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Clinical and Radiographic Outcomes of Two Biological Approaches Versus the Conventional One for Management of Dental Caries in Primary Teeth

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ABSTRACT

Purpose: to evaluate the clinical and radiographic outcomes of two biological approaches (Silver Modified Atraumatic Restorative Technique (SMART) and Hall Technique (HT)) versus the conventional approach for caries management in primary molars. **Materials and Methods:** A total of 90 healthy children ranging from 4 -8 years old of both sexes, were selected for this study after they met inclusion criteria. The patients were randomly assigned to the three groups, thirty patients for each group. The patients were recalled at 1, 3 and 6 months for clinical and radiographic evaluation. **Results:** The results showed no statistically significant difference between groups in clinical and radiographic success at 1and 3 months. In 6 months, there was statistically significant difference between groups in radiographic success but no significant difference clinically. The HT group had higher success rate ((100%) clinically and radiographically) followed by SMART group ((86.7%) clinically and (93.3%) radiographically), then the conventional approach group ((80%) clinically and radiographically). Pairwise comparisons showed that the Hall group had a significantly higher number of successful cases than conventional group ($p< 0.001$). **Conclusions:** Both SMART and HT are effective approaches for managing carious primary molars and can be used as alternatives to conventional approach.

KEYWORDS

Silver Modified Atraumatic Restorative Technique, Hall Technique, Biological Approach.

INTRODUCTION

Dental caries is a significant health problem in children. The 10th most prevalent condition, affecting millions of children worldwide is untreated carious deciduous teeth. Caries prevalence is higher among

- Paper extracted from Doctor Thesis titled "Clinical and Radiographic Outcomes of Two Biological Approaches versus the Conventional One for Management of Dental Caries in Primary Teeth"

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underprivileged populations and those from low-income countries than among those from high-income countries[1] .

If there is no proper treatment, caries can extend through the hard dental tissues to the pulp, leading to pain, inflammation and function loss. In addition, caries can result in chewing difficulty, tooth loss, weight loss, changes in behavior, poor academic performance and cognitive development in young children, so negatively impact the quality of life [2].

Accordingly, determination of an effective, affordable method for treating caries in children with high caries risk and with limited access to dental care is essential [3]. Currently, for carious lesions management in primary teeth, two treatment approaches are suggested; the conventional and the biological. Conventional treatment of caries includes surgical removal of all carious dental tissues, followed by restoration. Since this dental treatment often involves the destruction of considerable amounts of sound tooth structure, it is considered invasive [4].

On the other hand, using a biological approach does not require complete removal of carious tissue to achieve success in caries management. Preservation of more dental tissue, less irreversible damage to the dental pulp and easy toleration of children as there is less use of injections and rotary instruments are benefits to this approach [5].

Silver Modified Atraumatic Restorative Technique (SMART) and Hall Technique (HT) are two biological approaches. The SMART is a combination of silver diamine fluoride (SDF) application and Atraumatic Restorative Technique (ART). It arrests carious lesion using SDF and seals teeth with ART restoration [6-8]. The HT is a minimally invasive procedure in which caries is sealed under preformed metal crown (PMC) avoiding the use of injections and drilling [9, 10]. Therefore, the present study was performed to investigate outcomes of two biological approaches (SMART and HT) versus the conventional approach for caries management in primary molars.

MATERIAL AND METHODS

Study design and ethical approval

This secondary care-based three-arm, parallel-group, patient-randomized controlled trial was conducted in the outpatient clinic of Pedodontics Department, Faculty of Dental Medicine for Girls, Al-Azhar University. Research Ethics Committee approval with code **(REC18-076)** was obtained from Faculty of Dental Medicine for Girls, Al-Azhar University.

Informed Consent

Full details of procedures, possible discomfort and benefits of this study were explained to the parents and informed written consents were signed prior to children enrollment in the study.

Sample calculation

Assuming an alpha (α) level of 0.05 (5%) and a Beta (β) level of 0.20 (20%) i.e. power=80% and an effect size (w) of (0.37); the predicted sample size (n) was a total of (90) samples i.e. (30) for each group. Sample size calculation was performed using G*Power version 3.1.9.2.

Subject Selection

A total of 90 healthy children ranging from 4 -8 years old of both sexes and their parents, were asked to join to the present study after fulfillment of the following inclusion criteria:[11]

- Cooperative healthy children.
- At least one primary molar with cavitated occlusal or occluso-proximal carious lesion which radiographically not involved the pulpal 1/3of the dentin.
- The tooth had no previous infection or swelling.
- The tooth was asymptomatic.

When the child had more than one tooth suitable for inclusion in the study, only one tooth was selected by an independent operator.

Clinical and radiographic examination

Before treatment, detailed medical and dental histories were obtained then clinical and radiographic examinations were done. Patient information was collected and recorded in the patient examination chart. Preoperative radiographic assessment was done by digital periapical radiographs.

Randomization and Blinding Procedures

Following consent, participants were sequentially randomized, using a computer-generated random number list. The randomly generated sequence was enclosed in sealed envelopes to ensure the allocation concealment. The envelopes were randomly picked up by the children for group allocation. Follow up evaluations were carried out by a calibrated examiner who was not participant in the treatment procedures. There was no blinding.

Study Groups

Ninety subjects were randomly allocated to the three groups (Group I, Group II and Group III), thirty patients for each group, one primary molar in each patient was treated.

Protocols for interventions

- **Group I (SMART):** in this group, tongue and cheek were isolated from the affected teeth with cotton roll and gauze. Gross debris and soft caries were removed from cavity with an excavator without local anesthesia, and then the cavity was conditioned (Ketac™ conditioner, 3M ESPE, Germany) for 10 seconds before SDF application (e-SDF, Kids-e-Dental, India) for 2 minutes. Finally, the cavity was restored with GI restoration (GC Fuji™ IX GP FAST, GC Corporation, Tokyo, Japan) then coated with self -cure coat (GC corporation, Tokyo, Japan) (Figure 1)
- **Group II (HT):** in this group, for fitting a Hall crown, orthodontic separators were used especially in tight contacts and then removed after 3 days. Tongue and cheek were isolated from the affected teeth with cotton roll and gauze. Obvious food or debris was removed from the cavity, no caries removed, no preparation and no local anesthesia. Accidental swallowing of a loose Performed Metal Crown (PMC) was prevented by a gauze swab behind the tooth. The suitable size of PMC (3M™ ESPE, St. Paul, USA) was chosen. The GI luting cement (GC Fuji® I CAPSULE, GC Corporation, Tokyo, Japan) was used for crown cementation. After crown placement, the child was instructed to bite firmly to push down the crown over the tooth. Extruded cement was removed and once cement had set, excess cement in proximal contacts was removed by dental floss (Figure 2).
- **Group III (conventional approach):** in this group, isolation was with cotton roll or rubber dam. Molars were anesthetized by local anesthesia (Artinibsa, INIBSA laboratories, S.A, Spain). A high-speed hand piece was used to remove peripheral caries, a low-speed hand piece and an excavator were used to remove the carious dentin from the pulpal wall. The cavity was conditioned, rinsed, dried but not desiccated and then restored with GI restoration (Figure 3).

Follow Up

Recalling of children for clinical and radiographic evaluation was after 1,3and 6 months. The data was recorded in an evaluation chart. The outcomes were determined by the following criteria [12]:

Clinically:

Teeth showing no minor or major failures were considered as successful:

Minor failure:

- Premature exfoliation.
- Clinical indication of new carious lesion at the restoration margins.
- Restoration loss but the tooth remained asymptomatic.
- Occlusal wear of restoration placed.

Major failures:

- Presence of pain.
- Presence of sepsis.
- Presence of pain and sepsis.

Radiographically:

Teeth showing the following criteria were considered as successful:

- Absence of new carious lesion at the restoration margins.
- Absent pulp pathology.
- Absent pathological root resorption either external or internal.
- Absent pathological furcation involvement.

Figure (1) a) Preoperative photo; b) After application of SDF; c) postoperative photo.

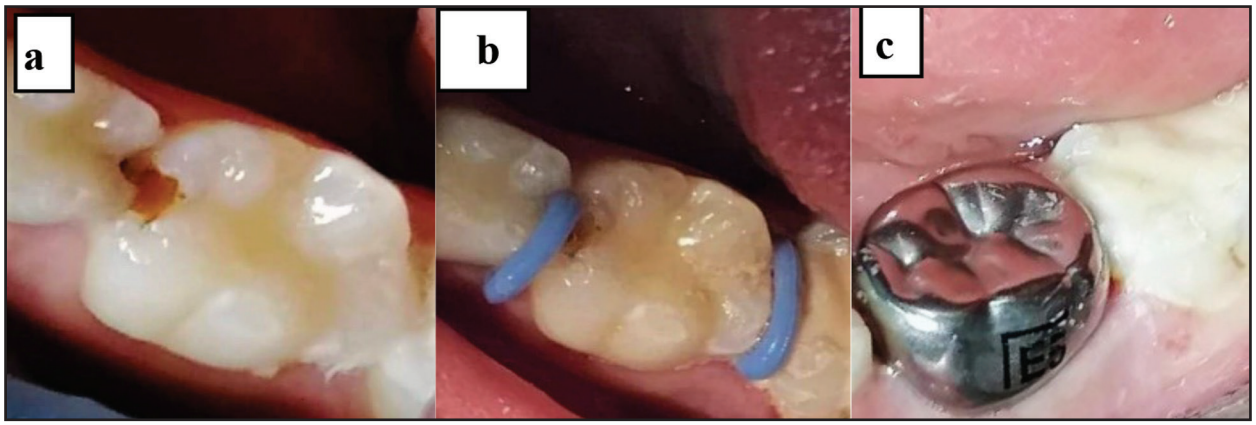

Figure (2) a) Preoperative photo; b) Application of orthodontic separators; c) postoperative photo.

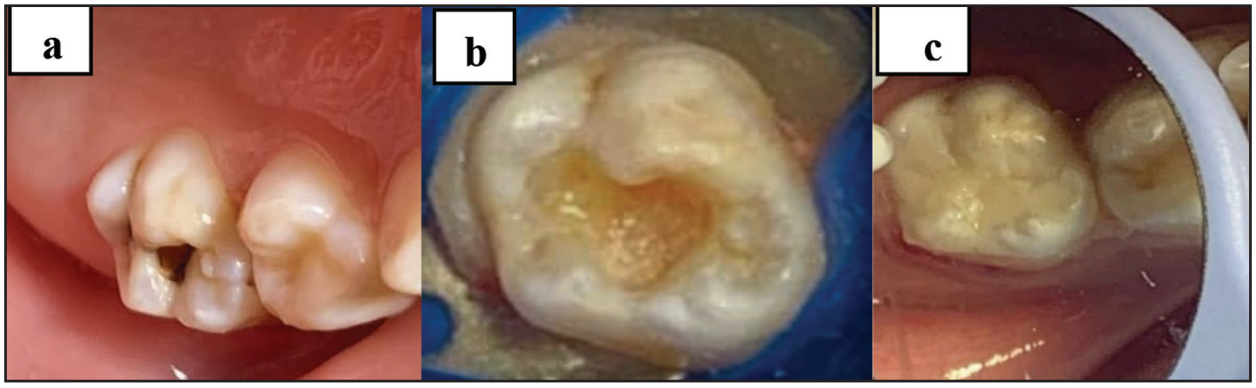

Figure (3) a) Preoperative photo; b) After caries removal; c) postoperative photo.

RESULTS

Statistical analysis:

Statistical analysis was performed using a commercially available software program (SPSS 19; SPSS, Chicago, IL, USA). Qualitative values were presented as number and percentages. Chi square test was used to compare categorical data. Quantitative values (age) were expressed as mean and standard deviation and were compared between groups using ANOVA. Microsoft excel was used for generation of representative figures. The level of significance was set at $P \leq 0.05$.

Clinical results:

- All failures occurred in occluso-proximal treated teeth. Clinical results are summarized in (Table 1) and (Figure 4).
- At 1 month, all cases showed success in all cases (100%) with no significant difference between groups (p=1).
- At 3 months, group I (SMART) and Group III (conventional) showed 2 cases (6.7%) of failure, while all cases (100%) of group II (Hall) showed clinical success Chi square test revealed no statistically significant difference in success frequency between groups(p=0.540).
- At 6 months, group I (SMART) showed 4 cases (13.3%) of failure and Group III (conventional) showed 6 cases (20%) of failure, while all cases (100%) of group II (Hall) showed clinical success. Chi square test revealed no statistically significant difference in success frequency between groups (p=0.059).

Radiographic results:

All failures occurred in occluso-proximal treated teeth. Radiographic results are summarized in (Table 2) and (Figure 5).

- At 1 month, all cases showed success in all cases (100%) with no significant difference between groups (p=1).
- At 3 months, Group III (conventional) showed 2 cases (6.7%) of failure, while all cases (100%) in group I (SMART) and group II (Hall) showed radiographic success. Chi square test revealed no statistically significant difference in success frequency between groups (p=0.326).

Table (1) *Descriptive statistics and comparison of clinical success and failure frequency in different observations time within the same group, (chi square test).*

		1 month		3 months		6 months		P value
		Success	Failure	Success	Failure	Success	Failure	
Group I (SMART)	No.	30	0	28	2 (minor failure: loss of restoration)	26	4 [minor failure: (loss of restoration)]	0.0043*
	%	100	0	93.3%	6.7%	86.7%	13.3%	
Group II (Hall)	No.	30	0	30	0	30	0	1^{ns}
	%	100	0	100	0	100	0	
Group III (conventional)	No.	30	0	28	2[major failure: (pain)]	24	6 [major failure: (pain)]	0.009*
	%	100	0	93.3%	6.7%	80%	20%	

** = Significant (significance level p≤0.05), ns=non-significant.*

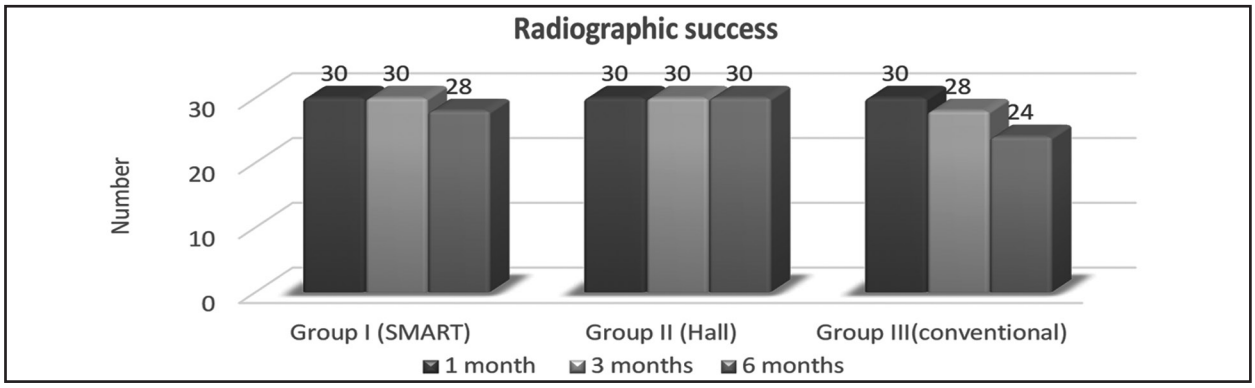

Figure (4) Bar chart illustrating frequency of clinical success in different groups at 1, 3 and 6 months.

Table (2) *Descriptive statistics and comparison of radiographic success and failure frequency in different observations time within the same group, (chi square test).*

		1 month		3 months		6 months		P value
		Success	Failure	Success	Failure	Success	Failure	
Group I (SMART)	No.	30	0	30	0	28	2 (exclusion of 2 cases due to clinical failure at 3 months	0.135^{ns}
	%	100	0	100	0	93.3%	6.7%	
Group II (Hall)	No.	30	0	30	0	30	0	1^{ns}
	%	100	0	100	0	100	0	
Group III (conventional)	No.	30	0	28	2 (pulp pathology)	24	6 (pulp pathology)	0.009*
	%	100	0	93.3%	6.7%	80%	20%	

*Significance level p≤0.05, *significant, ns=non-significant.*

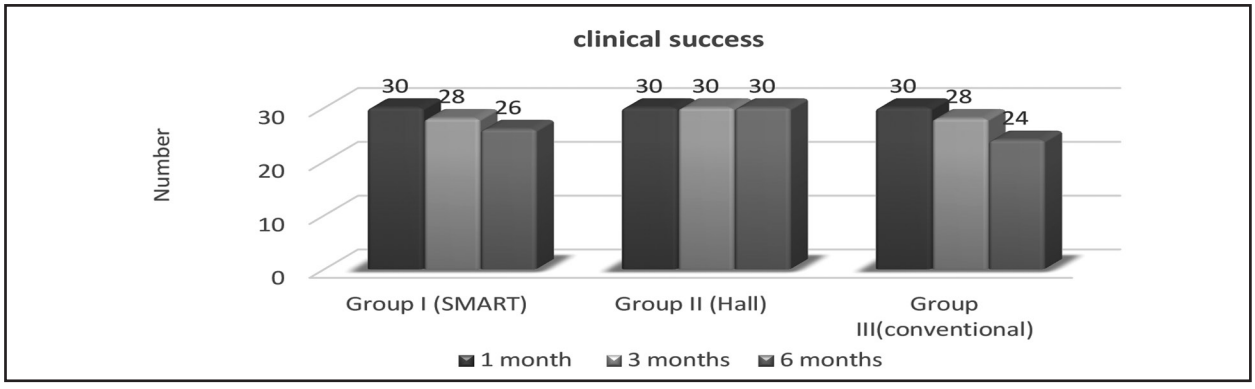

Figure (5) Bar chart illustrating frequency of radiographic success in different groups at 1, 3 and 6 months.

- At 6 months, Group III (conventional) showed 6 cases (20%) of failure and in group I (SMART) 28 cases (93.3%) showed radiographic success due to exclusion of 2 cases due to clinical failure at 3 months, while all cases (100%) in group II (Hall) showed radiographic success. Chi square test revealed a statistically significant difference in success frequency between groups (p=0.025). Pairwise comparisons showed that the Hall group had a significantly higher number of successful cases than conventional group (p< 0.001).

DISCUSSION

Nowadays conservation of healthy human body and function for every patient is an important goal for all workers in the medical field. Dentistry harmonizes with this philosophy. The loss of sound tooth structure must be regarded as a critical injury, so the most comprehensive and conservative care to both primary and permanent teeth should be provided. Both better understanding of the caries process and the evolution of biomimetic dental materials in the last decades, enable the clinician to provide minimally invasive and much more conservative treatment than was previously possible[13].

Consequently, treating carious lesions with the conventional approach, in which all decayed tissue is removed, has been gradually changed by more biological less invasive approaches that aims to arrest caries and preserve pulp vitality through principles of prevention, remineralization and minimal intervention. Recently there are several biological approaches used for management of carious lesions in deciduous molars [14], only two of them (HT and SMART) were the main focus in the present study.

In regard to tooth selection, clinical and radiographic assessments were used. Digital sensor improves the speed and efficiency of dental x-ray imaging process for both the patient and the operator[15].

Relating protocols for interventions, in SMART group the GIC was placed immediately after one SDF application. Placement of GIC after SDF on the same visit is particularly useful when, for any reason, the patient will not be able to coming back for another dental visit and it is believed beneficial to use a minimally invasive treatment better than nothing at all. Some examples include children, humanitarian dentistry in underserved communities, or when there are long waiting times for hospital dental care [16].

Among the available concentrations of SDF (10%, 12%, 30%, 38%), the SDF with concentration 38% was used in this study because it seems to be the most successful and effective concentration and also use of a 38% concentration SDF have been recommended in previous studies for prevention and arrest of dental caries in children[17-22]. The 38% concentration SDF contains 44,800 Ppm fluoride. It is the highest fluoride concentration among the fluoride agents available for use in dental practice[23].

Self-cure GIC restoration was selected in SMART group to avoid the use of light curing as it would strengthen the tooth and restoration blackening due to presence of free silver ions. For the same reason GIC coat was self- cured [16].

In regard to results, in Group I (SMART), all cases (100%) showed clinical success at 1 month. After 3 months, 2 cases (6.7%) showed minor failure (loss of restoration). At 6 months, another 2 cases (6.7%) showed minor failure (loss of restoration), giving a total of 4 cases of failure (13.3%). Concerning to radiographic results, all cases (100%) showed radiographic success at 1, 3 months. After 6 months, only 28 cases were evaluated due to exclusion of 2 cases due to clinical failure at 3 months and no failure occurred.

There were previous studies that showed using SDF before GIC restoration placement, however still now no randomized control trials evaluating SMART's efficiency compared to other restorative approaches [24].

In Group II (HT), all cases (100%) showed clinical and radiographic success at 1, 3 and 6 months. The higher rate of success for the HT may be due to durability of PMC giving complete isolation from the oral environment, slowing or arresting the progression of carious lesion. Likewise, GIC with the HT may have added benefit of carious lesion remineralization [11].

This high success rate in HT agreed with previous study in which, all cases (100%) show no failure after 6 months when examined clinically as well as radiographically[25]. Likewise, another study showed that at the first follow-up appointment, 178 (98.9%) of 180 of HT cases were clinically successful and of 87 crowns with available radiographs, 85 (97.7%) were radiographically successful. At the second follow-up appointment (after a mean of 20.1 months), 74 of 76 (97.4%) were regarded as clinically successful, and 37 of 39 (94.9%) were radiographically successful [26].

In Group III (Conventional approach), all cases (100%) showed clinical success at 1 month. After 3 months 2 cases (6.7%) showed major failure (pain). At 6 months, another 4 cases (13.3%) showed major failure (pain), giving a total of 6 cases of failure (20%). In regard to radiographic results, all cases (100%) showed radiographic success at 1 month. After 3 months 2 cases (6.7%) showed pulp pathology. At 6 months, another 4 cases (13.3%) showed pulp pathology, giving a total of 6 cases of failure (20%).

The HT group showed the higher number of successful cases followed by SMART group then the conventional group. Pairwise comparisons showed that the Hall group had a significantly higher number of successful cases than conventional group ($p< 0.001$). These observations were in agreement with number of previous studies. One of these studies showed that HT demonstrated higher success and significantly outperformed the conventional restorations [27].

Also, in another study after one year of follow up, HT seemed to be the most successful treatment modality in group of Lithuanian children [28]. In contrast, the results in previous study showed similar final outcomes of both biological and conventional treatment approaches and the two approaches were equally effective for carious lesion management in the primary teeth [12].

CONCLUSION

Taking into consideration the limitations of the present study, it was concluded that:

The HT group had higher success rate followed by SMART group then conventional approach group.

·The results of the present study strongly highpoint doubts over the conventional treatment and encourages the use of alternative options for caries management in primary molars.

·Both SMART and HT are effective approaches for management of carious primary molars and can be used as alternatives to conventional approach.

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RECOMMENDATIONS

- Further clinical, radiographic and histological in vivo studies with larger sample size and longer follow up periods are required to evaluate the outcomes of these biological approaches for managing carious primary teeth.
- Additional studies are needed to evaluate the effect of combining SDF with HT (Smart Hall).
- The HT and SMART are suggested as methods for delivering dental care to children from deprived communities instead of ART.

Conflict of Interest

No conflict of interest.

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