Volume (7) 2025 | Issue (4) | Pages 804-818

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Original Article

Parental Satisfaction Of Silver Diamine Fluoride Versus Hall Technique In The Management Of Carious Primary Molars:

A Randomized Clinical Trial

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Submitted: 06-08-2024 **Accepted**: 20-01-2025

Abstract

Aim: This study aims to assess parental satisfaction and treatment time of silver diamine fluoride versus Hall techniques in the management of carious primary molars.

Methodology: sixty carious primary molars with healthy pulp were assigned into two groups, intervention group: 38% silver diamine fluoride application after implementation of oral hygiene measures and removal of only food debris without caries removal. Control group: Hall technique which is the placement of a stainless-steel crown after removal of food debris only without caries removal. Parental satisfaction and treatment time were assessed at the treatment visit. Parental satisfaction was recorded using a 4-point Likert scale. Treatment time was recorded using a digital chronometer.

Results: Regarding parental satisfaction, there was no statistically significant difference between both group scores. However, silver diamine fluoride showed a lower satisfaction score by 0.1 points than Hall technique (P= 0.321). Silver diamine fluoride showed statistically significant less operating time than Hall technique (P= 0.010).

Conclusion: almost all parents were pleased and highly accepted both techniques. Hall technique showed 100 % parental satisfaction due to the feature of complete sealing and protecting the tooth unlike SDF which requires additional restoration to prevent food accumulation. Considering that silver diamine fluoride consumes less chair time in comparison to Hall technique, it's highly recommended in dental campaigns and areas deprived of facilities.

Keywords: parental satisfaction, treatment time, SDF, Hall technique, caries, primary molars

INTRODUCTION

Since the beginning of time, a lot of diseases have appeared and it's been feasible to bring them under control through vaccinations and improving nutrition and lifestyle meanwhile, other diseases seem to be difficult to control especially those of multifactorial background such as dental caries which is regarded as one of the most common diseases of childhood (Syreen et al., 2018).

Dental caries is considered a global burden with a chronic infectious nature where improper diet of frequent intake of fermentable carbohydrates and poor oral hygiene habits drive to a high prevalence among children and a negative influence on their quality of life, especially in developing countries (Abbas et al., 2019).

Leaving decayed teeth untreated is associated with an enduring impact on children's lives as it contributes to pain, pulpitis, dental abscesses, discomfort, poor school participation, sleeping disorders, and impaired daily activities. Parents are likewise affected by their children's sickness which is reflected in stress, perception of guilt, absence from work, and financial loads specifically in deprived communities (Abed et al., 2019).

Concerning asymptomatic carious primary molars with healthy pulp, conventional treatment is based on the removal of carious tissue, preparing a cavity and application of a restoration. This technique proved to be offensive to children due to pain and fear resulting from local anesthesia, rubber dam placement, the noise of water consumption drilling, from rotary instrumentation, time and effort consumed, and patient discomfort that possibly affect the quality of treatment. In addition, a surgical method removes massive tooth structure leaving the tooth with thin enamel and dentin walls approaching the relatively grand pulp chamber (El-Dehna et al., 2021).

Thanks to scientific development and advances in adhesive dentistry that help understand the mechanism of dental caries, minimally invasive dentistry has emerged based on the principle of maintaining tooth structure and enhancing patient comfort. Strategies of MID are grounded on early caries detection, optimal preventive measurements, remineralizing the demineralized tooth structure, and using restorative materials of biological characteristics (DINC and AŞAR, 2022).

With all respect to the previously mentioned surgical treatment, minimally invasive dentistry has proven a greater success in arresting carious lesions and preserving primary teeth for as long as possible until natural exfoliation. In comparison to the conventional approach, MID methods are more acceptable among children due to the no need for carious tissue removal or local anesthesia which favors a more comfortable situation and cooperation from a child. Minimal invasive dentistry includes a wide range of techniques such as non-restorative cavity control (NRCC), atraumatic restorative treatment (ART), Hall technique, and application of 38% silver diamine fluoride (*BaniHani et al.*, 2022).

Hall technique was first pioneered by the Scottish dentist doctor Norna Hall in the late 1980s, who used preformed metal crowns in covering carious primary molars without local anesthesia, caries removal or tooth preparation of any kind. Recently, the Hall technique has become a popular and successful technique in minimally invasive dentistry worldwide (*Poludasu et al.*, 2022).

Silver diamine fluoride was launched in Japan in the 1960s and proved its efficiency in arresting caries. SDF is a colorless solution applied on a carious lesion without the removal of carious tissue or local anesthesia therefore the technique is easy, painless, and child-friendly (Yan et al., 2022).

Egypt is considered a developing country where high rates of early childhood caries are registered, which elicits the need for a quick, easy and economical non-invasive treatment which requires no clinical skills or equipment to overcome the waiting lists of patients in hospitals and eliminate the need for general anesthesia. To the best of our knowledge, there is no RCT in the literature addressing a comparison between 38% and technique in Hall managing asymptomatic dentinal caries in primary molars (BaniHani et al., 2022).

Despite the promising outcomes of the Hall technique and silver diamine fluoride in the treatment of carious primary molars, their acceptability among parents and caregivers requires further research (*Lin et al.*, 2022).

Based on the previously mentioned facts, this RCT is carried out to address this gap in the literature and focus on whether the application of 38% SDF is better than PMCs using the Hall technique and to investigate their parental acceptability besides the time required for treatment.

SUBJECTS AND METHODS

1- Study design and study setting:

The current study assesses the efficacy of 38% SDF versus Hall technique in managing carious primary molars, investigating different outcomes and designed as a randomized clinical trial, 2 parallel arms with 1:1 allocation ratio. The present study was employed at the Department of Pediatric Dentistry and Dental Public Health at the Faculty of Dentistry, Cairo University where patients were enrolled from the out-patient clinic of the department. The utilized dental unit: Knight® by Midmark, Corporation, Patterson Blvd., Ohio, USA. The operator (H.E): a master degree student at the Department of Pediatric

Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University.

2- Ethical consideration and informed consent:

The protocol of this in-vivo study was reviewed and approved by the research ethics committee (REC), Faculty of Dentistry, Cairo University and the approval number was (27-9-22) for scientific content and compliance to applicable rehearse and human subjects' regulations. The study was fully described to parents/caregivers in terms of study methods, benefits of the study and possible adverse effects in a simple understandable method. Parents had complete freedom whether to participate in the study or not. In addition, a form of Arabic informed consent was signed by parents/caregivers.

3- Eligibility criteria:

The inclusion criteria involved: 4–6-yearold healthy children suffering from enamel/dentin caries not involving tooth pulp. The exclusion criteria involved irreversible pulpitis, badly decayed molars, teeth mobility, root resorption, periapical pathosis, tooth necrosis and TMJ disorders.

4- Sample size:

The sample size of this randomized clinical trial was calculated based on a previous study (Ebrahimi et al., 2020) as a reference. In the previous study, the response within each subject group was normally distributed with a standard deviation of 0.634. If the true difference between the intervention and control means is 0.5, minimally 30 study subjects were needed in each group (sample size =60) to be capable of rejecting the null hypothesis that the population means of the intervention and comparator groups are equal with power (probability) 0.8 (80%). Alpha (α) level of significance i.e. type I error probability

related to the test of this null hypothesis is 0.05 (5%). The statistical test used was a sample size of T-test 2-sides by PS programs.

5- Blinding:

Neither the operator, patients, parents nor the outcome assessor were blinded owing to the nature of the trial that used different materials however the statistician was blinded.

6- Randomization and allocation:

Random sequence was generated by using a random sequence generator program which was formulated in 2 columns using the website (HTTP//: www.random.org), where the samples (n= 60) were randomly distributed into 2 groups, in which for each group n= 30. Allocation concealment was performed away from the principle investigator via consecutively sealed opaque numbered envelopes from 1-60 by the assistant supervisor. Four-folded numbered papers were packed in sealed opaque envelopes to be drawn by patients. The written number on the paper will orient the patient either to the intervention or the comparator group based on the randomization table. The CONSORT flow diagram Figure (1) illustrates patient flow during the trial.

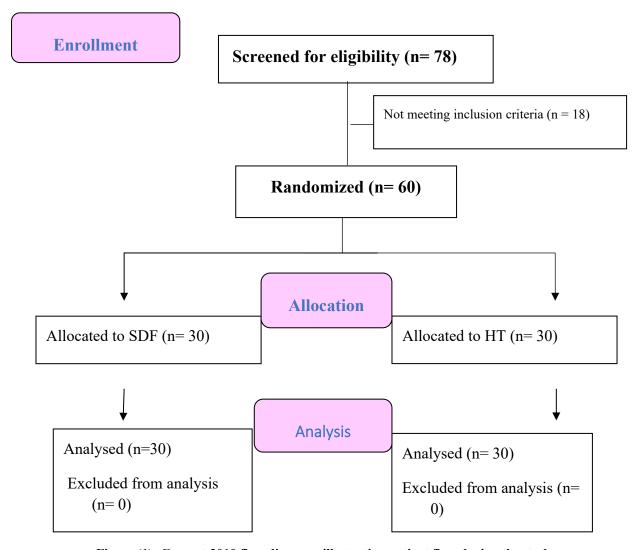


Figure (1): Consort 2010 flow diagram, illustrating patient flow during the study

7- Clinical procedures:

Primarily, phase 1 therapy includes removal of food remnants and plaque from the carious cavity without removal of caries using a spoon excavator followed by giving oral hygiene instructions.

Using an EOS 700D Canon digital camera (Tokyo, Japan), Standardized digital photographs (occlusal, frontal and lateral) were taken for the patient with the aid of cheek retractors and a metal intraoral mirror.

The selected teeth were clinically examined on the dental chair by the principal investigator to ensure fulfilling the inclusion criteria using a mouth mirror and a dental probe.

Standardized digital periapical radiographs were taken using X-mind intra-oral DC X-Ray machine with a size 1 digital x-ray plate to ensure fulfilling the inclusion criteria and ensure high image quality. In both groups, there was neither application of local anesthesia, tooth preparation nor caries removal.

In control group, orthodontic separators were placed in case of tight contacts and left for 3-5 days other than that, a suitable size of SSC crown (3M ESPE, St. Paul, MN, USA) giving the feeling of "spring back" was selected then dried and filled with self-cure Riva Star GIC (SDI Limited, Victoria, Australia) and seated over the tooth with finger pressure till it snugly fits then asking the child to bite over in place for 2 minutes till the cement sets and help secure the SSC. Any excess cement was wiped off and the patency of contact areas was checked by a dental floss. Parents were assured in case of bite elevation since it subsides within 1-2 weeks due to dento-alveolar compensation or physical intrusion.

In intervention group, 38% Riva Star SDF (SDI Limited, Victoria, Australia) was selected as it achieves the best effect in arresting caries

compared to other forms with less concentration such as 12% SDF. On the other hand, 40% silver fluoride (AgF) was avoided as it contains a significantly higher fluoride concentration than the permitted level of 60,000 ppm which carries a high risk of toxicity and inducing fluorosis when treating young children. Cacao butter was applied on the lips of the child to prevent staining and irritation to soft tissues. The tooth to be treated was dried then isolated with cotton rolls. One drop of step 1 Riva Star SDF was applied on the carious cavity and left to dry for at least 1 minute, then application of one drop of step 2 potassium iodide (KI) on the carious cavity and left to dry for 3 minutes. Finally, Careful disposal of cotton rolls, brushes and gloves into a waste bag.

Clinical procedures were documented via taking digital camera photos and digital x-ray radiographs as shown in figure (2) and (3). According to the participant timeline, outcomes were assessed in the same visit after finishing the clinical procedures and no follow-up was required.

8- Outcome assessment:

According to Ebrahimi, 2020, parental satisfaction was measured by asking the parent/caregiver a single question: "What is the degree of your satisfaction with the treatment your child received?" using an ascending 4-point Likert scale (1-2-3-4); 1= very low, 2= low, 3=medium and 4=high, 1 denotes complete rejection of the treatment, 2 denotes inability to fully accept the treatment, 3 indicates accepting the treatment to some degree and 4 means strong approval and high satisfaction with the treatment.

The treatment time of both treatments was evaluated using a digital chronometer in accordance with Ebrahimi et al, (2020) starting from sitting the child on the dental chair till dismissing the patient. A digital chronometer

provides high reliability, ease of manipulation, easy portability and low power consumption.

9- Statistical analysis:

Numerical data were explored normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Age data showed normal (parametric) distribution while operation time and satisfaction scores showed parametric distribution. Numerical data was presented as mean, standard deviation (SD), median, range, Inter-Quartile Range (IQR) and 95% Confidence Interval (95% CI) for the mean values. For parametric data, Student's t-test was used to compare mean age values in the two groups. For non-parametric data, the Mann-Whitney U test was used to compare the two groups. Qualitative data were presented as frequencies and percentages. The Chi-square test and Fisher's exact test were used for comparisons between the two groups regarding qualitative data. The significance level was set at $P \le 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp

RESULTS

This clinical trial was carried out on 60 participants (n=30) per group. Results revealed no statistically significant difference between gender distributions (P=0.114) or mean age values in the two groups (P=0.325) as illustrated in table (1). There was no statistically significant difference between teeth types in the two groups (P=1) and also there was also no statistically significant difference between arch distributions in the two groups (P=0.438) shown in table (2).

The statistical analysis of parental satisfaction scores on a 4-point Likert scale revealed no statistically significant difference

between SDF and Hall technique groups. However, SDF showed a lower satisfaction score of 0.1 points than Hall technique. The mean value of the SDF group after the procedure scored 3.77 (SD \pm 0.43) and the mean value of the Hall technique group scored 3.87 (SD \pm 0.35). Nevertheless, the mean difference between scores of parental satisfaction of both groups was (-0.1 with a 95% CI: -0.3-0.1) with *P*-value=0.321 denoting that the Hall technique was highly accepted by all parents while the SDF technique was highly accepted by the majority of parents with one parent who didn't fully accept the treatment.

The median 4-point Likert scale of both SDF and Hall technique groups after the procedure was (4) with range (3-4). Results manifested that 67% of parents of the SDF group scored (4, rate: high) revealing strong approval of the procedure, 30% of parents scored (3, rate: medium) revealing acceptance and wiliness about the procedure while the rest 3% scored (2, rate: low) denoting inability to fully accept the treatment and presence of some negative perspective. Regarding the Hall technique group, 87% of parents scored (4) and the rest 13 % scored (3) which illustrate that parental satisfaction with Hall technique is higher than SDF treatment illustrated in table (3).

The statistical analysis of treatment time of both SDF and Hall technique groups revealed statistically significant difference. SDF showed less operation time than Hall technique by 2:16 minutes. The mean time of SDF treatment was 8:36 with SD (2:05) and the mean time of Hall technique was 10:52 with SD (3:24) resulting in mean difference of (-2:16) with a 95% CI: (-3:43-0:48) and a (P value of 0.010) indicating that SDF required less chair time than Hall technique, shown in table (4) and figure (8).



Figure (2): a 5-year old child diagnosed with simple decay of lower primary second molars treated with SDF. Figure A preoperative clinical photo, figure B postoperative clinical photo



Figure (3): pre-operative clinical photos of a 6-year old girl diagnosed with simple caries of upper and lower primary secondary molars and treated with Hall technique.



Figure (4): post-operative clinical photos of the Hall technique case

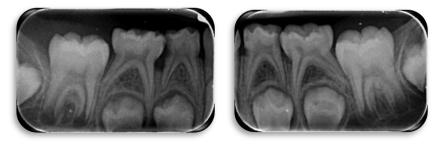


Figure (5): preoperative radiographic photos of the SDF case

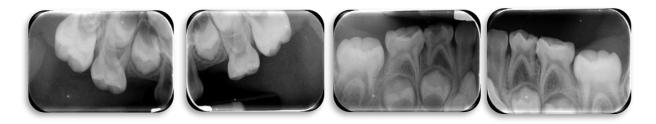


Figure (6): Pre-operative radiographic photos of the Hall technique case

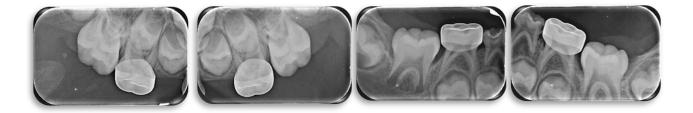


Figure (7): Post-operative radiographic photos of the Hall technique case

Table (1): Descriptive statistics and results of Chi-square test and Student's t-test for comparisons between demographic data of the two groups

Demographic data	SDF (n = 30 patients)	Hall technique (n = 30 patients)	<i>P</i> -value	
Gender [n, (%)]				
Boy	21 (70%)	15 (50%)	0.114	
Girl	9 (30%)	15 (50%)	0.114	
Age [Mean, SD]	4.9 (0.66)	5.07 (0.64)	0.325	

Table (2): Frequencies (n), percentages (%), and results of Chi-square test for comparisons between teeth data of the two groups

Teeth data	SDF ($n = 30$ teeth)		Hall technique (n = 30 teeth)		<i>P</i> -value	
•	n	%	n	%		
Tooth type						
First deciduous molar	12	40	12	40	1	
Second deciduous molar	18	60	18	60	1	
Arch						
Lower	17	56.7	14	46.7	0.429	
Upper	13	43.3	16	53.3	0.438	

Table (3): Descriptive statistics and results of Mann-Whitney U test for comparison between parental satisfaction scores in the two groups

SDF (n = 30 teeth)		Hall technique (n = 30 teeth)		<i>P</i> -value	Mean	95% CI for the	Effect
Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	r -varue	difference	mean difference	size (d)
4 (3-4)	3.77 (0.43)	4 (3-4)	3.87 (0.35)	0.321	-0.1	-0.3-0.1	0.172

Table (4): Descriptive statistics and results of Mann-Whitney U test for comparison between operation times (minutes) in the two groups

SDF ($n = 30$ teeth)		Hall technique (n = 30 teeth)		P-	Mean	95% CI for the	Effect
Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	value	difference	mean difference	size (d)
8:36 (5:24- 13.54)	8:36 (2:05)	10:18 (5:16- 16:54)	10:52 (3:24)	0.010*	-2:16	-3:43 0:48	0.702

*: Significant at $P \le 0.05$

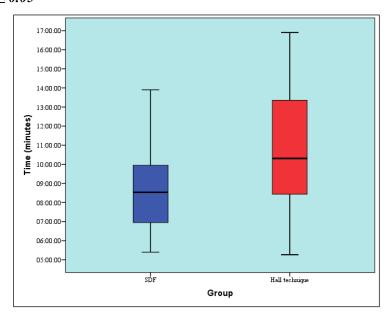


Figure (8): Box plot representing median and range values for operation times in the two groups

DISCUSSION

Early childhood caries has recently increased in developing countries as a result of

growing consumption of sugar, inadequate oral hygiene practices and difficulties in the

affordability to dental services. In the Middle East and North Africa region, ECC is noticed to be rapidly increasing among children and left untreated (*Elamin et al., 2021*). In Egypt, it's been reported that early childhood caries ranks 74% among pre-school children which is regarded as high prevalence (*Abd Al Gawad et al., 2022*).

The implementation of simple and conservative methods in the management of carious primary molars is advocated. Thus, adopting the MID approach has been gaining popularity in the pediatric dental field such as Hall technique and SDF (Sanders et al., 2021).

Hall technique is a biological, simple and durable method based on covering the carious tooth with a stainless-steel crown and sealing the decayed lesion off the oral environment, without any tooth preparation or local anesthesia (Almonaqel et al., 2021). Hall technique has been selected in the current research as a control because studies have proven its success in treating caries in primary molars besides being cheap and affordable which is convenient for developing countries (Ayedun et al., 2021).

Silver diamine fluoride (SDF) is a non-invasive solution used to arrest decayed lesions and reduce hypersensitivity of carious cavities. It's been selected in the current study as an intervention for being effective in arresting dentin caries of primary teeth, painless and affordable in the Egyptian dental market (*Osama et al.*, 2023).

Recently, minimally invasive dentistry started to replace conventional dental treatment for its ability to achieve successful results in managing carious primary teeth with a combination of ease of application and short time reaching a high level of child cooperation, minimal anxiety and satisfaction among parents, children and clinicians. In the literature, there is no available randomized clinical trial comparing the application of 38% SDF to Hall technique regarding parental satisfaction and treatment time

(BaniHani et al., 2022 and Lin et al., 2022). Hence, the current trial is performed to fill this gap of knowledge.

The overall parental satisfaction was almost similar in both treatment groups and the trial didn't register a significant difference between them (*P*-value =0.321). Almost all parents were highly satisfied with both intervention and control treatments (from 97% to 100%) respectively, in terms of ease of application and quality of treatment. Parents were impressed with delivering the treatment to their children without the hassle of anesthetizing or drilling the tooth within minimal treatment time in comparison to conventional treatments which favored a calm and cooperative child behavior.

Regarding Hall technique, 100% of parents were pleased with the approach despite causing their children some discomfort and no complaints about its metallic color were reported which is in line with (Seifo et al., 2021). Also, the majority of children were happy about their new silver tooth which played a role in enhancing parental satisfaction. Our findings are parallel to those of other trials performed around the world. For instance, it's been evaluated by Santamaria et al in their study that most parents (>74%) were very satisfied with treating their children's teeth with the Hall technique and more than 98% were pleased to repeat the treatment experience (Santamaria et al., 2014). Equally, when Page et al carried out group discussions and individual interviews in New Zealand with parents and their children to evaluate their perception of Hall technique, it came out with analogous results where most parents were pleased with PMCs placed by Hall technique and commented on its durability and longevity in comparison to standard restorations that fail and expose them to multiple dental visits for retreatment (Page et al., *2014*).

Similarly, the results of Hesse et al showed that both parents and children favored HT and

ART and preferred them over traditional restorations (Hesse et al., 2016). This also agrees with a retrospective cohort study conducted in Saudi Arabia evaluating the efficacy and parental satisfaction with Hall technique declared that the majority of parents were satisfied with Hall technique being non-invasive where 96% of participants were pleased with Hall technique and 92% had the desire to treat other carious teeth with the same technique. Additionally, 96% of children did not complain about their bite after the treatment which is comparable with the present study outcomes (Almaghrabi et al., 2022).

On the contrary, a previous RCT comparing ART restorations to Hall technique conducted by Araujo et al where more than 70% of parents' responses were "strongly agree" and "agree" while 23.4% of parents disagreed with the aesthetic appearance of PMCs (Araujo et al., 2020). A systematic review and meta-analysis performed in 2022 registered that both HT and ART are well accepted by parents however parental acceptance of the Hall technique (85.7%) is lower than that of ART (95.7%) revealing that esthetic appearance formalizes an interest among parents (Lin et al., 2022). Another recent research supports the previous literature where an RCT conducted in Turkey by Oz et al comparing ART restorations to Hall technique, illustrated that parents viewed PMCs favorably however 5% of them objected to the esthetic appearance (Oz et al., 2023).

Regarding treatment time, SDF treatment showed a statistically significant less operating time than Hall technique by 2:16 minutes (*P*-value = 0.010). Chair time is a crucial factor to be taken into consideration when setting a treatment plan for a pediatric patient as children, especially preschool ones, cannot tolerate lengthy procedures that trigger irritability and discomfort. We recorded an evident shorter treatment time of SDF than Hall technique which was positively reflected in children behavior. As for Hall technique, it took more working time than SDF as

it required multiple clinical steps such as selecting the suitable crown size, try-in, cementation and biting and in case there were tight contacts, orthodontic separators were placed for 3-5 days and treatment was executed on two visits. The average time taken for the intervention group was (5:24-13.54) minutes while it was (5:16-16:54) minutes for the control group.

Our outcome agrees with a previous RCT carried out in Brazil where the researchers compared SDF to ART restorations and registered less SDF operating time with a mean time of 6.97 minutes while ART registered a mean time of 13.88 minutes (p < 0.001) (Vollú et al., 2019). The latter is also in line with a recent RCT by Abdellatif et al. (2021) where SDF was compared to ART and working time rated a significant difference between both groups, SDF recorded less operating time of median = 3.3 minutes in comparison to 14.4 minutes for ART (P < 0.0001).

It's been stated in a systematic review and meta-analysis that SDF treatment provides less treatment time and cost in comparison to ART restorations, which makes SDF an effective alternative minimally invasive approach for preschool children and in public health programs (Wakhloo et al., 2021). Similarly, when Cleary et al compared SDF to restorative treatments, SDF was easier and recorded significant less working time than RT (P < 0.001), with mean SDF time =5 minutes vs. 30 minutes for RT (Cleary et al., 2022). The most recent systematic review by Hafiz et al. (2022) evaluating the efficacy of SDF treatment in arresting caries illustrated the scarcity of trials in literature recording SDF chair time in comparison to other restorations, hence the current study aimed to assess SDF operating time to support the previous studies.

As for Hall technique, when Innes et al carried out an RCT comparing HT to conventional restorations, the recorded treatment time for both groups was almost similar; the mean

time for the control group was 11.3 minutes while its counterpart for the intervention group was 12.2 minutes (Innes et al., 2007). On the contrary, Elamin et al. conducted their trial where conventional PMCs were compared to HT, results revealed statistically significant less operating time of HT than PMCs placed by the conventional method (p<0.001), mean time of conventional crowns was 33.9 minutes while that of HT was 9.1 minutes (Elamin et al., 2019). The same outcome was attained in the RCT performed by Ebrahimi et al. where they compared HT to mART and traditional SSCs with mean working time of 8.4 ± 4.9 , 11.1 ± 5.2 , and 17.3 ± 5.1 minutes, respectively, and showing the least operating time for HT (Ebrahimi et al., 2020). A recent RCT comparing HT to conventional SSCs confirmed the previous result as well where HT showed less chair time compared to traditional PMCs (P value = 0.01) which makes HT an effective alternative technique for managing carious primary molars especially disadvantaged communities (Ayedun et al., 2021).

CONCLUSION

Within the results of the current research, the following can be concluded:

- The majority of parents were highly satisfied with both the Hall technique and SDF treatments.
- 2. 38% SDF showed significantly less operating time than the Hall technique which is useful in campaigns and overcoming waiting lists in hospitals.

STUDY LIMITATIONS

- 1. This research was carried out on a sample size from the outpatient clinic of Cairo University; thus, it should be taken into consideration whether the results can be generalized to the general population.
- 2. Neither the operator nor patients were blinded owing to the nature of the trial.

3. Assessing parental satisfaction through a single question other than multi-item questionnaires couldn't cover various aspects of satisfaction.

Consent for publication: Not applicable.

Availability of data and materials: The datasets used or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflict of interest: No conflict of interest.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics: This study protocol was approved by the ethical committee of the faculty of dentistry-Cairo university on: 27-9-22, approval number: 27922

Acknowledgments: Not applicable

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