental caries, a prevalent global oral health concern is the deterioration of tooth structure and functionality.[1] Addressing this challenge requires the constant evolution and refinement of restorative materials and techniques. One such promising avenue in this pursuit is Atraumatic Restorative Treatment (ART).[2]

Unlike conventional methods, ART selectively removes infected dentin and unsupported enamel, aiming to preserve healthy structure.[3] The choice of restorative materials plays a pivotal role

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in ensuring the success of ART.[4] Furthermore, ART is considered a viable option in resource-limited settings where access to sophisticated dental equipment may be restricted. Given these advantages, the adoption of ART has gained momentum Globally, making it essential to continually refine and optimize the materials employed in the process.[5]

The High Viscosity variant of Glass Ionomer Cement (HV-GIC) is specifically designed with fluoride release properties and enhanced handling characteristics making it conducive for application in situations where stability and adaptability are crucial. The potential advantages of HV-GIC in ART warrant a comprehensive examination to elucidate its comparative effectiveness in contrast to other restorative materials.[6,7]

In recent years, Alkasite has emerged as a potential alternative to conventional restorative materials like GIC. Alkasite being a resin-based restorative material combines the benefits of glass ionomer and composite resin technologies.[8] While Alkasite has shown promise in various dental applications, its efficacy in the context of ART remains an area that warrants thorough investigation.[9]

The rationale behind this study is rooted in the need to enhance evidence-based guidance in the selection of restorative materials in Atraumatic Restorative Treatment. While HV-GIC has established itself as a reliable choice, emerging materials like Alkasite (Cention N) introduce new considerations.

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Thus, the study was conducted with the aim to assess and compare the clinical performance of Alkasite restorative material with High-viscosity Glass Ionomer Cement when used as Atraumatic Restorative Treatment in molars of deciduous dentition at the end of 6 months. We hypothesize that there is no difference in the clinical performance between HV-GIC and Alkasite when used as restorative materials in ART.

MATERIALS AND METHODS

A Randomized Controlled Trial (RCT) with a split-mouth study design was employed and compared the clinical performance of High-viscosity Glass Ionomer Cement (HV-GIC) and Alkasite restorative materials. Among children aged 6 to 11 years at the end of 3 and 6 months.

The nature and purpose of the study protocol were proposed to the Institutional Review Board. Ethical clearance was obtained ***(MADC/IEC-III/099/2022)*** to conduct this study**.** The trial protocol was registered in the Clinical Trials Registry-India **CTRI/2022/12/047804.** Prior to the start of the study, permissions from the Head of the school authorities were secured.

The inclusion criteria for this study encompass subjects aged 6 to 11 years with Class I cavities on bilateral primary molars with dental caries affecting enamel or dentin. Additionally, children with pre-existing restorations, teeth with physiological or pathological mobility, teeth associated with swelling or fistula, and a history of tooth pain were excluded from the study.

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Sample size calculation was performed using G*Power (v 3.0.1, Franz Faul, Universität Kiel, Germany). The significance level was set at 0.05, and a power of 0.80 was used with proportions of 1.0 in Group 1 and 0.78 in Group 2,19 The final sample size was determined to be 60 patients, indicative sample size of 30 in each group.

The Chief investigator was clinically trained to perform ART, as per the manufacturer's instruction, and calibrated to ensure uniform recording of Clinical criteria to evaluate ART restorations and Modified United States Public Health Service (USPHS) criteria. Training exercises were carried out under the guidance of an experienced Public Health Dentist.

The study participants were provided with information sheets, Informed consent was obtained from parents/caregivers, and verbal assent was procured from the children. Among 400 screened school children, 30 with bilateral class I cavities were selected using Convenience sampling. A lottery method was then used to randomly assign restorative materials to either side of each participant's mouth, ensuring balanced and unbiased allocation. ***(Flow chart)***

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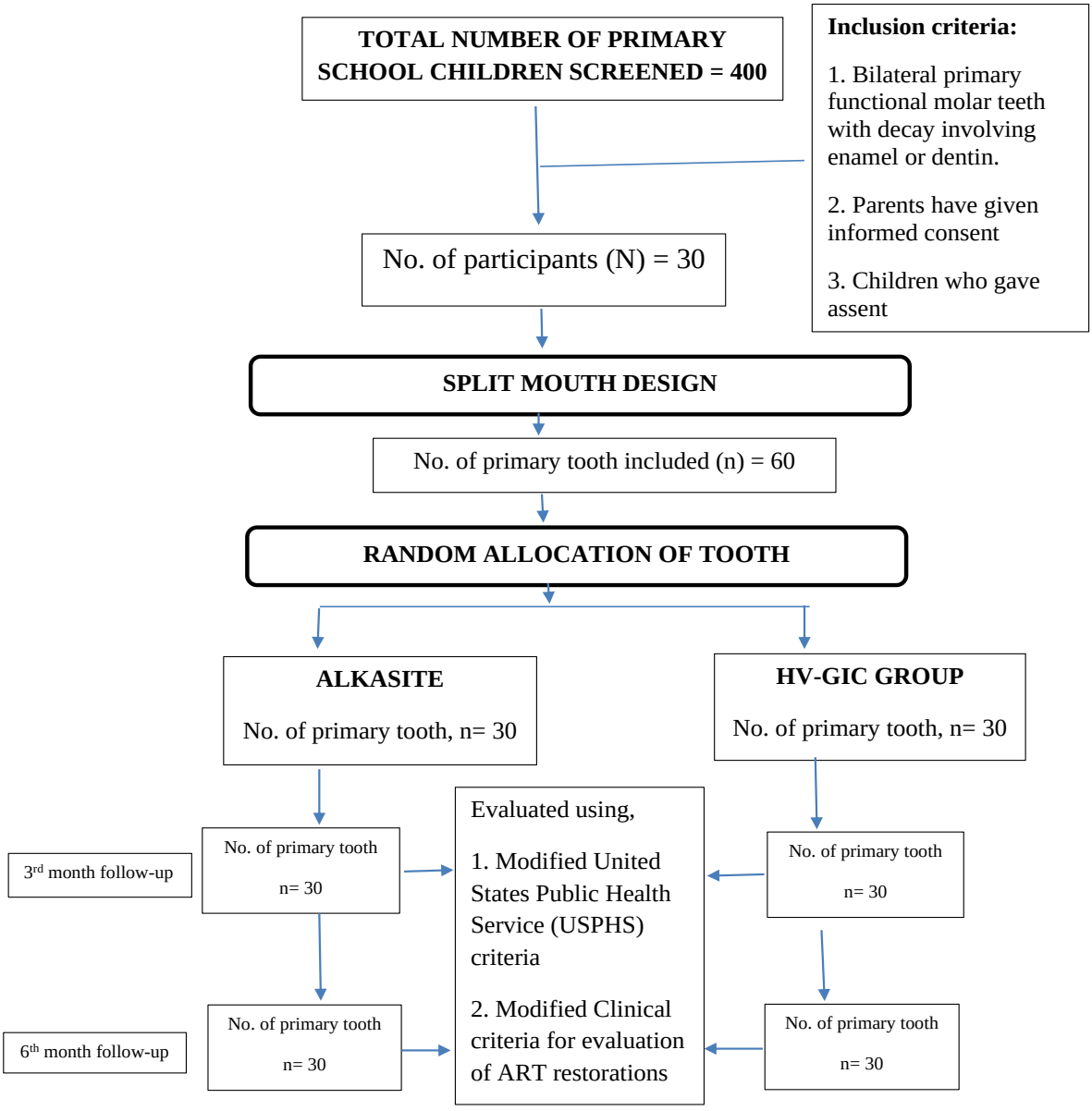

Standardized Aseptic protocol was ensured throughout the treatment. Excavation of infected dentin on bilateral decayed primary molars was performed using hand instruments, followed by isolation with cotton rolls to prevent

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saliva contamination and restoration with permanent restorative material.

On one side of the arch, the primary molar tooth was restored using Alkasite (Group– A) while on the other side using HV- GIC (Group– B) upon randomization and participants were advised to follow the post-operative instructions provided by the principal investigator. The clinical performance of HV-GIC and Alkasite restorative materials in the primary molars were assessed at the end of 3rd and 6th-month follow-ups.

Criteria used for evaluation were,

1. Modified United States Public Health Service (USPHS) criteria by Ryge in the year 1980.[10]
2. Modified Clinical criteria for evaluation of ART restorations by 1996.[11]

The data was collected and tabulated in Microsoft Excel. The obtained data was subjected to Fiser's exact test and Kaplan Meyer Test. Statistical analysis was performed using SPSS software version 19 (IBM Corp. Chicago, IL, USA).

RESULTS

Thirty children were included in the study based on the eligibility criteria. The age of the study participants ranges from 6 to 11 years old, with a mean age of 8.4±1.5 years. Among them, 53% of participants were male and 47% were females.

Table 1. Comparison of alkasite (group-1) and high viscosity- glass ionomer cement (group-2) using modified United States Public Health Service (USPHS)

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CATEGORY	SCORE	3 MONTHS		6 MONTHS	
		ALKASITE n(%)	HV-GIC n(%)	ALKASITE n(%)	HV-GIC n(%)
FRACTURE	A	30 (100)	30 (100)	30 (100)	30 (100)
	B/ C/ D	0	0	0	0
p- VALUE		-		-	
ANATOMIC FORM	A	27 (90)	30 (100)	27 (90)	30 (100)
	B	3 (10)	0	3 (10)	0
	C/ D	0		0	0
p- VALUE		0.23*		0.23*	
SECONDARY CARIES	A	30 (100)	30 (100)	30 (100)	30 (100)
	B/ C/ D	0	0	0	0
p- VALUE		-		-	
MARGINAL DISCOLORATION	A	30 (100)	30 (100)	27 (90)	28 (93)
	B	0	0	3 (10)	2 (7)
	C/ D	0	0	0	0

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p- VALUE		-		0.95*	
MARGINAL ADAPTATION	A	27 (90)	30 (100)	27 (90)	30 (100)
	B	3 (10)	0	3 (10)	0
	C/ D	0	0	0	0
p- VALUE		0.23*		0.23*	
POST-OPERATIVE SENSITIVITY	A	30 (100)	30 (100)	30 (100)	30 (100)
	B/ C/ D	0	0	0	0
p- VALUE		-		-	
SURFACE ROUGHNESS	A	30 (100)	30 (100)	30 (100)	30 (100)
	B/ C/ D	0	0	0	0
p- VALUE		-		-	
RETENTION	A	30 (100)	30 (100)	30 (100)	30 (100)
	B/ C/ D	0	0	0	0
p- VALUE		-		-	

n- number

%: percentage

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A – Alpha (Good), B – Bravo (Clinically acceptable), C – Charlie (require repair), D - Delta (Clinically unacceptable)

HV-GIC: High Viscosity Glass Ionomer Cement

* Fisher's exact p-value

Table 1 compared the Modified United States Public Health Service (USPHS) criteria in Class I cavity on primary molars evaluated at 3 months and 6 months restored with Alkasite and HV-GIC. From the table under *Fracture, Secondary Caries, Post-Operative Sensitivity, Surface Roughness, and Retention Categories* it was observed that both Alkasite and HV-GIC exhibited scores of 100% (n= 30) in the Alpha, 0% in the Bravo, Charlie, and Delta at 3rd months and 6th months follow-up. It suggested that there were no observed differences in the outcomes between Alkasite and HV-GIC. The *Anatomic Form Category* was similar in the alpha and beta categories of modified USPHS criteria between Alkasite and HV-GIC, with 100% (n= 30) for HV-GIC and 90% (n= 27) for Alkasite at 3rd and 6th months but this difference was statistically insignificant (p>0.05).

Marginal Discoloration Category at 3 months follow-up revealed both Alkasite and HV-GIC had 100% (n= 30) Alpha scores. At the end of 6 months follow-up, there was a minimal range of marginal discoloration of about 7% (n= 2) in HV-GIC and 10% (n= 3) in Alkasite reported (Bravo score). A Fisher's exact p-value of >0.05 suggested no statistically

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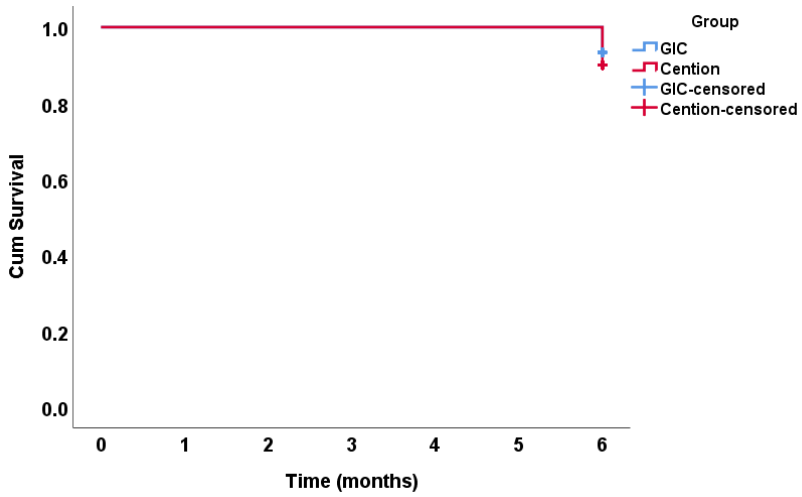
significant difference in the occurrence of marginal discoloration between Alkasite and HV-GIC at the end of 6 months. ***Graph 1*** shows Kaplan-Meier survival analysis for marginal discoloration over time for Alkasite and HV-GIC. The log-rank test reports a p-value of > 0.05, suggesting a trend towards a difference, but it does not reach conventional significance levels.

GRAPH 1. Kaplan-Meier survival estimates of *Marginal Discoloration* among the HV-GIC and Alkasite in primary teeth (log-rank p = 0.064)



HV-GIC shows superior *Marginal Adaptation* of 100% (n=30) at the end of 6 months than Alkasite. About 10% restorations in Alkasite group displayed Bravo score at 3rd month and 6th months follow-up. Fisher's exact p-value of >0.05 indicated statistically insignificant difference in marginal adaptation between

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HV-GIC and Alkasite at both time periods. This criterion showed comparable performance in terms of marginal adaptation clinically for these two restorative materials over the 6 month.

Table 2. Modified clinical criteria for evaluations of art restorations

	3 MONTHS		6 MONTHS	
SCORE	ALKASITE n(%)	HV-GIC n(%)	ALKASITE n(%)	HV-GIC n(%)
0	27 (90)	30 (100)	27 (90)	30 (100)
1	3 (10)	0	3 (10)	0
2- 9	0	0	0	0
p- VALUE	0.23*		0.23*	

n- number

%: percentage

0- Present, good

1- Present, slight marginal defect for whatever reason, at any one place which is less than 0.5 mm in depth: no repair is needed

HV-GIC: High Viscosity Glass Ionomer Cement

* Fisher's exact p-value

The Modified Clinical Evaluations of ART (Atraumatic Restorative Treatment) restorations that were conducted in 3rd month and 6th month intervals on Alkasite

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and HV-GIC. The distribution of scores as presented in ***Table 2*** revealed that at 3rd month, restorations using HV-GIC scored 0, indicating a 100% success rate. For Alkasite, 90% of restorations scored 0, and 10% scored 1. The findings at both time intervals were similar. By this Modified ART criteria, HV-GIC showed superior results than Alkasite. Though there was a noticeable clinical significance the statical difference was insignificant ($p > 0.05$). Additionally, the Kaplan-Meier survival analysis in ***Graph-2*** illustrates Kaplan-Meier survival analysis for the Anatomic Form, Marginal Adaptation, and clinical longevity of ART restorations which had obtained similar values. The log-rank p-value of 0.078 suggests a trend towards a difference in survival estimates between Alkasite and HV-GIC, although it does not reach statistical significance ($p > 0.05$). Further observation and analysis may be needed to draw more definitive conclusions regarding long-term clinical performances.

GRAPH- 2. Kaplan-Meier survival estimates of *Anatomic Form, Marginal Adaptation, Clinical Evaluations* of ART Restorations among the Alkasite and HV-GIC in primary teeth (log-rank p = 0.078)

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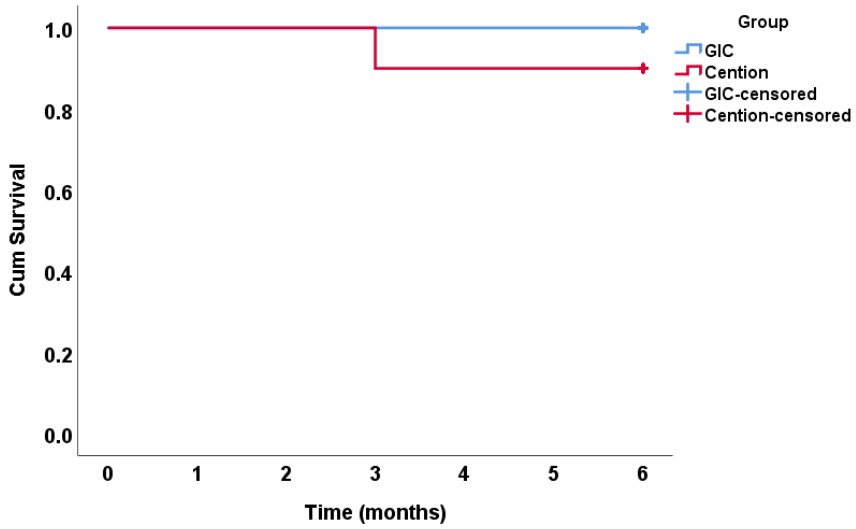

DISCUSSION

In this study, the clinical effectiveness of two different restoratives was assessed in class I primary molars among the study participants. The evaluation of Alkasite (GROUP -1) and HV-GIC (GROUP -2) was done using Modified Criteria for ART and Modified USPHS after a follow-up period of 3rd month and 6th months. Even though both groups produced clinically acceptable results, noticeable differences were found in a few categories but they were insignificant ($p > 0.05$). In light of the findings, the null hypothesis was accepted. HV-GIC with its excellent clinical properties had been favored for ART over a long period of time. Considering Alkasite as an alternative allows an unbiased comparison considering its adhesive properties, biocompatibility, durability, and ease of handling.

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Exclusion criteria were implemented to further refine the study population. Children with already filled bilateral molar teeth were excluded to maintain homogeneity and avoid confounding variables related to previous restorative treatments.[22] Participants presenting with dental complaints characterized by swelling or a fistula were excluded from the study due to their indication of active infectious lesions. Additionally, individuals with a history of pain were not included, as it may involve infections that could alter oral occlusal and masticatory forces along with potential discrepancy in the chewing ability of the participants.[12]

The present study employed two assessment criteria. Firstly, the Modified USPHS standards, developed by Ryge in 1980,[10] were utilized. These criteria offer a standardized and widely accepted framework for evaluating a range of restorations. Their applicability extends beyond specific procedures, ensuring a comprehensive analysis of restorations that go beyond those associated with a particular treatment methodology. On the other hand, Modified Clinical Criteria Evaluation of ART Restorations, 1996,[11] is exclusive to ART procedures. By incorporating both Modified USPHS and Clinical criteria to evaluate ART, this study adopts a dual approach that captures the general and procedure-specific dimensions of restoration evaluation towards ART, resulting in a more nuanced and thorough examination of the outcomes.

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Statistical analysis of Modified USPHS standards under fracture category both, HV-GIC and Alkasite exhibited equal performance by acquiring a 100% alpha score which is in contrast to a study conducted by Soneta SP et al., in 2022 that revealed 100% retention of Alkasite restorative material, and 90% retention of HS-GIC at the end of 6 months and also concluded that Alkasite had increased retentive properties than HS-GIC.[13]

Under Anatomic Form, Bravo sore was obtained in three restorations in the Alkasite group at 3rd month and 6th month follow-ups. All 30 restorations in the HV-GIC group scored alpha and the difference was insignificant ($p > 0.05$). A similar study conducted by Derchi G et al., in 2022 revealed that the two materials exhibited similar behaviour, with values declining over time of about 65% in HV-GIC and 53% in Alkasite during the 12th month. They further concluded that the performance of the Alkasite material was comparable to that of the Fuji IX GIC.[14]

Under the category of Post-Operative Sensitivity (POS), both GIC and CN demonstrate comparable outcomes at both 3 months and 6 months follow-up. In both groups, all participants (100%) scored the lowest sensitivity level (ALPHA) at both time points. This suggests that both restorative materials, GIC and CN, exhibit a high degree of effectiveness in minimizing post-operative sensitivity over the specified follow-up periods. This is in agreement with the study conducted by Mushtaq U et al., in 2021 that analyzed POS in relation to Class I

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restorations and concluded that both Type 9 GIC and Alkasite revealed negligible POS.[15]

Previous studies have investigated the clinical effectiveness of GIC and Alkasite restorative materials seeking to understand their performance in various dental applications. Attia R et al., 2022,[16] examined Class I restorations, and Arora D et al., 2022,[17] specifically investigated proximal restorations of primary molars. These studies collectively suggest that Alkasite restorative material stands out as a promising alternative to GIC.

STRENGTH- Double-blinded study design, that minimizes bias by ensuring that both participants and the statistician are unaware of the assigned treatment which strengthens the validity of the results. Split mouth study design that controls for inter-individual variability, which improves the precision.

Study limitations include longer durations of observation could yield an improved understanding of the durability and restorations. Additional researches are needed to evaluate the clinical performance of restorative materials in permanent teeth.

CONCLUSION

Our findings revealed that both Alkasite and High Viscosity- Glass Ionomer cement demonstrated clinically acceptable outcomes in the restoration of

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dental cavities through Atraumatic Restorative Treatment. This supports the notion that both materials can be viable options for restorative procedures in the ART approach. However, noteworthy results emerged when examining specific aspects within each group.

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