Clinical and radiographic evaluation of nano silver fluoride versus calcium hydroxide in indirect pulp treatment of deep carious second primary molars: Randomized Clinical Trial

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Abstract

Aim: The aim of this study was to evaluate the clinical and radiographic success of nano silver fluoride versus calcium hydroxide in indirect pulp treatment of deep caries in second primary molars.

Materials and methods: This Randomized Clinical Trial included 40 vital primary second molars with deep caries in 37 healthy and cooperative children aged from 4-7 years. The teeth were randomly divided into two groups. Group I: the pulp was indirectly capped with Nanosilver fluoride and group II: the pulp was indirectly capped with Dycal. The treatment was performed in a single visit and teeth were restored with amalgam restoration as a core. After one year follow up, teeth were finally restored with stainless steel crowns. Clinical success was evaluated regularly at 1, 3, 6, 9 and 12 months while radiographic success was evaluated regularly at 6 and 12 months.

Results: On statistical analysis of clinical and radiographic outcomes between both groups, indirect pulp treatment using Nanosilver fluoride showed 85% success rate at 12 month follow up whereas indirect pulp treatment using Dycal showed 90% success. However, there was no statistically significant difference found between the two groups.

Conclusion: Clinical and radiographic outcomes of Nano Silver Fluoride showed similar results to Dycal and it can be used as an effective alternative to Dycal for Indirect pulp treatment of primary teeth.

Keywords: Nano silver fluoride; calcium hydroxide; IPT; primary; pulp capping; vital pulp therapy.

Introduction

Dental caries is the name of a disease where an ecologic shift within the dental biofilm environment, driven by frequent access to fermentable dietary carbohydrates, leads to a move from a balanced population of microorganisms of low cariogenicity to a microbiological population of high cariogenicity (more aciduric and acidogenic) and to an increased production of organic acids. This promotes dental hard tissue net mineral loss and results in a carious lesion.[1]

Dental caries is considered one of the major problems of oral and dental health. The main cause of tooth pain and loss is dental caries. The World Health Organization (WHO) reported that school children experience to dental caries was 60–90% of worldwide.[2]

Deep caries is defined as radiographic evidence of caries reaching the inner third or inner quarter of dentine with a risk of pulp exposure. These deep carious lesions approaching a healthy pulp are considered a challenge to the dental practitioner. The conventional treatment of deep carious lesions requires the removal of all infected and affected dentin to avoid more cariogenic activity however, this procedure increases the risk of pulp exposure.[3]

Advances in the field of cariology regarding the biofilm with improvement in materials have challenged this perspective. In the recent decades, there has been an evolution toward a more minimally invasive approach.

Indirect pulp treatment (IPT) is one of the treatments that are recommended for teeth with deep carious lesions with a healthy vital pulp. The main aim of this minimal intervention technique is based on alteration of the microenvironment of the carious dentin by arresting the cariogenic process and at the same time preserving the tooth structure and pulp vitality. Many restorative materials have been used for indirect pulp treatment in primary molars such as calcium hydroxide, dentin bonding agents, glass ionomer cement and zinc oxide eugenol.[4]

Calcium hydroxide $Ca(OH)_2$ was introduced by Hermann in 1920. It has a bactericidal action. Antimicrobial activities of calcium hydroxide are characterized by damaging the bacterial cytoplasmic membrane, damaging DNA and protein denaturation which promote the health of the pulp.[5]

Although calcium hydroxide is the material of choice for all conservative pulp treatment, multiple tunnel defects and cell inclusions in the calcified bridges are presented after

capping which may lead to leakage and bacteria penetration into pulp tissue.[6]

Thus, there is a great evolution of science taking the humanity to new era called nanotechnology. One of these nano particles is nano silver fluoride (NSF). Nano silver fluoride (NSF) is a new material consisting of nano silver particles, chitosan and sodium fluoride.[7]

Materials and Methods:

Trial registration, study design and settings:

All procedures in the current trial were carried out in accordance with the ethical standards of the Research Ethics Committee of the Faculty of Dentistry, Cairo University (Ref. 24/9/19). Verbal consent was obtained orally from the eligible child, and written consent was signed by the child's guardian, agreeing to the clinical procedures. A protocol of the present clinical study has been registered on ClinicalTrials.gov (NCT04005872). The current investigation is a randomized clinical trial using a parallel study design, a 1:1 allocation ratio, and a superiority framework. The current study was carried out in the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry at Cairo University.

Sample size calculation:

Sample size calculation was done by an expert statistician using G* power 3.1.7 software based on the previous research entitled "Indirect pulp treatment: in vivo outcomes of an adhesive resin system vs calcium hydroxide for protection of the dentin-pulp complex". [8] This power analysis used success in controlling caries as the primary outcome. The effect size (z) = 1.96 was calculated based upon the results of Falster et al., 2002 who reported the success of Calcium Hydroxide = 96% after 12 months. The success of intervention group was estimated to be 60% by expert opinion. Using alpha (α) level of (5%) and Beta (β) level of (20%) i.e. power = 80%; the minimum estimated sample size was 40 molars. To compensate for a drop-out rate of 25%, the number was increased to a total of 50 molars (25 molars per group). Sample size calculation was performed using G*Power Version 3.1.9.2. The sample size was reviewed and approved by the Medical Biostatistics Unit (MBU), Faculty of Dentistry, Cairo University.

Eligibility criteria:[8]

Inclusion criteria:

Patients:

1. Cooperative children.
2. Both genders.
3. In age range from 4 to 7 years.

Teeth:

1. Vital second primary molars with deep caries limited to occlusal surface.
2. No clinical signs or symptoms of irreversible pulpitis or pulp necrosis.
3. No radiographic abnormalities
4. Restorable teeth.

Exclusion criteria:

1. Children with systemic conditions.
2. Parents who refused to participate.

Recruitment:

Patients were recruited from Outpatient`s Clinic of Pediatric Dentistry and Dental Public Health Department at Faculty of Dentistry, Cairo University, where there was continuous and high patient flow to screen all children during diagnosis for their chief complain. Children with deep caries in lower second primary molars were enrolled in the current study if they met eligibility criteria and their legal guardian provided informed consent to participate. Screening of the attending children continued till the planned sample size was achieved. Consort flow diagram showing participants' flow through each stage of the current randomized clinical trial.

Allocation of participants:

Forty second primary molars with deep caries were selected and randomly divided into two equal groups with 20 teeth in each group as follows:

Group A: Teeth were treated with nano silver fluoride (NSF).

Group B: Teeth were treated with calcium hydroxide (Dycal).

Eligible consented participants were randomly assigned to either the intervention or comparator group according to a sequence generated on a Microsoft Excel sheet where the intervention (A) and the control (B) were simply randomized (https://www.random.org). The table of sequence generation was kept with the co-supervisor and concealed from the main researcher. Once the study consent was signed, a phone call was made to the Co-supervisor; Dr. Ayman Abdel Hamid Sabbah, to assign which tooth will be included to either intervention or control groups according to the generated random sequence.

Interventions:

Local anaesthesia administration

and rubber dam isolation:

Each tooth was anesthetized using infiltration technique, by applying topical anesthetic gel (I-gel, Dent dental supply, USA) (20% benzocaine) at site of needle insertion for 2-3 minutes, followed by injection of local anesthesia by the use of 4% articaine. [9] Isolation was done using rubber dam after suitable selection of rubber dam clamps (KSK dentech, Tokoyo, Japan), sheets (Sanctuary Dental Dam, Perak, Malaysia) and frame (SedraDent solutions, Cairo, Egypt).

Cavity preparation procedures:

Cavity preparation was done using a sharp hand excavator leaving last soft carious layer to avoid pulp exposure. Then, the cavity was washed with distilled water and dried with gentle air flow by airway syringe of the dental unite and sterile small cotton pellet.[9] After cavity preparation, allocation of the case was concealed by withdrawing and opening a sealed white envelope containing a folded paper containing the name of the pulp capping material that would be used.

Indirect pulp capping:

Nano silver fluoride (Test group):

Preparation of Nano silver fluoride (NSF):

• Nano silver fluoride was prepared in Nano-Gate Company, Nasr City, Egypt.

• To prepare the colloidal silver, 1.0 g of chitosan was dissolved in 200 mL of 2 percent acetic acid. The solution was stirred overnight before being vacuum- filtered. Then, 30 minutes before adding sodium borohydride, an aliquot of 60 mL of chitosan solution was placed in an ice bath while being stirred, and 4.0 mL was added to a silver nitrate solution 0.012 mol L1. The mass ratio of silver nitrate (AgNO3) to sodium borohydride (NaBH4) was maintained at 1:6 and the solution was added dropwise. The reduction of silver ion (Ag+) was initiated immediately, as the solution changed from colourless to light yellow and ended up more darker. The silver nanoparticles were spherical and had an average size of 3.2 ± 1.2 nm. At the end of the experiment, sodium fluoride (NaF) was added to enhance the solution's stability. The concentrations of each component, as expressed in micrograms per millilitre, were as follows: Chitosan [28,585 mg/mL]; Ag+ [376.5 mg/mL] and sodium fluoride [5028.3 mg/mL].[10]

Clinical steps:

According to manufacture instruction; Nano silver fluoride13 was carried out from the

bottle by using pipette then each tooth received two drops of NSF with a micro brush and it was left in contact with the tooth surface for 2 minutes.[10]

Dycal group (Control group):

Dycal was applied after mixing equal volumes of base and catalyst pastes until a homogenous mix was achieved. Approximately 0.5 mm thickness of this mix was applied by small ball burnisher to cover the remaining innermost layer of the carious dentine and left to dry. After that, any set excess was removed with a sharp spoon excavator to provide proper sealing.[11]

After placement of test/control pulp capping material for each group, Intermediate Restorative Material (IRM) was placed at the floor of the cavityover the capping material as a cavity base. Then, it was restored with amalgam restoration as a core material. After that, the rubber dam was then removed, occlusion was tested and adjusted using articulating paper. Postoperative intraoral photograph and standardized postoperative digital radiograph were taken as a baseline record and the children of both groups were instructed to follow the oral hygiene practices.

Outcome assessment:

Clinical assessment was done at baseline, 1, 3, 6, 9 and 12 months intervals while radiographic assessment was done at baseline, 6 and 12 months by three blinded assessors, in case the assessors differ in score, they discussed till reaching for a consensus. Outcomes were described in Table 1.

Final restoration placement:

After one year follow up, tooth preparation was done to be finally restored with stainless steel crown in both groups.

Statistical analysis:

Qualitative data were presented as frequencies and percentages. Chi-square test or Fisher's Exact test were used for comparisons between the two groups. Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Age data showed normal (parametric) distribution, so Student's t-test was used to compare between the two groups. Age data were presented as mean and standard deviation (SD) values. Kaplan-Meier survival curve was constructed to calculate the estimated mean survival estimates of the two groups. Comparison between survival times was performed using Log rank test. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM

SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Results:

Demographic data:

The current study included 40 vital second primary molars with deep caries in 38 healthy cooperative children (23 boys and 15 girls). The patients were allocated randomly from the outpatient clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, their ages ranged between 4 to 7 years. The selected molars were divided into two groups (20 molars in each group); Group 1(tested group) was treated using Nano silver fluoride and Group 2 (control group) was treated using Dycal. After 12 months, 38 participants completed the follow-up with 100% retention rate. Mean age within intervention group was 5±0.7 years, while within the control group mean age was 5.3±1.1 years, there was no statistically significant difference between both groups regarding age (P=0.433). Regarding gender, there were 23 boys and 15 girls in the current study, in the nano silver group (NSF) group there was 9 boys and 10 girls, while in the calcium hydroxide (Dycal) group there were 14 boys and 5 girls, there was no statistically significant difference between both groups regarding gender (P=0.097).

Clinical evaluation:

The overall clinical success rate of nano silver fluoride (NSF) was 85% with three patients suffering from clinical failure due to spontaneous pain while the overall clinical success rate of calcium hydroxide (Dycal) was 95% with one patient suffering from clinical failure due to spontaneous pain (P-value 0.605) (table 2).

Radiographic evaluation:

The overall radiographic success rate of nano silver fluoride (NSF) was 100% after 12 months, while the overall radiographic success rate for calcium hydroxide (Dycal) was 95% with one patient suffering from radiographic failure due to internal root resorption after 6 and 12 months (P-value 2.053) (table 2).

Frequency and percentage for clinical and radiographic evaluation scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods (table 3).

Discussion

Dental caries is considered one of the major problems of oral and dental health. It is a disease where an ecologic shift within the

dental biofilm environment driven by frequent access to fermentable dietary carbohydrates that produce acids which promote demineralization of dental hard tissue resulting in a carious lesion. This chronic disease especially deep carious lesions approaching a healthy pulp can compromise the life quality of the affected children.[1]

The treatment of deep caries lesions is mandatory as it carries a number of hazards for the pulp, including pulpal exposure and postoperative pulpal complications, particularly in deciduous teeth, which could compromise the tooth's retention. Therefore, pediatric dentists should concentrate on their treatment.[12] Vital pulp therapy is one of the best treatment options for deep dentinal caries in primary teeth depending on a precise diagnosis of the preoperative pulp status which can be determined through clinical and radiographic evaluations. Indirect pulp treatment (IPT) leaves some caries in place to avoid pulp exposure and covers it with biocompatible material such as calcium hydroxide, glass ionomer cement, mineral trioxide aggregate and others that have the ability to stimulate the pulp-dentin complex and produce reparative dentin.[13]

This study was conducted to evaluate the effectivness of two different materials in indirect pulp treatment of deep caries in second primary molars. It aimed to assess and compare clinical and radiographic success of nano silver fluoride and calcium hydroxide in terms of post- operative pain, clinical symptoms (pain on percussion, swelling, sinus or fistula and mobility) and radiographic success between them.

The rationale for carrying out this study was based on the fact that sealing carious dentin by NSF helps in stopping or inactivating the progression of dental caries. In pediatric dentistry, this NSF is gaining more popularity due to its anti-carious effect besides being simple and inexpensive.[14]

The null hypothesis of this trial suggests that the nano silver fluoride is as effective as calcium hydroxide regarding both clinical and radiographic success.

The study design was decided to be a randomized controlled trial (RCT), as it is the design of choice in paediatric clinical investigations to compare between experimental and another already known, one employed as a reference to the intervention.[15]

This study was triple blinded, as the patients, assessors and the statistician were blinded to the type of pulp-capping material used.

However, it was impossible to blind the operator as the nature of the materials used for IPT was easily identified as they were totally different from each other. To prevent biases, the operator was blinded up until the randomization of the groups, this was in agreement with pervious study.[16]

The calculated sample size was the number of teeth required to statistically detect the treatment effect. The sample size was 40 molars which based upon the results of previous study as a representative sample for the target population.[8]

This study was carried out on 40 second primary molars with deep carious lesions for 38 children attending the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University during the period from October 2019 to November 2022 which was the end of follow up period.

Moreover, the age of all participants ranged between four to seven years as most of them are to a great extent co-operative during dental work as well as the physiological root resorption would not have started or maybe minimal.[17]

Additionally, healthy patients were selected to be free from any physical or mental condition that could affect the treatment procedure as well as they were free from any systemic diseases that might affect the dental pulp reaction toward the capping materials.[18]

In the current study, the mandibular molars were selected rather than the maxillary molars as they have less superimposition of the succedaneous teeth on the radiographs which make it easier to be visualized.[19] Only the mandibular second primary molars were selected. The success rate of second primary molars was higher than that of the first primary molars.[20] On the contrary, the failure rate of second primary molars was higher than that of first primary molars. This difference in failures might be attributed to the restoration size with a high C-factor,tooth position in the arch and various events acting over the restorations after long-term function in the oral.[21]

Digital radiography was done immediately before and after treatment as a base line radiograph and during follow up periods to evaluate the radiographic outcomes. They were used instead of conventional radiography as they exposed the child patient to less radiation and provide more accurate diagnosis.[22]

It was necessary to use rubber dam in order to protect soft and hard tissues and to avoid or reduce bacterial contamination of the treatment site.[23]

One step excavation approach of IPT was chosen.[24] This approach has several advantages over stepwise excavation such as it doesn't need to reenter the tooth which decrease risk of pulp exposure, arrest caries progression and reduce the time spent in clinic by both the dentist and patient.[25]

In the present study, calcium hydroxide was selected as a control group against which the new material was tested. It was the gold standard in vital pulp treatment for decades due to its beneficial properties such as induction of mineralization, high pH and minimal cytotoxicity. However, the use of calcium hydroxide had declined due to several disadvantages such as poor sealing ability, insufficient adherence to dentinal walls and tunnel defects in the induced dentin bridge.[26]

This cleared the path for future silver-based products such as silver diamine fluoride (SDF) which has several advantages including antimicrobial properties, fluoride release and enamel remineralization. Besides, it is a non-invasive, simple and of low cost treatment. However, it has a few drawbacks such as blackening of teeth and metallic taste.[27]

So, there is a great evolution of science taking the humanity to new era called nanotechnology. One of these nano particles is nano silver fluoride (NSF) which selected in this study as a test group. It is a silver nanoparticles (AgNPs) product comprising nano silver particles, chitosan and sodium fluoride. It has already been evaluated clinically and found to be efficient in preventing and arresting caries in the enamel and dentin without causing tooth discoloration.[14]

Intermediate restorative material (IRM) was applied over NSF/ $Ca(OH)_2$ as a base material to overcome the drawbacks of sealing ability of both NSF/ $Ca(OH)_2$ as it has the ability to seal the cavity from any bacterial penetration. [20, 28] In addition, calcium hydroxide liners don't adhere to the dentinal walls so they provide a poor seal.[26]

In both groups, Amalgam restoration was applied over IRM as a core material till the end of the follow up period due to its beneficial properties including ease of manipulation, durability, cost effectiveness, decreased microleakage and less technique sensitive compared to other restorative materials.[29] However, there are problems that decrease survival rate of amalgam restoration like tooth fracture and recurrent caries.[30]

So, stainless steel crown was selected as a final and applied over amalgam restoration in

both study groups after 12 months follow up period to overcome the limitations of amalgam restoration since stainless steel crown has several advantageous properties including strength, preventing recurrent caries, long term durability and survival rate especially over amalgam restoration.[20, 25]

In the current study, the follow up period was 12 months. This period range was appropriate to evaluate clinical and radiographic changes.[9]

Statistical analysis of the demographic data of the sample population showed no statistically significant difference between mean age values in the two groups**.** There was also no statistically significant difference between gender distributions in the two groups. Thus, these results ensured the absence of cofounders and confirmed the homogeneity of the tested population in both groups.

Although several previous studies examined the effectiveness of nano silver fluoride (NSF) in arresting dental caries, up to our knowledge, no RCTs of indirect pulp treatment made for nano silver fluoride and no direct comparison made between nano silver fluoride and calcium hydroxide.[10, 31, 32] So, this study was the only RCT that compared the nano silver fluoride with calcium hydroxide in indirect pulp treatment in a postgraduate setting. Thus, comparison with previous studies may be difficult due to the absence of previous clinical trials that directly compared calcium hydroxide with nano silver fluoride in indirect pulp treatment.

However, there were two RCTs of indirect pulp treatment that directly compared calcium hydroxide versus silver diamine fluoride (SDF).[33, 34] SDF contained fluoride and silver particles with a particle size larger than that of NSF and this made SDF to act nearly in the same performance as NSF.[35] Thus, these RCTs studies might help to explain the results of the current study.

According to clinical evaluation, nano silver fluoride showed 100 % clinical success with no pain on percussion, swelling, sinus/fistula and mobility throughout follow up period where SDF showed the same success. [33] This might be attributed to its bactericidal effect and caries arrest capabilities.[14]

Regarding spontaneous pain, nano silver fluoride treated teeth showed three patients presented with pain at one month follow up and there was no change in prevalence of pain by time. This was in accordance with previous study that reported patients presented with pain in teeth treated with nano silver fluoride throughout follow up period. [36]

The authors attributed this result to the deeper penetration of nano silver particles inside the dentinal tubules and extend to the pulp chamber resulting in pulp inflammation and this was based on a study that found silver diamine fluoride with a silver particle's size lager than that of nano silver fluoride had the ability to penetrate deeper inside the dentinal tubules and causing pulp inflammation so it should be used with caution on a deep carious lesion and misdiagnosis of pulpal status was also a factor causing failureof IPT irrespective of the agent being used.[37, 33]

Regarding radiographic evaluation, nano silver fluoride treated teeth showed 100% radiographic success as there was no any furcation or periapical radiolucency, no widening of periodontal membrane space, no internal and external root resorption. This was in accordance with previous study where SDF showed 100% radiographic success. [33] This result might be attributed to the known advantage that nano silver fluoride has antimicrobial efficacy and lower cytotoxicity.[36] The strict patient selection, meticulous case selection and strict oral hygiene measures were also factors that might be attributed to these results.

According to clinical evaluation, calcium hydroxide treated teeth showed 100 % clinical success with no complaint of pain on percussion, swelling, sinus/fistula and mobility. This was in accordance with previous study.[38] This might be due to its several advantageous features such as induction of mineralization, high pH and minimal cytotoxicity.[26] On the contrary, there was a study reported one case failed due to sinus discharge at 6 months follow up and another study reported mobility in one tooth at 6 months follow up.[39, 40] These differences can be attributed to different methods used, differences in sample size and teeth treated, age of patients, technique used for carious removal and final restorative material used.

Regarding spontaneous pain, calcium hydroxide treated teeth showed one patient presented with pain at one month follow up and there was no change in prevalence of pain by time. This was in accordance with previous study that reported one tooth failed with pain at 3 months follow up and another study who reported two teeth presented with pain at 11 months follow up. This might be attributed to the known disadvantages of the calcium hydroxide such as non-adherence to dentine, dislodgement of particles within the body of the pulp and misdiagnosis of pulpal status was also a factor causing failure of IPT.[33, 41] On the contrary, there was study reported 100% clinical success throughout the

follow-up period. This difference might be attributed to the misdiagnosis of the pulp status.[42]

The overall clinical success of calcium hydroxide treated teeth reported in this study goes in accordance with the results reported earlier in previous studies.[8, 38, 42] This might be attributed to its several advantages including biocompatible properties, antibacterial properties which can eliminate bacterial penetration into the pulp and its high alkaline pH which helped to induce reparative dentine.[33]

Regarding radiographic evaluation, the results of the current study reported that calcium hydroxide treated teeth showed 100 % radiographic success with no furcation or periapical radiolucency, widening of periodontal membrane space and external root resorption throughout the follow up period and this was in accordance with previous study.[33] On the contrary, there was study reported that there were 4 cases failed in the calcium hydroxide group as the radiographic examination showed radioluciences in the periapical and furcation regions throughout the follow up period.[43] These differences might be attributed to the proper case selection, proper isolation and technique protocol, high aseptic standard and appropriate use of calcium hydroxide as an indirect pulp capping agent.[41]

For internal root resorption, calcium hydroxide treated teeth showed one tooth failed with internal root resorption at 6 months follow up and there was no change in prevalence of internal resorption by time. This was in accordance with previous study that reported one patient presented with internal root resorption treated with calcium hydroxide at 18 months follow up also another study reported one patient presented with internal root resorption treated with calcium hydroxide at 25 months follow up.[8, 44] Additionally, there were two patients presented in previous study with pathological root resorption treated with calcium hydroxide at 6 months follow up.[40] This might be due to chronic inflammatory response to high alkaline pH of calcium hydroxide which might trigger undifferentiated mesenchymal cells (predonoclast) to transform into odontoclasts and thus initiate internal root resorption.[45]

In the present study, it was observed that the clinical success in the teeth treated with calcium hydroxide was the same as the radiographic success, this finding was in accordance with previous study reported that

the clinical success was the same as the radiographic success.[46]

Limitations:

1) There was a difficulty in the patients' follow up due to pandemic covid 19 however, I was able to peruse them to show up for their appointments.

2) No RCT of indirect pulp treatment made for nano silver fluoride and no direct correlation made between nano silver fluoride and calcium hydroxide. Thus, comparison with previous studies may be difficult due to the absence of previous clinical trials that directly compared calcium hydroxide with nano silver fluoride in indirect pulp treatment. So, the author depended on comparison between SDF that previously compared with calcium hydroxide in several research works as SDF contained fluoride and silver particles with a particle size larger than that of NSF and this made SDF to act nearly in the same performance as NSF.

Conclusions:

Based on the results of this study, the following conclusions were drawn:

1) In the overall clinical and radiographic success, both nano silver fluoride and dycal were successful indirect pulp treatment medicament of deep carious second primary molars as the success rates were 85% and 90%, respectively.

2) After a 12 months' postoperative period, nano silver fluoride was proved to be effective as a successful indirect pulp treatment medicament of deep carious second primary molars.

3) Nano silver fluoride is a good alternative to dycal as a pulp capping agent for indirect pulp treatment procedures, as it associated with 85% clinical success and 100% radiographic success.

Clinical recommendations:

1) More RCTs and long term follow up are recommended to investigate the long term success of nano silver fluoride in indirect pulp treatment of deep carious primary molars.

2) Careful case selection, proper isolation and technique protocol are the keys for successful indirect pulp treatment.

3) Due to the ease of application, better sealing ability and anticaries effect, nano silver fluoride is recommended as an alternative to dycal in pediatric restorative dentistry.

Acknowledgements: Nil

Conflicting Interest: The author declares that there is no conflict of interest.

Source(s) of Funding: This study was self-funded by the authors.

Ethical policy and Institutional Review board statement: The Research Ethics Committee (CREC) of Faculty of Dentistry, Cairo University with approval number 24-9-19.

Patient declaration of consent statement:

We have obtained all appropriate patient consent forms. The legal guardians understand that their children names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Table (1): Outcomes

Evaluation	**Outcome**	**Tool/device**	**Unit**
Clinical	Postoperative pain	By asking the patient [8]	Binary • Yes • No
	Swelling	Visual examination by the operator [8]	Binary • Yes • No
	Sinus or fistula		
	Tooth mobility	Mobility and percussion test using back of the mirror [8]	
	Pain on percussion		
Radiographic	Occurrence of radiolucent lesion at furcation or periapical region	Radiographic examination using standardized digital periapical radiograph by parallel technique using film holders [43]	
	Widening in the periodontal membrane space		
	Presence of internal or external root resorption.		

Table (2): Overall clinical and radiographic success

Overall clinical success	**Nano-Silver Fluoride (n =20 teeth)**		**Calcium Hydroxide(n = 20 teeth)**		*P*-value	*Effect size (OR)*
	n	%	n	%		
Success	17	85	19	95	0.605	1.587
Failure	3	15	1	5		
Overall Radiographic success	Nano-Silver Fluoride (n = 20 teeth)		Calcium Hydroxide (n = 20 teeth)		*P*-value	*Effect size (OR)*
	n	%	n	%		
Success	20	100	19	95	1	2.053
Failure	0	0	1	5		

Table (3): Frequency and percentage for clinical and radiographic evaluation scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods

I. Clinical evaluation						
2. Postoperative pain						
Follow up	Nano-SilverFluoride (n = 20 teeth)		Calcium Hydroxide (n = 20 teeth)		*P*-value	*Effectsize (v)*
	n	%	n	%		
One month	3	15	1	5	0.605	0.167
Three months	3	15	1	5	0.605	0.167
Six months	3	15	1	5	0.605	0.167
Nine months	3	15	1	5	0.605	0.167
12 months	3	15	1	5	0.605	0.167

1. Pain on percussion, Swelling, Sinus or fistula and Tooth mobility,									
Follow-up	Nano Silver Fluoride				Dycal				P value
	No	Yes			No	Yes			
Baseline	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
1 month	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
3 months	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
6 months	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
9 months	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
12 months	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000

II. Radiographic evaluation									
1. Occurrence of radiolucent lesion at furcation or periapical region, widening in the periodontal membrane space and presence of external root resorption									
Follow-up	Nano Silver Fluoride				Dycal				P value
	No	Yes			No	Yes			
Baseline	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
6 months	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
12 months	20 (100%)	0 (0%)			20 (100%)	0 (0%)			P = 1.0000
2. Presence of internal root resorption									
Follow-up	Nano Silver Fluoride				Dycal				P value
	No	Yes			No	Yes			
6 months	20 (100%)	0 (0%)			19 (95%)	1 (5%)			1
12 months	20 (100%)	0 (0%)			19 (95%)	1 (5%)			1