Original Article

Clinical and Radiographic Evaluation After the Use of Silver Modified Atraumatic Restorative Treatment Versus Atraumatic Restorative Treatment in the Management of Occlusal Caries of Primary Molars in Preschool Children: A Randomized Clinical Trial

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Abstract

Objective: This parallel randomized clinical trial was conducted to evaluate the effectiveness of silver-modified atraumatic restorative treatment versus atraumatic restorative treatment (ART), comparing their clinical and radiographic outcomes.

Subjects and methods: The study included 50 children 4-6 years of age presenting with occlusal caries (ICDAS 5 and 6) on lower primary second molars. The primary outcome was success or failure based on the code of the ART assessment criteria; radiographic outcome was evaluated based on the pixel grey values on the pre- and post-operative radiographs; pain and parental esthetic perception were recorded, and the OHRQoL (Oral Health Related to Quality of Life) (A-ECOHIS) questionnaire was done pre- and post-operatively.

Results: Regarding the ART clinical assessment criteria and pixel gray values, no statistically significant difference was observed at 12 months' follow-up intervals, showing p-values of 0.637 and 0.545, respectively. The p-value of pain reported was 1 in the 3-months follow-up; the OHRQoL questionnaire showed a p-value of 0.876, and the parental esthetic perception showed a p-value of 0.009. All outcomes showed no statistically significant difference between the two groups except for the parental esthetic perception outcome.

Conclusion: Both groups were comparable in their efficiency and remineralization effects except for the esthetic perception outcome that favored the control group.

Keywords: Silver diamine fluoride; atraumatic restorative treatment; quality of life; pixel grey value.

1. INTRODUCTION

Preserving the health of primary teeth is crucial for a child's overall well-being. Primary dentition plays a vital role in functions such as articulation, aesthetics, speech, maintaining space for permanent teeth, and preventing detrimental habits. To prevent dental caries, it is important to minimize the formation of dental plaque, alter the bacterial composition of plaque, and make dietary adjustments. [1] Managing Early Childhood Caries (ECC) involves interventions such as restorations, providing guidance on diet, educating parents about practices that promote decay, promoting good oral hygiene, and utilizing preventive measures like topical fluorides and other agents. [2]

Treating early childhood caries (ECC) can be costly, often involving conventional restorative procedures and early extraction of teeth. In some cases, general anesthesia or deep sedation may be necessary, as young children may struggle to cope with the demanding nature of these treatment procedures. The development of minimally invasive techniques has been of great interest in the last few years as their use started a new era of tooth conservation, parental and child acceptance, and caries arrest. [3]

Atraumatic restorative treatment (ART) is known as a minimally invasive approach to managing dental caries in children. It involves the removal of carious tissue with hand instruments and the placement of a glass ionomer restoration. This approach does not require local anesthesia, and the procedure can be performed quickly, without the use of drills or other dental equipment. It has been shown to be effective in managing caries in many populations, including children in rural and low-income areas. [4] The ART technique has involved a lot of modifications that enhance the idea of caries arrest and remineralization, one of these techniques involves the incorporation of silver diamine fluoride, known as SMART technique. [5,6]

The introduction of the Silver Modified Atraumatic Restorative Technique (SMART) has significantly expanded recently as a caries prevention tool in dentistry, moving beyond traditional restorative therapies. [7] Silver diamine fluoride associates the remineralization of the dental structures provided by sodium fluoride with the antibacterial effect on the caries microorganisms by the action of silver nitrate. It has been shown in an "ex vivo" study that dentin carious lesions treated with silver diamine fluoride exhibited a remineralized zone rich in calcium and phosphate, similar to arrested carious lesions, with collagen fibrils protected by these minerals, avoiding further degradation. [8]

In the Silver Modified Atraumatic Restorative Technique (SMART), SDF can be applied immediately before the placement of conventional glass ionomer cement. This procedure aims to eliminate cariogenic bacteria by sealing the restoration, while also promoting pulp vitality and facilitating remineralization of the carious lesion. [9] This parallel randomized clinical trial was conducted to evaluate the effectiveness of silver modified atraumatic restorative treatment versus atraumatic restorative treatment comparing their clinical and radiographic outcomes. Based on a null hypothesis, no difference was expected between the two groups.

2. MATERIALS AND METHODS:

This study was carried out in the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University. Patients attending the outpatient clinic of the department presenting second primary molars with occlusal caries were diagnosed and examined for their eligibility. The study included 50 patients having lower second primary molars with occlusal caries. Ethical approval was obtained from the Research Ethics Committee, Faculty of Dentistry, Cairo University. The trial's protocol was registered on clinicaltrials.gov (#NCT04354636) and reported following the CONSORT guidelines.

2.1.Sample size calculation:

A power analysis was designed to have adequate power to apply a 2-sided statistical test of the research question regarding the effect of silver-modified atraumatic restorative treatment when compared to conventional atraumatic restorative treatment in arresting occlusal caries in primary molars. According to the results of ***da Franca et al.***, in which the probability of success in the control group after one year was (50.6%) and based on the expert's opinion which, estimated the success rate in the intervention to be (90%) with an alpha (α) level of 0.05 (5%), a beta (β) level of 0.2 (20%), i.e., power = 80%, and a critical z value of (-1.96), the predicted sample size (n) was a total of 40 cases. [10] Sample size was increased by (25%) to compensate for possible dropouts to be 50 cases. Sample size calculation was performed using G*Power version 3.1.9.4.

2.2.Eligibility criteria:

This study included children (ages 4-6 years) presenting with occlusal caries (ICDAS 5 and 6) on lower primary second molars, [11] patient and parent cooperation and compliance, healthy children, no clinical signs and symptoms indicating pulp involvement, no radiographic abnormalities, and no previous allergic reactions to any of the materials used.

After proper diagnosis, history taking, and preoperative radiographs, patients filled the OHRQoL questionnaire and were randomly allocated to one of two groups (Group I or group II) using www.random.org, and the allocation was concealed using sequential white opaque envelopes done by a trial-independent individual who was not participating in the study. Inspection of the cavity was done using a WHO blunt probe.

In group I, 25 second primary molars with occlusal caries were treated with the application of SDF 38% followed by sealing with high-viscosity glass ionomer restoration. In group II, 25 second primary molars with occlusal caries were treated with atraumatic restorative treatment using high-viscosity glass ionomer restoration. All the study steps were discussed with the child's legal guardian using simple words; verbal assent was considered from the participating child, while written consent was signed from the legal guardian of each participating child who participated in the trial. All consent forms were in the Arabic language.

2.3.Operative procedure:

The tooth was cleaned with a low-speed brush, then isolated with cotton rolls and a saliva ejector. Caries was excavated with a spoon excavator. The tooth was treated according to the group assigned. In group I, protection of the face’s skin and gums with petroleum jelly to avoid staining before the application of the SDF. The SDF was applied with a micro brush and left for 3 minutes, then rinsed with water. The cavity was dried with a small pellet, new cotton rolls were placed, and then the cavity was filled with glass ionomer restoration. The glass ionomer was pushed into the cavity using thumb pressure coated with petroleum jelly, and the excess was removed with a cotton roll and a carver when needed. [12]

In group II; the cavity was cleaned with water and dried with a small cotton pellet and then was filled with glass ionomer restoration. The glass ionomer was pushed into the cavity using thumb pressure coated with petroleum jelly, and the excess was removed with a cotton roll and a carver when needed.

2.4.Outcomes assessment:

The restoration was assessed at the follow-up intervals of 3, 6, and 12 months by the conventional visual/tactile method using a WHO probe. The restorations were categorized following the ART criteria by ***van Gemert-Schriks et al***. Scores 00 and 10 were considered successful; any other score was considered as a failed restoration. [13] A validated Arabic version of the Early Childhood Oral Health Impact Scale (A-ECOHIS) questionnaire was distributed to the patient's caregiver before the treatment, and then a new questionnaire was filled out 3 months after treatment by the same caregiver to assess OHRQoL, The two questionnaires' scores were compared for each patient. [14]

Digital periapical radiographs were taken pre-operatively then 6 and 12 months postoperatively with Acteon X mind xray machine using a digital sensor. The sensor was then inserted in Kavo-scan exam one digital scanner and the radiograph was digitally transferred and revealed on the laptop using cliniview 11.6.1 software. Two areas were selected on the radiographic image at the dentine (below and lateral to the cavity) to assess the pixel grey value pre-operatively and then the same areas were re-assessed at 6- and 12-months intervals in order to be compared. For each area there were 2 different readings, then a range was calculated, and a ratio was concluded out of both readings (Higher value and lower value). At the time intervals the higher the calculation the more was the increase in the radiodensity. [15]

Parental esthetic perception was recorded after 3 months of treatment by directly asking the parent about his esthetic acceptance (yes/no). Pain (pain reported) was recorded at the time intervals of 3, 6, and 12 months after treatment [12]. Blinding was not feasible because of having an extra step in the SMART technique (SDF application) and the discoloration caused by SDF.

Statistical analysis:

Inter-rater reliability for ART criteria was analyzed using Cohen's kappa coefficient, while pixel value was analyzed using the Intra-class correlation coefficient (ICC). Categorical and ordinal data were presented as frequencies and percentages and analyzed using chi-square test intergroup comparisons, Cochran's q-test, and pairwise comparisons utilizing multiple McNemar's tests. Numerical data are presented as a means and standard deviation (SD). They were tested for normality by viewing distribution and using Shapiro-Wilk's test.

Age data were normally distributed and were analyzed using an independent t-test. Pixel data were normally distributed as well and were analyzed using two-way mixed model ANOVA followed by simple effects comparisons. Quality of life scores were non-parametric and were analyzed using Mann-Whitney U and signed rank tests for inter and intragroup comparisons, respectively. P-values were adjusted for multiple comparisons using Bonferroni's correction. The significance level was set at $p<0.05$ for all tests. Statistical analysis was performed with R statistical analysis software version 4.4.2 for Windows. [16]

3. RESULTS:

The study was conducted on 50 children (i.e., 25 children per group). In group (I), there were 15 boys and 10 girls, while in group (II), there were 13 boys and 12 girls. In group (I), the mean age of the cases was (5.44±0.65) years, and in group (II), it was (5.34±0.68) years. There was no significant difference between both groups regarding gender and age ($p>0.05$). Regarding ART criteria and clinical outcome, at the baseline and after 3 months, all cases in both groups were successful. After 6 months, a single case in group (II) failed. After 12 months, two cases in group

(I) and three in group (II) failed. There was no significant difference between both groups within different intervals, and there was no significant difference between different intervals within both groups (p>0.05).

After 3 and 6 months, all cases in both groups were free of pain. After 12 months, a single case in both groups reported pain. There was no significant difference between both groups within different intervals, and there was no significant difference between different intervals within both groups (p>0.05), as demonstrated in **Table (1)**. According to **Table (2)**, six cases in group (I) found the esthetic outcome unacceptable. However, all the cases in group (II) found the treatment acceptable and the difference was statistically significant (p=0.009).

Within all intervals, **Table (3)** pointed out that there was no significant difference in pixel values measured in both groups (p>0.05). Within both groups, there was a significant difference between values measured at different intervals, with values measured after 12 months being significantly higher than values of other intervals (p<0.05). For all questions in the OHRQoL questionnaire, **Tables (4-5)** illustrated that there was no significant difference between both groups regarding scores measured in both intervals (p>0.05). For "Pain" question, there was no significant difference between group (II) scores measured in both intervals (p=0.061). For other questions, there was a significant reduction in measured scores after 3 months (p<0.05).

4. DISCUSSION:

The aim of this study was to evaluate the clinical and radiographic outcomes after the use of silver modified atraumatic restorative treatment versus atraumatic restorative treatment in the management of occlusal caries of primary molars in preschool children. The SMART technique integrates the caries-arresting properties of SDF with the remineralization potential obtained by the fluoride release from glass ionomer restorations. Additionally, evidence from various studies suggests that the application of a glass ionomer restoration over SDF may lessen the aesthetic drawbacks associated with discoloration commonly observed with SDF treatment. [5]

Based on the findings of the present study, cavities treated with the SMART technique exhibited complete discoloration of the glass ionomer restoration during follow-up intervals. This phenomenon may be attributed to the precipitation of silver phosphate (Ag_3PO_4) resulting from the application of SDF. [17] In the present study, the SMART technique was implemented in a single visit. However, recent recommendations suggest performing the procedure over two visits to allow sufficient time for SDF to achieve its maximum caries-arresting effect and to mitigate the issue of restoration discoloration. This approach may address the potential impact of silver ion leaching on the setting process of the glass ionomer restoration. [18]

There were some limitations regarding blinding for the operator, assessor and the patient. These limitations were primarily due to the additional step of applying SDF in the SMART technique, as well as the inherent discoloration effect of SDF. The coded ART criteria employed for clinical assessment in this study served a dual purpose, first, to categorize clinical outcomes and second, to determine the need for repair or alternative treatment. This approach ensured a comprehensive evaluation of the restoration’s performance and guided subsequent clinical decisions. [13,19]

In this study, there was no significant difference in OHRQoL scores, as measured by the A-ECOHIS, between the SMART and ART groups. These findings align with a study ***by Jiang et al.***, which reported positive changes in OHRQoL following both treatment modalities with no significant difference between them. However, a subsequent study by ***Jiang et al.*** affirmed that children's OHRQoL did not significantly change over the study period. This was attributed to a relatively low baseline score, indicating parental acceptance of their children's dental conditions. [18,20]

Conversely, ***Vollu et al.*** reported that ART had a lesser impact on OHRQoL compared to SDF, possibly due to higher parental acceptance of SDF, which involves shorter chair time and simpler application. Despite this, ***Vollu et al.*** recognized no significant difference in parental aesthetic perception between ART and SDF. In contrast, the present study observed a statistically significant difference in parental aesthetic perception favoring ART, as SDF caused complete discoloration of the overlying glass ionomer restoration. [12]

Contrary to the present findings, ***Ahmed et al.*** recorded no statistically significant difference in parental aesthetic perception between SMART and ART groups. These conflicting results highlight the variability in parental perceptions and suggest the need for further studies to clarify the aesthetic implications of both techniques. [21] Radiographic assessment in this study focused on changes in dentine radio-opacity before and after treatment at intervals of 0, 6, and 12 months. These changes were used to evaluate the potential increase or decrease in remineralization following SMART and ART techniques. [22]

One previous study examined radiodensity changes following SMART and ART, including cavities classified as ICDAS 4, 5, or 6. In contrast, the present study included only class I cavities with ICDAS 5 or 6. The prior study concluded that SMART resulted in a greater increase in radiodensity compared to ART, which differs from the findings of this study. These discrepancies may be attributed to differences in case selection and sample size, highlighting the need for additional research on dentine radiodensity changes. [5]

This study found no statistically significant difference in pixel grey values between the two groups. However, a significant increase in radiodensity was observed over time, particularly after 12 months. This result may reflect the remineralization effect of the glass ionomer restoration, facilitated by the release of ions such as fluoride and strontium. [23]

In the SMART group, a transient decrease in pixel grey value was noted at the 6 months' follow-up. This finding highlights the importance of investigating the potential effects of the single-visit SMART technique on glass ionomer bonding and remineralization capabilities. Recent reviews have suggested that pre-etching the dentin before SDF application in the SMART technique could enhance its remineralization effect by increasing the surface area and forming microtags that facilitate SDF incorporation into the dentine. [24]

Pain reported during the study was exclusively associated with secondary caries or new deep carious lesions and was not linked to adverse events related to the materials used in either treatment option. Both treatment options demonstrated comparable positive outcomes in this study. Future research should focus on enhancing the SMART technique by exploring modifications such as the addition of etching, the use of potassium iodide, or the comparison of single versus two-visit SMART approaches. [9]

5. CONCLUSION

Both techniques demonstrated comparable outcomes with no statistically significant differences observed in the ART criteria, pixel grey value measurements, clinically reported pain, or OHRQoL questionnaire results. However, a statistically significant difference was noted in parental aesthetic perception, attributed to the discoloration caused by the application of SDF.

Recommendations:

- SMART technique enhancement to increase remineralization effectiveness as the use of etching before SDF application.
- To decrease the glass ionomer discoloration in the SMART technique: two visits versus single visit SMART technique.

  The use of potassium iodide with the SDF to decrease the discoloration effect.
- Cost effectiveness of SMART versus ART techniques.
- More studies comparing radiographic outcomes.

Abbreviations

OHRQoL	Oral Health Related to Quality of Life
ICDAS	International caries detection and assessment system
ART	Atraumatic restorative treatment
ECC	Early Childhood Caries
A-ECOHIS	Early Childhood Oral Health Impact Scale

SMART	Silver Modified Atraumatic Restorative Technique
SDF	Silver diamine fluoride
ICC	Intra-class correlation coefficient
SD	Standard deviation

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Table 1. Inter, intragroup comparisons and summary statistics for Pain incidence.

Time	Pain incidence	n (%)		p-value
		Group (I)	Group (II)	
3 months	**No**	25 (100.00%)	25 (100.00%)	**NA**
	Yes	0 (0.00%)	0 (0.00%)	
6 months	**No**	25 (100.00%)	25 (100.00%)	**NA**
	Yes	0 (0.00%)	0 (0.00%)	
12 months	**No**	24 (96.00%)	24 (96.00%)	**1**
	Yes	1 (4.00%)	1 (4.00%)	
p-value		**0.368**	**0.368**	

Table 2. Intergroup comparisons and summary statistics for esthetic perception

Esthetic perception	n (%)		p-value
	Group (I)	Group (II)	
Not acceptable	6 (24.00%)	0 (0.00%)	**0.009***
Acceptable	19 (76.00%)	25 (100.00%)	

Table 3. Inter, intragroup comparisons and summary statistics for pixel value score

Time	Pixel value (Mean±SD)		p-value
	Group (I)	Group (II)	
Baseline	1.18±0.09	1.18±0.10	**0.874**
6 months	1.16±0.07	1.19±0.09	**0.215**
12 months	1.21±0.09	1.23±0.11	**0.545**
p-value	**0.004***	**0.022***	

Table 4. Inter, intragroup comparisons and summary statistics for OHRQoL score (child)

Question	Time	Quality of life score		p-value
		Group (I) Mean±SD	Group (II) Mean±SD	
Pain (symptoms)	**Baseline**	2.32±1.18	1.96±1.02	**0.210**
	3 months	1.44±0.71	1.56±0.71	**0.616**
	p-value	**<0.001***	**0.061**	
Difficulty drinking hot or cold beverages (function)	**Baseline**	2.28±1.10	1.80±1.22	**0.161**
	3 months	1.24±0.83	1.24±0.83	**0.901**
	p-value	**<0.001***	**0.009***	
Difficulty in eating (function)	**Baseline**	1.96±1.17	2.00±1.04	**0.832**
	3 months	1.20±0.87	1.16±0.90	**0.798**
	p-value	**<0.001***	**0.002***	
Pronunciation difficulty (function)	**Baseline**	2.12±1.20	1.80±1.19	**0.348**
	3 months	1.00±0.71	1.04±0.73	**0.849**
	p-value	**<0.001***	**0.003***	
Missed school or daycare (function)	**Baseline**	2.08±1.26	1.64±1.15	**0.247**
	3 months	1.24±0.72	1.16±0.90	**0.860**
	p-value	**0.003***	**0.036***	
Trouble sleeping (psychology)	**Baseline**	2.20±1.19	1.64±1.15	**0.093**
	3 months	0.88±0.78	1.04±0.84	**0.542**
	p-value	**<0.001***	**0.005***	
Irritability or frustration (psychology)	**Baseline**	2.24±1.13	1.92±1.04	**0.427**
	3 months	0.96±0.79	1.20±0.91	**0.340**
	p-value	**<0.001***	**0.002***	
Avoid smiling or laughing (self-image and social interaction)	**Baseline**	1.88±1.01	1.80±1.29	**0.904**
	3 months	1.32±0.90	0.92±0.81	**0.127**
	p-value	**0.013***	**0.002***	
Avoid talking (self-image and social interaction)	**Baseline**	1.72±1.02	1.84±1.21	**0.623**
	3 months	1.12±0.88	1.00±0.91	**0.659**

Question	Time	Quality of life score		p-value
		Group (I) Mean±SD	Group (II) Mean±SD	
	p-value	0.004*	<0.001*	
Total (child)	Baseline	18.80±8.59	16.40±8.52	0.409
	3 months	10.40±5.45	10.32±5.45	0.977
	p-value	<0.001*	<0.001*	

Table 5. Inter, intragroup comparisons and summary statistics for OHRQoL score (family)

Question	Time	Quality of life score		p-value
		Group (I) Mean±SD	Group (II) Mean±SD	
Been upset (parental distress)	Baseline	2.16±1.07	2.16±1.28	0.818
	3 months	1.52±0.92	1.20±0.76	0.192
	p-value	0.005*	0.001*	
Felt guilty about child's oral health (parental distress)	Baseline	2.32±1.22	1.88±1.09	0.246
	3 months	1.16±1.03	1.12±0.97	0.951
	p-value	<0.001*	0.001*	
Taken time off work (family function)	Baseline	2.00±1.04	2.16±1.21	0.676
	3 months	1.08±0.81	1.16±0.90	0.675
	p-value	<0.001*	<0.001*	
Financial impact (family function)	Baseline	2.24±0.88	2.20±1.29	0.960
	3 months	1.28±0.68	1.32±0.99	0.925
	p-value	<0.001*	0.002*	
Total (family)	Baseline	8.72±3.63	8.40±4.60	0.946
	3 months	5.04±2.88	4.80±3.15	0.718
	p-value	<0.001*	<0.001*	