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Original Research Article

Clinicoradiographic evaluation of different intracoronal and extracoronal restorative materials for the restoration of carious primary molars: a twelve month follow-up study

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ABSTRACT

Background: To assess clinical and radiographic efficacy of conventional GIC, stainless steel crown (HT), and Alkasite restoration (Cention N) as management options for cavitated primary molars and to evaluate their success clinico-radiographically in terms of survival, patient's acceptance and parental satisfaction over a minimum period of 12 months.

Methods: IOPAs were taken to assess the extent of caries. Cavitated primary teeth were subjected to following procedures randomly: GROUP I- (GIC) - Isolation followed by soft caries removal, then restoration of cavity with GIC. Patient recalled after 24 hours for finishing and polishing of restoration. GROUP II- (SSC) - Proper isolation followed by soft caries removal. Appropriately sized prefabricated SSC fit and cemented by luting GIC. GROUP III- (AK) - Isolation followed by soft caries removal, restoration of cavity with Alkasite and light cured for setting and finished.

Results: In terms of pain, secondary caries and pulpal involvement, 10% cases failed in group I and group III while 100% success was seen in group II. In terms of longevity, maximum dislodgement was seen in group I (30%) followed by group III (10%) while 100% success was seen in group II. In terms of patient and parent acceptance, group III was most widely accepted by patients at baseline while parents were satisfied with group II at the end of the study.

Conclusions: All restorative materials were clinically and radiographically successful in restoration of primary molars in terms of survival, patient acceptance and parental satisfaction, however Stainless-Steel crowns proved to be most efficacious.

Keywords: Dental caries, Primary teeth, Restorative therapy, Glass ionomer cement, Alkasite, Stainless-steel crowns

INTRODUCTION

Dental caries though largely preventable, still remains as one of the biggest threats to oral health and if left untreated, it may result in severe destruction of teeth hampering a child's general health and quality of life.[1] Thus, the practice of restorative dentistry for children requires extensive knowledge and understanding of materials available and their techniques. Furthermore, selecting the appropriate material for the right clinical situation depends on the requirements of the particular patient, his/her cooperation level and the comfort of the dentist using them, to ensure optimal function, long-term performance and esthetics.[2] Since ages, GIC has been used in pediatric patients over amalgam because of potential advantages such as fluoride (F) release, chemical bonding to tooth structure and good biocompatibility. Though conventional GIC does not

require any complicated dental equipment, however, it is slow setting with low fracture toughness and poor wear resistance.[3,4]

Since their introduction in 1950, Stainless steel crowns (SSCs), are used for the treatment of primary and young permanent teeth with pulp therapy, multisurface caries, and developmental defects.[5] Although durable and clinically successful, many clinicians find them difficult to fit due to lack of patient cooperation, prolonged chair time, and/or the need to administer local anaesthesia. Thus, the Hall technique (HT) was introduced which is a simplified method of managing carious primary molars using SSCs without local anaesthesia, caries removal, or tooth preparation and has been shown to have high success rate.[6]

Recently, a new "Alkasite" bulk fill restorative material, commercially available as Cention N, has been introduced in the field of Pediatric dentistry which refers to a new category of filling material, which is like compomer or ormocer materials and is essentially a subgroup of the composite material class.[7] However, literature regarding the clinical efficacy of Alkasite restorative material in primary posterior teeth and its comparison with the traditional restorative materials/techniques is sparse. Hence, the present study was designed to assess the clinical and radiographic efficacy of conventional GIC restoration, Stainless Steel crown (Hall Technique), and Alkasite restoration (Cention N) as management options for cavitated primary molars and to evaluate their success clinico-radiographically in terms of their survival, patient's acceptance and parental satisfaction over a minimum period of 12 months.

METHODS

In the present prospective, in vivo study, a total of 30 cavitated primary molars indicated for restoration in children aged between 4-8 years were selected from the outpatient Department of Pediatric and Preventive Dentistry, Subharti Dental College and Hospital (from December 2020 to December 2021) and randomly divided into 3 groups on the basis of the restoration given: group I (conventional GIC, n=10), group II (stainless-steel crown, n=10) and group III (Alkasite, n=10). Permission of the Institutional Ethical Committee was obtained prior to start of the study. Informed consent was obtained from parent/guardians of the children participating in the study.

Inclusion criteria

Inclusion criteria for current study were; systemically healthy children aged 4-8 years, primary molars with clinically and radiographically single or two surface caries extending into dentin and cooperative child (Frankel Behaviour rating 3 and 4).

Exclusion criteria

Exclusion criteria for current study were; children with any systemic illness/medically compromised children, uncooperative children, non-restorable teeth, history of nickel allergy, mobile teeth, teeth near exfoliation and teeth in which almost half of the root is resorbed.

Restoration technique

Intraoral periapical radiographs/RVG were taken to assess the extent of the caries. Cavitated primary teeth were then subjected to the following procedures randomly: group I- (GIC); after proper isolation, soft caries was removed by a high-speed air rotor and cavity was restored with GIC. Patient was recalled after 24 hours for the finishing and polishing of the restoration. Group II (SSC) Proper isolation of the selected tooth followed by soft caries removal. Appropriately sized prefabricated SSC was fit and cemented by luting GIC. Group III (AK) after proper isolation, soft caries was removed by a high-speed air rotor and cavity was filled with Alkasite material and light cured for setting. Finishing and polishing was done after restoration sets.

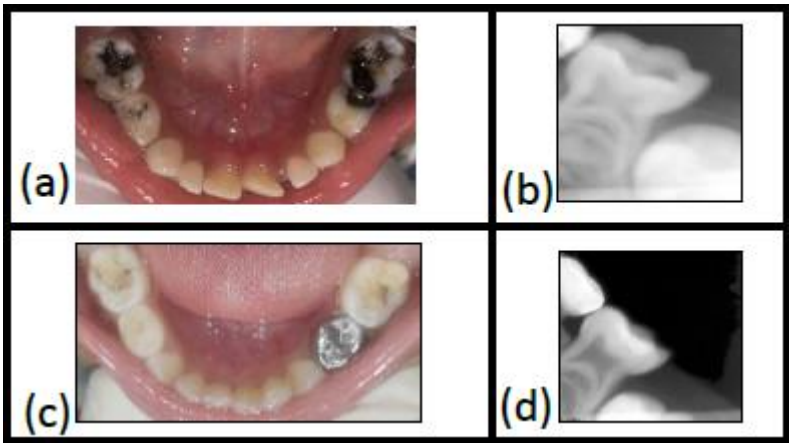

Figure 1: GIC restoration w.r.t 85; (a) clinical preoperative picture; (b) radiographic preoperative picture; (c) 1 year follow up clinical image (d) 1 year follow up radiographic image.

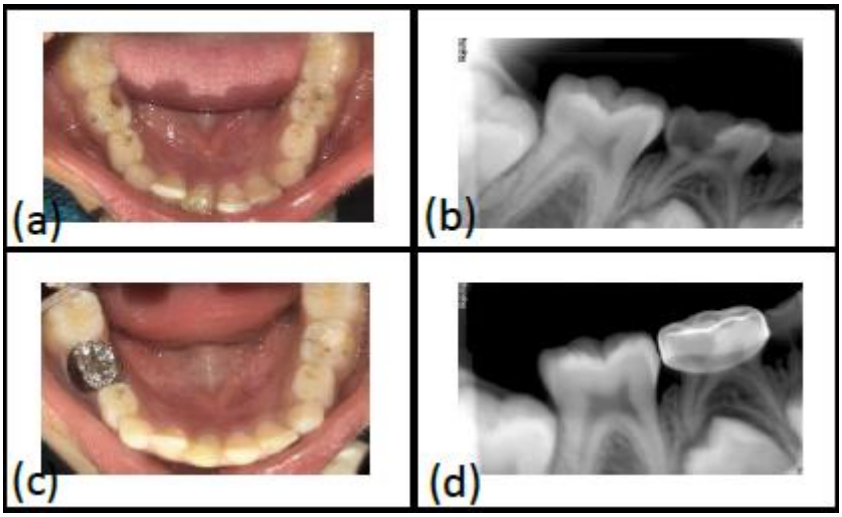

Figure 2: SSC restoration w.r.t 84; (a) clinical preoperative picture; (b) radiographic preoperative picture; (c) 1 year follow up clinical image (d) 1 year follow up radiographic image.

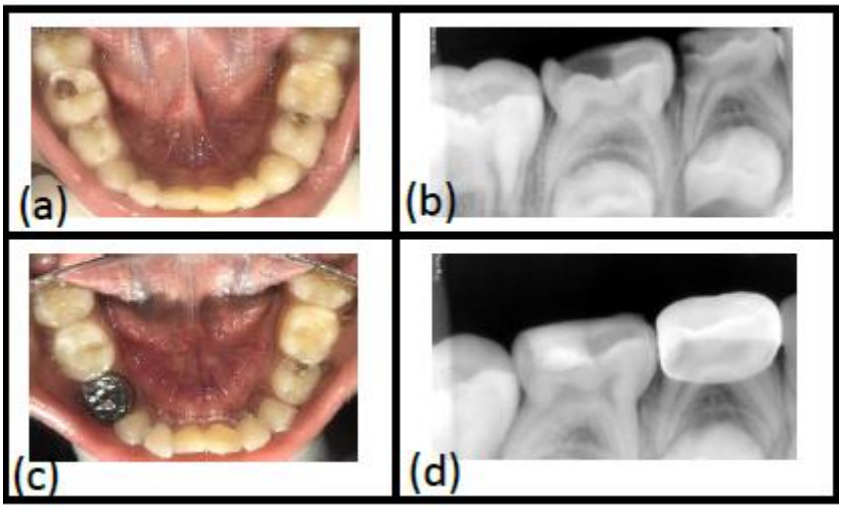

Figure 3: Cention restoration w.r.t 85; (a) clinical preoperative picture; (b) radiographic preoperative picture; (c) 1 year follow up clinical image; (d) 1 year follow up radiographic image.

Follow up

The clinical evaluation was done on the basis of presence/ absence of pain, presence/ absence of sinus/swelling and presence/absence of dislodged restoration while radiographic evaluation was done based on the presence/ absence of secondary caries, presence/ absence of pulpal involvement and presence/ absence of periapical pathology at 1 day, 3, 6, 9 and 12 months follow-up intervals (Figure 1-3).

Statistical analysis

Data collected was calculated, compared and statistically analyzed using the SPSS 19 software. The following formulae were employed for calculations: Friedman test, Cochrane Q test, Chi-square test, Kruskal Wallis test and Mann Whitney U test.

RESULTS

In terms of presence/absence of pain (Table 1), Secondary caries (Table 2), and Pulpal involvement (Table 3), over the due course of time, no statistically significant difference was observed as group I and group III showed similar results (10% failure each) as compared to Group II which proved to be the most efficacious. On comparison in regard to presence/absence of dislodgement (Table 4), in group I, 30% samples showed dislodged restorations after 9 months and 12 months each. None of the samples in group II (SSC) showed dislodgement throughout the study duration. In group III (Alkasite), only 10% samples showed dislodgement at 9

months and 12 months each. Evaluation of presence/absence of sinus/swelling (Table 5) and periapical pathology (Table 6) in all the three groups showed similar results at 1 day, 3, 6, 9 and 12 months interval, thus revealing that none of the restorative procedure showed radiographic failure during the entire course of the study.

As far as patient acceptance (Table 7) towards the restoration being performed was concerned, Group III was most widely accepted (70% highly satisfied) due to their superior esthetics and ease of placement, followed by Group I (40% were satisfied).

Table 1: Comparison of pain at different time intervals.

Groups	Pain	1 day	3 months	6 months	9 months	12 months	P value
Group I	Present	0	0	0	0	1	0.392 (NS)
	Absent	10	10	10	10	9	
Group II	Present	0	0	0	0	0	-
	Absent	10	10	10	10	10	
Group III	Present	0	0	0	0	1	0.392 (NS)
	Absent	10	10	10	10	9	

Cochrane's Q test; NS: Non-significant difference.

Table 2: Comparison of secondary caries at different time intervals.

Groups	Sec. caries	1 day	3 months	6 months	9 months	12 months	P value
Group I	Present	0	0	0	0	1	0.392 (NS)
	Absent	10	10	10	10	9	
Group II	Present	0	0	0	0	0	-
	Absent	10	10	10	10	10	
Group III	Present	0	0	0	0	1	0.392 (NS)
	Absent	10	10	10	10	9	

Cochrane's Q test; significant difference at $p \leq 0.05$.

Table 3: Comparison of pulpal involvement at different time intervals

Groups	Pulpal inv.	1 day	3 months	6 months	9 months	12 months	P value
Group I	Present	0	0	0	0	1	0.392 (NS)
	Absent	10	10	10	10	9	
Group II	Present	0	0	0	0	0	-
	Absent	10	10	10	10	10	
Group III	Present	0	0	0	0	1	0.392 (NS)
	Absent	10	10	10	10	9	

Cochrane's Q test; significant difference at $p \leq 0.05$.

Table 4: Comparison of discoloration/dislodgement at different time intervals.

Groups	Score	1 day	3 months	6 months	9 months	12 months	P value
Group I	0	10	10	10	6	6	0.018*
	1	0	0	0	1	1	
	2	0	0	0	3	3	
	3	0	0	0	0	0	
Group II	0	10	10	10	10	10	--
	1	0	0	0	0	0	
	2	0	0	0	0	0	
	3	0	0	0	0	0	
Group III	0	10	10	10	9	9	0.135 (NS)
	1	0	0	0	0	0	
	2	0	0	0	1	1	
	3	0	0	0	0	0	

Friedman test; * indicates significant difference at $p \leq 0.05$.

Table 5: Comparison of swelling/sinus at different time intervals.

Groups	Swelling	1 day	3 months	6 months	9 months	12 months	P value
Group I	Present	0	0	0	0	0	--
	Absent	10	10	10	10	10	
Group II	Present	0	0	0	0	0	--
	Absent	10	10	10	10	10	
Group III	Present	0	0	0	0	0	--
	Absent	10	10	10	10	10	

Table 6: Comparison of periapical pathology at different time intervals.

Groups	Swelling	1 day	3 months	6 months	9 months	12 months	P value
Group I	Present	0	0	0	0	0	--
	Absent	10	10	10	10	10	
Group II	Present	0	0	0	0	0	--
	Absent	10	10	10	10	10	
Group III	Present	0	0	0	0	0	--
	Absent	10	10	10	10	10	

Table 7: Comparison of patient acceptance (baseline/1 day).

Groups	Score 1	Score 2	Score 3	Score 4	Score 5	P value
Group I	0	0	0	7	3	0.001*
Group II	2	4	1	3	0	
Group III	0	0	0	3	7	

Kruskall-Wallis test; *indicates significant difference at p≤0.05

Table 8: Comparison of parental satisfaction (9 months).

Groups	Score 1	Score 2	Score 3	Score 4	Score 5	P value
Group I	0	3	3	4	0	0.008*
Group II	0	0	0	4	6	
Group III	0	1	0	5	4	

Kruskall-Wallis test; * indicates significant difference at p≤0.05

Group II were the least accepted procedure by patients (40% were dissatisfied) due to the slight invasive nature of the procedure, along with an unesthetic appearance. A statistically significant difference was recorded. Finally, in terms of parental satisfaction (Table 8), Group II were the most widely accepted form of restoration by the parents (60% were highly satisfied) as they had the best retention in the oral cavity throughout the period of 12 months, followed by Group III (40% were highly satisfied), while least accepted restorative material was Group I (30% were dissatisfied) due to multiple factors such as discoloration, dislodgement, repeated treatment required etc. A statistically significant difference was recorded.

DISCUSSION

The practice of dentistry for children requires extensive knowledge and understanding of restorative materials which can be broadly classified as Intra coronal restorations (placed within a prepared tooth) and Extra coronal restorations/full coverage restorations (placed on the outside of the tooth).[2]

While numerous Intra-coronal restorations have been used since time immemorial due to their ease of placement, better patient acceptance and time saving factors, none of them have ever been as effective as Extra-coronal restorations in terms of their clinical efficacy and longevity. Although SCCs are considered durable and clinically successful, their major disadvantage is in terms of aesthetics. Furthermore, many clinicians find them difficult to fit due to lack of patient cooperation and prolonged chair time. Thus, extensive research has been done to come up with an intracoronal restoration that could be esthetic, have better mechanical and chemical properties than GIC, and be as effective as SSCs in terms of their retention in the oral cavity for a longer period of time. To meet these requirements, a new "Alkasite" bulk fill restorative material, commercially

available as Cention N was recently introduced in the field of Pediatric dentistry.

In the present study, on intragroup comparison of presence or absence of pain and secondary caries none of the samples in the three groups showed presence of pain or development of secondary caries at 1 day, 3, 6 and 9 month intervals, however, at 12 month follow up, one case (10%) each in Group I (GIC) Group III (Alkasite) reported pain along with secondary caries. The reason for presence of pain in Group I could be attributed to the fact that GIC as permanent restorative material is unable to counteract secondary caries formation after a certain time of clinical service.[8,9] However the results were in contrast to several studies which clearly reflected the merits of GICs as restorative materials for both dentitions: GICs show fluoride release and consequently offer some potential to inhibit secondary caries.[10-15] In the present study, while 10% cases did fail on the completion of the study, 90% success was recorded in Group I at 12 months. The reason for failure of just one case could thus be attributed to variable depth of the carious lesion due to a non-standardized case selection. As no particular depth was specified for the inclusion of molars, this particular case could have failed due to presence of a deeper lesion. Microleakage is considered as one of the primary reasons for development of secondary caries.[16] Several studies by Mazumdar et al, Sujith et al etc. reported that the mean microleakage score for Cention N was the lowest score when compared to GIC, amalgam and composite restorative materials.[16,17] Furthermore, Kini et al reported that teeth restored with Cention N after application of adhesive presented the least microleakage, followed by teeth restored with Cention N without adhesive.[18]

However, in the present study, failure in terms of secondary caries was seen in 10% molars (1/10) restored with Group III which similar to Group I, could be attributed to the variable depth of the carious lesion due to non-standardized case selection. This particular case could have failed due to the presence of a deeper lesion. Moreover, the alkasite material was used without an adhesive in the study. Thus, in terms of presence/absence of pain and secondary caries, Group II i.e., SSCs using Hall Technique proved to be the most clinically effective as compared to Group I and Group III. Such a result is in accordance with studies conducted by Innes et al, Fontana et al etc.[19,20] who demonstrated that sealing caries by using the Hall Technique was more effective statistically and clinically, in the long term as compared to GIC, Amalgam and Composite restorations.

On intragroup comparison of dislodgement of the restoration, a statistically significant difference (p=0.018) was seen in Group I (GIC). None of the cases showed dislodgement at 3 and 6 months interval. However, 30% cases showed dislodgement after 9 months and 12 months each. The reason for this could be attributed to low fracture toughness and poor wear resistance of GIC. Furthermore, several studies conducted on primary molars have elated that GIC is not recommended for Class II cavities due to unacceptable high fracture rates; however, Class I cavities may be restored.[21,22] Several reviews have also indicated that the annual failure rate with GIC is estimated to be around 8%.[22,23] Frankenberger et al clearly explained the inferior potential of GIC in Class II cavities being attributable to extensive wear and insufficient flexural strength as well as fatigue behaviour.[24] In the present study, the failure of 30% cases could be accredited to the same fact that it was used in class II cavities. In group II (SSC), None of the cases showed dislodgement throughout the study duration. Thus, signifying that Group I (SSC) restoration was the most efficacious in terms of its longevity in the oral cavity of the patient. Similar results have been shown in studies by Innes et al, Fontana et al etc which concluded that delivering SSCs by hall technique, clinically and significantly outperformed conventional intracoronal restorations in terms of longevity in the oral cavity.[19,20]

In group III (Alkasite), only 10% cases were dislodged after 9 and 12 months each. 90% of the cases (9/10) restored with the alkasite material were retained in the oral cavity over the due course of the study which could be attributed to its superior physical properties. Cention N includes a special patented Isofiller which acts as a shrinkage stress reliever which leads to reduced polymerization stress and allows its bulk placement, increased compressive strength and lesser microleakage.[25] Several authors have reported that the ion releasing property and durability of Cention N makes it an excellent choice as a posterior restorative material.[26] Furthermore, according to Chowdhary and Guha, the compressive strength of amalgam and Cention N are almost similar which accounts as a major criterion for posterior restorations as they bear masticatory forces.[27] However, the reason for the failure/dislodgement of 10% cases restored with alkasite material might be due to the fact that it was used in a deeper proximal lesion without an adhesive in the present study.

On intragroup comparison of pulpal involvement, none of the samples in any group showed pulpal involvement at 1 day, 3, 6 and 9 months' interval. However, 10% cases in group I (GIC) reported pulpal involvement after 12 months' time interval. This might be due to the material irritancy or thermal conduction through the bulk of the restorative material which resulted in pulpal insult. Similar results were also seen in a study conducted by Innes et al which stated that 16.5% of teeth restored with GIC out of a total of 132 showed pulpal involvement after a period of 5 years. However, no sample restored with Glass Ionomer Cement in the present study developed or periapical pathology unlike results shown by Innes et al.[19] None of the samples restored with group II (SSC) showed any pulpal involvement or periapical pathology over the entire course of study because of the fact that SSCs provide a good seal and a durable, reliable restoration.[28] Furthermore ensuring an adequate marginal adaptation of

the SSC reduces microleakage around the tooth-crowns margins.[29]

Only, 10% cases in group III (Alkasite) showed pulpal involvement after 12 months interval, which could be because of microleakage, that might have caused hypersensitivity, secondary caries and pulpal pathosis. According to Punathil et al it was seen that significantly more microleakage was associated Cention N in primary molars unlike contrasting results seen in permanent molars.[30,31] As discussed earlier, lesser microleakage is associated with the alkasite when it is used with an adhesive, the fact that no adhesive was used in the present study could explain the failure of 10% cases in terms of pulpal involvement. However, no sample restored with the alkasite material in the present study developed periapical pathology. In the present study patient acceptance and parental satisfaction was also assessed in all the three groups using Likert 5-point scale because patient acceptability and satisfaction is now considered a key part to the improved health care quality. Likert-type scale has been used in most patient satisfaction studies due to its simple application with adequate reliability and validity.[32] As satisfied patients and parents tend to show better compliance with prescribed treatments, patient/parent satisfaction should be of prime concern.

On intragroup comparison it was revealed that in group I (GIC), 30% patients were very satisfied at baseline and 70% patients were satisfied due to ease of the restorative procedure. In group II (SSC), 30% patients were satisfied, 10% remained neutral, 40% were dissatisfied and 20% patients were highly dissatisfied with the restorative procedure. Lastly, in group III (Alkasite) 70% patients were very satisfied due to the highly esthetic nature of the material and 30% remained satisfied with the restorative procedure. These results signify that Group III (Alkasite) was highly accepted by patients as it was far more esthetically superior to GIC. Group II (SSC by Hall Technique) on the other hand was least accepted amongst patients owing to its increased level invasiveness and esthetically unappealing. Similar results were seen in a study conducted by Zimmerman et al, who reported that Stainless steel crowns were not preferred over esthetic restorations if given a choice.[33] However, when parental satisfaction with each procedure was taken into consideration over 9 months follow up, intragroup comparison proclaimed that in group I (GIC), 40% parents were satisfied, 30% dissatisfied and 30% parents remained neutral. In group II (SSC), 60% parents were very satisfied and 40% were satisfied. Lastly, in group III (Alkasite) 40% parents were very satisfied and 50% parents remained satisfied with the restorative procedure however 10% were dissatisfied due to its failure at 12 months. The results thus suggest that parents were highly satisfied with Group II (SSC by hall technique) as they had the best retention in the oral cavity throughout the period of 12 months while least satisfaction was seen with Group I (GIC) due to multiple factors such as discoloration, dislodgement, repeated treatment required etc. Group III (Alkasite) was also well accepted by the parents overall. While results of the present study show that stainless-steel crowns given by Hall Technique were in fact the best restorative procedure for cavitated primary molars, Alkasite also showed promising results especially in terms of its longevity in the oral cavity and patient acceptance. However, more research on a larger sample size, comparing other newer and better intracoronal restorations are needed to further affirm the results of this study.

Limitations and clinical significance

Within the limitations of the study, it can be recommended to use Stainless Steel crowns for single surface as well as multi surface caries in order to seal the lesion. However, if esthetics is of a prime concern, Alkasite material along with an adhesive may be recommended for better results. However, further studies are suggested to be conducted with a larger sample size and long-term follow-up to validate the clinical efficacy of Alkasite, a relatively new restorative material in Pediatric dental practice.

CONCLUSION

Within the constraints of the present study, the following conclusions were drawn: all the three restorative materials were clinically and radiographically successful in the restoration of primary molars in terms of survival, patient acceptance and parental satisfaction. When clinical success was taken into consideration, Group I and Group III showed a similar efficacy in terms of pain, secondary caries and sinus/swelling while Group II proved to be the most superior restoration of the three, thus showing an overall efficacy as: SSC>Alkasite~GIC. With regard to survival of the restoration, Group II were the most efficacious at the end of the study, closely followed by Group III while maximum dislodgement was seen with Group I. Thus, the efficacy of the three materials in terms of survival was: SSC>Alkasite>GIC. All the three tested materials showed comparable radiographic success in terms of absence of periapical/furcal pathology. However, in terms of pulpal involvement, only 10% failure was seen in Group I and Group III, while Group II exhibited 100% success, thus proving an efficacy of SSC>Alkasite ~GIC. As far as patient acceptance towards the restoration being performed was concerned, the Alkasite restorations were most widely accepted due to their superior esthetics and ease of placement, followed by GIC. SSCs were the least accepted due to invasive nature along with an unesthetic appearance. Thus, in terms of patient acceptance, preference was as follows: Alkasite > GIC>SSC. In terms of parental satisfaction, SSCs were the most widely accepted form of restoration by the parents on the completion of the study, followed by Alkasite restoration, while the least accepted restorative material was GIC. Thus, in terms of parental satisfaction, the preference was as follows: SSC>Alkasite>GIC.

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