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Silver Diammine Fluoride Use in Paediatric Dentistry:

A Retrospective and Cross-sectional Analysis

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1. Summary

Background and Objectives: Silver diamine fluoride (SDF) has been incorporated into the treatment of dental caries in children, mainly in countries with high caries prevalence. In Europe, however, SDF started to gain popularity during the COVID-19 pandemic. This study aimed to investigate the efficacy of SDF and to evaluate dentists'/parents' acceptance of SDF use in paediatric patients treated in a German university setting.

Materials and Methods: A retrospective analysis of all patients treated with SDF between 2017 and 2020 was carried out. Only teeth with no reported clinical/radiographic evidence of irreversible pulpal inflammation were included. The outcome measures were success, minor failures (caries progression, reversible pulpitis) and major failures (irreversible pulpitis, abscess). The treatment acceptance by dentists and the parents of SDF-treated children was cross-sectionally evaluated using questionnaires.

Results: A total of 93 patients (mean age 5.3 ± 2.9 years) with 455 treated teeth (418 primary/91.9%; 37 permanent/8.1%) were included and followed up for up to 24 months (19.9 ± 10.5 months). SDF was used for dental caries (98.2%) and hypersensitivity relief on MIH teeth (1.8%). Most teeth did not show any failure (total success 84.2%). A total of 5 teeth (1.1%) showed minor failures, and 67 teeth (14.7%) showed major failures ($p = 0.001$). Success/failure rates were not affected by patient compliance, gender, dentition, or operator ($p > 0.05$). In total, 30 questionnaires were collected from parents (mean age 36.8 ± 6.4 years). SDF was applied on anterior (n = 2/6.7%), posterior (n = 15/50%) and anterior/posterior teeth (n = 13/43.3%). At the 1-week follow-up, 80% of parents noticed black teeth discoloration. Treatment satisfaction was higher for posterior (95.2%) than for anterior teeth (36.4%; $p < 0.001$). In the 27 responses from clinicians, SDF was generally considered a viable option in paediatric dentistry (n = 23; 85%).

Conclusions: SDF was found to be effective and well-accepted by parents and dentists for caries inactivation in a paediatric dentistry German university setting.

2. Kurzzusammenfassung

Ziel: Ziel dieser Studie ist es, die Wirksamkeit der Behandlung mit Silber-Diamin-Fluorid (SDF) nach einem Follow-up von 24 Monaten an einer Abteilung für Kinderzahnheilkunde einer Uniklinik zu bewerten. Die Meinung der Eltern und Erfahrung der Zahnärzte wurde auch erforscht.

Materialien und Methoden: Es wurde eine retrospektive Analyse durchgeführt an alle Patienten, die im Zeitraum von Januar 2017 bis Februar 2020 behandelt wurden. Behandelte Zähne ohne klinische oder röntgenologische Pulpabeteiligung wurden analysiert. Die Wirksamkeit der SDF-Behandlung wurde je nach Erfolgsraten bzw. Misserfolg bewertet. Akzeptanz und Erfahrung der Behandlung aus Sicht der Eltern und Zahnärzte wurde durch Fragebögen auch erfasst.

Ergebnisse: Insgesamt wurden 93 Patienten aufgenommen, mit einem mittleren Alter von 5,3 ± 2,9 Jahren. 455 Zähne (418 Milchzähne/91,9%; 37 bleibende Zähne/8,1%) wurden behandelt und analysiert nach einem Follow-up von 24 Monaten (19,9 ± 10,5 Mo.). SDF wurde hauptsächlich bei Karies verwendet (98,2%) und MIH-Überempfindlichkeit (1,8%). Die Mehrheit der Zähne zeigten keinen Therapiemisserfolg (Erfolgsrate von 84,2%). 5 Zähne (1,1%) zeigten kleine Misserfolge und 67 Zähne (14,7%) zeigten große Misserfolge ($p = 0{,}001$). Die Erfolgsraten bzw. Misserfolge sind nicht von anderen Faktoren wie Kooperationsbereitschaft des Kindes, Geschlecht, Gebiss, oder Behandler abhängig ($p > 0.05$). Insgesamt haben 30 Eltern teilgenommen (Mittelwert Alter 36,8 ± 6,4 Jahre). SDF wurde an Frontzähnen ($n = 2$/6.7%), Backenzähnen ($n = 15$/50%) und Front/Backenzähnen verwendet ($n = 13$/43.3%). Nach einer Woche Follow-up, 80% der Eltern haben die schwarze Verfärbung gemerkt. Therapie Akzeptanz war höher bei Backenzähnen (95,2%) als Frontzähne (36,4%; $p < 0.001$). 27 Zahnärzte haben an der Umfrage teilgenommen. Die Mehrheit der Teilnehmer findet, SDF sei eine gute Therapieoption in der Kinderzahnheilkunde angenommen ($n = 23$; 85%).

Schlussfolgerung: Zusammenfassend wurden hohe Erfolgsraten der SDF-Behandlung aufgewiesen und die Behandlung wurde gut angenommen von Eltern und Zahnärzten einer Uniklinik als Therapieoption um Karies zu inaktivieren bei Kindern.

3. Introduction

Until today, dental caries continues to be a significant oral health problem among children. The WHO Global Oral Health Status Report estimates a prevalence of 43% of primary teeth caries worldwide [WHO Global Oral Health Status Report, 2022]. Several risk factors have been involved in the aetiology of caries such as insufficient oral hygiene, bad eating habits, and shifts in oral bacterial flora. The increasing prevalence, especially in countries with low socio-economic status, affects children's quality of life and presents a public health burden and challenge in managing dental caries [Butera et al., 2022].

Biological-based minimally invasive treatment strategies have been widely advocated in recent literature. Among these is caries inactivation using silver diamine fluoride (SDF) which has been a research topic of interest, particularly in the last decade [Qasim et al., 2021]. SDF has been intensively studied and several systematic reviews have demonstrated its effectiveness in arresting caries in primary teeth, showing up to 91% success rates with biannual application [Schmoeckel et al., 2020; BaniHani et al., 2022; Santamaría et al., 2020]. As a result, SDF was then listed as an essential medicine for the treatment of carious lesions by the World Health Organisation [WHO, 2021]. Its affordability and ease of use made it especially advantageous in countries with high caries prevalence and regions with limited access to dental care [Chu et al., 2002; dos Santos et al., 2012].

Over time, the growing body of evidence supporting its efficacy has led to the widespread implementation of SDF nearly around the whole world [Gao et al., 2021]. However, its use in Europe has been more limited, primarily due to the absence of formal national guidelines and its constrained off-label application. SDF has been advocated to treat hypersensitivity in primary and permanent teeth [Abudrya et al., 2023] and as an alternative treatment for treating carious lesions in (young) children or those who struggle to cooperate with invasive restorative procedures. Recently, organizations such as the European Organisation for Caries Research (ORCA), the European Federation of Conservative Dentistry (EFCD), and the German Association of Conservative Dentistry

(DGZ) issued a consensus statement strongly endorsing the use of high-concentration SDF in managing early childhood caries (ECC) [Splieth et al., 2020].

With a significant body of research and increasingly growing strength in evidence, SDF could be considered the new “silver lining” to the global oral health issue of dental caries, especially for the management of ECC, as it could enhance the otherwise complex treatment of dental caries among children.

4. Literature review

While there has been growing interest in SDF for the past decade in research, its use in the treatment of caries is not a new concept. In 1969, SDF was first introduced by Nishino et al. in Japan and has been used since then to treat caries in children [Nishino et al., 1969]. Nishino and colleagues produced the first SDF product called Saforide®. An SDF solution in 38%, meaning each milliliter of the product contains 380 mg (38 weight/volume%) of SDF or $Ag(NH_3)_2F$. Combining silver, an antimicrobial agent (Ag, 25% weight/volume), and fluoride (F, 5%), a potent remineralizing mineral, gives a synergistic effect in the treatment of caries. The addition of ammonia helps keep the compound at a stable property (ammonia 8%) [Horst, 2018].

Later on, with the introduction of more products, SDF spread to China, Australia, and Brazil. In the 2000s, research regarding SDF increased, supporting its effectiveness. This gave way to the clearance of SDF in 2014 by the US Food and Drug Administration (FDA) as a dentin-desensitizing agent. In 2015, the first SDF product became available in the US market but only for treating hypersensitivity in adults. In 2016, the FDA awarded SDF a breakthrough therapy status in the treatment of early childhood caries, which allows for the evaluation of new drugs for a disease with no available treatment. This allowed clinical trials to take place in the US, to evaluate the caries arrest efficacy of SDF. The American Academy of Pediatric Dentistry then published a Guideline for the use of SDF encouraging its off-label use in the treatment of caries [Crystal, and Niederman, 2019]. In 2018, the WHO published recommendations for public health intervention against ECC. Among those, was the use of SDF as a minimally invasive method to control caries as an alternative to other conventional caries management procedures [Phantumvanit et al., 2018].

4.1. Mechanism of action

A recent literature review by Zhao et al. (2018) describes and summarizes the mode of action of SDF in arresting caries in three main ways:

1. **Bactericidal and bacteriostatic** by reducing the growth of cariogenic bacteria like Streptococcus oralis and Lactobacillus casei.
2. It **inhibits demineralization** and **promotes remineralization**, by forming calcium fluoride and silver phosphate when reacted with hydroxyapatite, thus increasing the mineral content of enamel and dentin.
3. It **protects dentine collagen** from degradation by inhibiting collagenases (matrix metalloproteinases and cysteine cathepsins), the enzymes that contribute to the destruction of the collagen matrix [Zhao et al., 2018].

4.2. Indications and contraindications

Like any other treatment modality, correct diagnosis is key to the success of the treatment. Hence the following criteria must be met to present an indication of SDF treatment.

- At the **tooth** level:

1. Coronal caries in primary and permanent teeth or root caries in permanent teeth
2. Cleansable cavities
3. Asymptomatic carious teeth
4. No pulpal involvement
5. Non-carious lesions with dental hypersensitivity
6. Hypersensitive teeth due to molar incisor hypomineralization (MIH)

Figure 1 shows an example of a carious primary tooth indicated for SDF treatment.

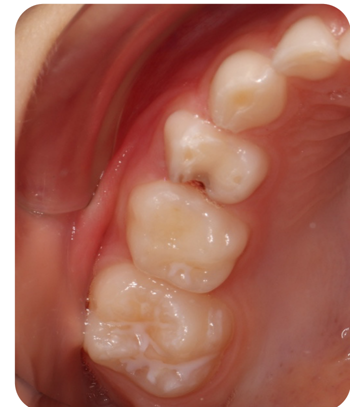


Figure 1. Clinical photograph of carious tooth 54 in a 5-year-old child.

- At the **patient** level:

1. Pre-cooperative children with a treatment need but lack the cooperation required.
2. Medically compromised patients with high caries risk independently of age.

The use of SDF is contraindicated with any of the following conditions:

- At the **tooth** level:

1. Clinical or radiographic signs and symptoms of pulpal involvement.

- At the **patient** level:

1. Patients having allergies to silver, fluoride, ammonia, and potassium or iodine.
2. Patients with ulcerations, mucositis, or stomatitis.
3. Potassium iodide, a component of one of the SDF products (Riva Star®), is contraindicated with pregnant/breastfeeding women, and patients undergoing thyroid gland treatment [Seifo et al., 2020b].

4.3. Evidence behind SDF in the treatment of caries

A recent umbrella review of systematic reviews, which yields the highest level of evidence based on all studies investigating the use of SDF in the treatment of caries from 1970 to 2018, stated that there is consistent and continuously increasing strong research regarding the effectiveness of SDF. It reports strong evidence for the prevention and arrest of root caries in older patients, based on only four but of high-quality clinical trials. For the arrest of coronal caries, an increasing number of trials show strong evidence for the use of SDF in primary teeth. There is however a limited number of high-quality studies regarding its use in permanent teeth or its use as a preventive agent against coronal caries [Seifo et al., 2019]. In terms of evidence and clinical recommendations, the American Dental Association (ADA) in 2018 published “Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions". The ADA recommended the use of 38% SDF biannually to arrest cavitated coronal caries in primary teeth. The ADA rated this recommendation as strong with moderate-certainty evidence [Slayton et al., 2018]. The same applies to permanent teeth but as a conditional recommendation with low-certainty evidence. Despite the lack of direct evidence on the use of SDF in permanent teeth, the expert panel assumed that the effectiveness of SDF on carious primary teeth would not be significantly different than in permanent teeth [Slayton et al., 2018].

4.4. Caries arrest using SDF in children

Many clinical trials have been conducted on the effectiveness of SDF in the treatment of ECC, either against a placebo or in comparison to other fluoride products like Fluoride Varnish (FV) or other treatment methods like Atraumatic Restorative Treatment (ART).

One of the major studies done in this regard is a clinical trial conducted in China by Chu et al. (2002). This study compared the effectiveness of annual application of SDF to that of 3-month interval application of FV. The participants were children aged 3-5 years with carious upper anterior primary teeth. They were divided into the following groups:

1. Annual application of SDF after soft caries removal
2. Annual application of SDF
3. FV application every 3 months after soft caries removal
4. FV application every 3 months
5. Control group

After a follow-up of 30 months, 308 children were examined, and the mean number of arrested carious surfaces was recorded. The results were 2.5, 2.8, 1.5, 1.5, and 1.3 for the five groups, respectively. The authors reported a 100% caries arrest rate following the SDF treatment with or without caries excavation in comparison to 26%, 66%, and 42% with other groups. The evidence from this study supports the effectiveness of SDF in the treatment of carious anterior primary teeth [C.H. Chu et al., 2002].

According to a systematic review by Chibinski et al., arresting caries with SDF was 66% higher than by other active materials like FV or ART at 12 months follow-up, and 154% higher than placebo. The overall caries arrest rate was 89%. This means that arresting caries in primary teeth using SDF is 89% more effective than other treatments or placebos. The meta-analysis performed in this systematic review included 4 studies, 3 of which were assessed as having a low risk of bias (Zhi et al., 2012; dos Santos et al., 2014; Duangthip et al., 2016) and 1 with an unclear risk of bias (Seberol and Ökte, 2013). All of which had high sample sizes and similar populations, and the data showed no

heterogeneity. Thus, the overall evidence of the meta-analysis was of high quality [Chibinski et al., 2017].

It is worth noting that among the studies included in the meta-analysis of this systematic review, is a trial that used Nano Silver Fluoride (NSF) and not SDF (dos Santos et al. 2014), since SDF and NSF differ in the composition. In this trial, the effectiveness of NSF (33,989.8 mg/mL) was investigated in treating dental caries in children. They reported a 66.7% caries arrest rate at the 12-month examination compared to 34.7% of the placebo, indicating that NSF could be another option for the treatment of caries due to its anti-cariogenic properties similar to SDF but without the side effect of black staining of carious lesions [Dos Santos et al., 2014].

Another systematic review that investigated the effectiveness of SDF in arresting dental caries among children was done by Gao et al. (2016). In this systematic review, a meta-analysis was performed on 8 studies (Chu et al., 2002; Fukumoto et al., 1997; Llodra et al., 2005; Wang, 1984; Yang et al., 2002; Ye, 1995; Yee et al., 2009; Zhi et al., 2012). All of the studies, except Zhi et al. 2012, were not covered by the previously mentioned systematic review; Chibinski et al. (2017). The authors reported high caries arrest rates using 38% SDF solution with follow-up from 6 to 30 months. An overall caries arrest rate of 81% was reported using different application frequencies. Out of 19 clinical trials done on the use of SDF in children, no adverse effects were reported other than the black staining of caries lesions [Gao et al., 2016].

One of the most important studies included in this meta-analysis was by Llodra et al. (2005). A clinical trial was conducted in Cuba to study the effectiveness of 38% SDF in arresting and preventing caries in children with semi-annual applications. A caries arrest rate of 77% was reported with 373 children followed up to 36 months. This caries arrest rate also included the first permanent molars. Hence, the trial shows that treatment with SDF at the 6-month interval was not only able to control caries in primary teeth but also in permanent teeth.

4.5. Caries prevention using SDF in children

The same trial by Llodra et al. (2005) also reported on the prevention using SDF. They found 0.29 mean number of new carious surfaces in primary teeth of the SDF group as compared to 1.43 in the control group, with a preventive fraction of 79.7%. The children in the intervention group also received an SDF application every six months on the occlusal surfaces of any first permanent molar. After 36 months, the authors reported a preventive fraction of 65% in this group [Llodra et al., 2005].

Another recent systematic review on the caries prevention effect of SDF was published by Oliveira et al. (2018). The meta-analysis was performed on 2 studies comparing SDF to placebo. After a follow-up period of more than 24 months, SDF was found to have a 77.5% preventive fraction and was able to reduce caries increment in treated and untreated primary teeth [Oliveira et al., 2019].

The same could not be said true to permanent teeth. A clinical trial by Monse et al. investigated the preventive effect of a single application of SDF in permanent first molars in comparison to ART or placebo. After 18 months of follow-up, no additional caries preventive effect was found with SDF. With ART sealants, however, new carious lesions were significantly reduced [Monse et al., 2012].

4.6. Application frequency using SDF

Zhi et al. (2012) conducted a clinical trial in China to compare the effectiveness of SDF with annual and semi-annual application, as well as with the annual application of a flowable glass ionomer in arresting caries in primary teeth. They reported 91% caries arrest with the semi-annual application of SDF after 24 months of follow-up. Followed by 82% with glass ionomer application. Comparable results were found with annual application of SDF by 79% caries arrest rate. The results of this long-term study support the semi-annual application of SDF and shows that both SDF and glass ionomer are effective in arresting caries in children. Hence, the choice of treatment relies more on the availability of the materials, the dental setting, and parents' perception of aesthetics [Zhi et al., 2012].

Another trial by Duangthip et al. (2016) studied different fluoride protocols using FV and SDF to compare the effectiveness of SDF in arresting caries among high-risk pre-school children in a fluoridated area in Hong Kong. The first intervention group received 30% SDF once a year. The second and third groups received 3 weekly intensive applications of 30% SDF, and 5% NaF varnish, respectively. The approach of frequent applications in a short period of time was thought to fasten the caries arrest process. At the 18-month follow-up visit, they reported a 40% caries arrest rate with the SDF group (once a year), 35% and 27% caries arrest rates with the weekly SDF group and FV group respectively. Lesions on anterior teeth and buccal/lingual surfaces had a higher chance of being arrested. Also, the absence of plaque at the surface played a major role in speeding up the caries arrest process. The authors explained the reasons for lower caries arrest rates compared to previous studies, possibly as a result of strict assessment criteria and examiners. Other than the black staining of caries lesions, no adverse effects were reported in the trial [Duangthip et al., 2016].

4.7. Different SDF concentrations

There are several SDF products with different concentrations in the market. SDF concentration ranges from 12% - 38%. Many trials have been done to study the relation between the concentration and the effectiveness.

In a major randomized clinical trial done by Fung et al. (2018), the effectiveness of SDF was studied in terms of concentration and frequency of application. The authors reported a 75.7% caries arrest rate in primary teeth with the semi-annual use of 38% SDF. The total number of children participating in this trial was 799 at the 30-month follow-up. The rest of the children who were randomly allocated in the following groups: 12% SDF annual application, 12% SDF semi-annual application, and 38% SDF annual application, had a caries arrest rate of 55.2%, 58.6%, and 66.9% respectively. Thus, the high arrest rates in this long-term study support the 38% SDF concentration. The authors reported a 15% increase in the caries arrest rate with semi-annual compared to annual application. Frequent applications are particularly beneficial for children with poor oral hygiene, as a

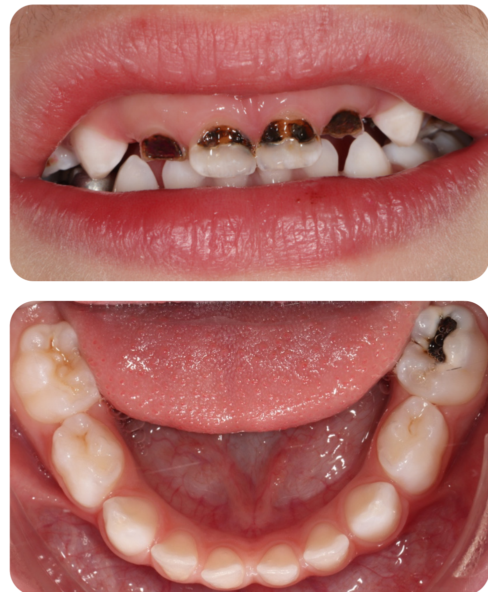
significant relationship was found between the frequency of SDF application and oral hygiene [Fung et al., 2018].

Another trial conducted by Yee et al. (2009) in Nepal investigated the effectiveness of the one-time application of 38% SDF combined with tannic acid (tea) as a reducing agent to accelerate the process, 38% SDF alone, and 12% SDF alone in comparison to placebo. After following up for two years, 634 children were examined and participated in the trial. The results showed that the single application of 38% SDF with or without a reducing agent arrests a higher number of carious surfaces in primary teeth than 12% SDF or placebo. However, the caries arrest rate decreased over the two years by 50%. They also reported no significant differences in the 38% SDF with or without tannic acid; hence it was concluded that a reducing agent has no significant effect on arresting caries. There was also no significant difference between the one-time application of 12% SDF group or the control group, showing that 12% SDF was ineffective in arresting caries. [Yee et al., 2009].

4.8. Adverse effects associated with SDF

As seen with all the previously mentioned studies in this review, no adverse effects have been reported with the use of SDF other than the black discoloration of carious lesions (Figure 2). The systematic review by Gao et al. (2016) included 19 clinical trials with different concentrations of SDF and frequency of use with up to 36 months follow-up, none of which had reported significant complications [Gao et al., 2016]. The clinical trial by Duangthip et al. (2017) focused more on the adverse effects of SDF. With a sample size of 799 children and a follow-up of 30 months, no acute systemic signs and symptoms or major adverse effects were reported. Minor adverse effects such as tooth/gum pain, gum swelling, and gum

Figure 2. Clinical photographs of carious teeth after treatment with SDF.



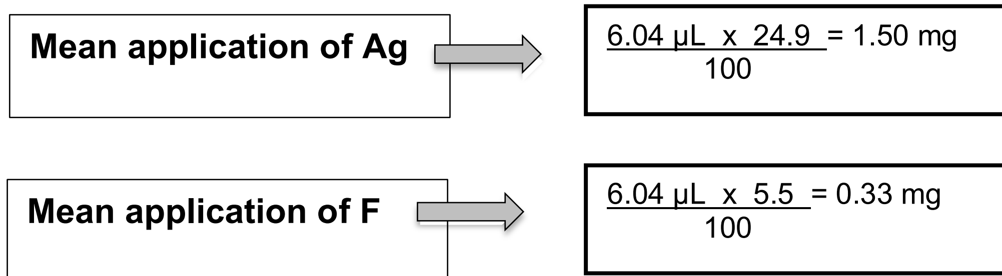
bleaching were reported at 6.6%, 2.8%, and 4.7% respectively. The black staining of carious lesions was found among all the intervention groups and increased as the concentration of SDF and frequency of application increased. The authors concluded that the use of SDF in children is safe and the mild adverse effects, which were rarely reported, had probably not been as a result of SDF treatment, since some of the parents also reported adverse effects after receiving a placebo [Duangthip et al., 2018; Brignardello-Petersen, 2018].

4.9. Safety and dosage

38% SDF solution is composed of 44,800 ppm fluoride ion concentration and 255,000 ppm silver ion concentration [Mei et al., 2013]. Although past thorough research has shown no systemic adverse effects or toxicity associated with the use of SDF. There have been some concerns about toxicity or fluorosis due to the high concentrations of silver and fluoride ions. However, calculating the dose applied to a patient shows that it is well below the lethal dose.

A study by Vasquez et al. (2012) in Peru studied the safety of SDF use in 6 adults and its maximum serum concentrations over a short term. The mean amount of SDF solution applied to treat three teeth per participant was 6.04 µL. The concentrations of silver (Ag) and fluoride (F) in the SDF product used were 24.9% (weight/volume) and 5.5% (weight/volume), respectively. The authors then used these values to calculate the mean amount of silver and fluoride applied to each patient (Figure 3).

Figure 3. Calculation of the mean volume of silver and fluoride applied per patient.



In the results reported by this study, in the 4 hours after SDF application, the mean maximum fluoride concentration was 1.86 μmol/L and the mean maximum silver concentration was 206 nmol/L. These findings were then compared to the current US Environmental Protection Agency (EPA) oral reference dose (RfD) for daily F and Ag exposure based on each participant's weight.

As defined by the EPA, oral reference dose is an estimate of daily exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime [The US Environmental Protection Agency, 2012].

The fluoride exposure was far below the US Environmental Protection Agency (EPA) oral reference dose. Occasional use of silver was also far below doses associated with toxicity. The authors concluded that serum concentrations of fluoride and silver after topical application of SDF have little or no toxicity risk in adults [Vasquez et al., 2012].

The clinical trial by Duangthip et al. (2018) also used the mean amount of SDF applied from the previous study to calculate the maximum amount of silver applied to 20 carious teeth of a child and compared it to a median lethal dose produced from rat studies. The lethal dose was found to be 380 times the applied dose indicating a wide safety margin of SDF [Duangthip et al., 2018].

The guidelines and evidence-based recommendation developed by the American Academy of Pediatric Dentistry (2017), as well as a commentary published by Crystal and Niederman (2016), also supported the safety of SDF application regarding the fluoride concentration, as a drop of SDF application contains almost half of the fluoride content in a typical fluoride varnish topical application. 1 drop (0.05 ml) of 38% SDF contains 2.24 F ion mg/dose while (0.25 ml) application of 5% Sodium Fuoride varnish contains 5.65 F ion mg/dose [Crystal, and Niederman, 2016; Crystal et al., 2017b].

4.10. Parental acceptance and satisfaction with SDF

One main drawback to the use of SDF is the permanent black staining of the carious lesion due to excess free silver ions at the lesion surface. Although the black discoloration is considered a sign of successful treatment and inactivation of caries, it does however, play a major role in the treatment planning process since it alters the dental appearance, especially with front teeth application. Therefore, parents should be informed about this consequence, and an informed consent must be obtained before commencing with SDF treatment in children. Parental acceptance and satisfaction regarding the staining have been recently further studied. A scoping review was recently published by Magno et al. (2019) evaluating aesthetic perception and acceptance of parents and dental professions. This scoping review included 9 studies. The authors reported higher acceptance with increased patient needs of advanced behavior guidance techniques, such as treatment under general anesthesia. Other factors that influenced the satisfaction were the type of the tooth (anterior/posterior), family income, ethnicity, and parental schooling. Overall, the authors concluded that SDF staining did not influence parental acceptance nevertheless it was related to a lower dental professionals' satisfaction, as the dentists assume its drawbacks would not be accepted by the parents and thus do not offer it as a treatment option [Magno et al., 2019].

4.11. Final restoration following SDF treatment

Another disadvantage of SDF is that it acts by inactivating the carious process without sealing the carious lesion, leaving a cavitated tooth that still requires treatment. On the other hand, this is also seen as an advantage since SDF works by treating the disease rather than the symptom when compared to a restoration, which usually results in a cycle of repeated “drill and fill” due to secondary caries.

Various methods have been proposed in the restorative treatment of caries following SDF. Among these include the SMART method which stands for Silver Modified Atraumatic Restorative Treatment. Alvear Fa et al. (2016) published a case report where a carious lower anterior of a 70-year-old patient was treated with SDF followed directly by a restoration using glass ionomer cement. The authors described this technique as

minimally invasive and particularly beneficial for patients who cannot show-up for another dental appointment, such as underprivileged communities in remote areas [Alvear Fa B, Jew JA, Wong A, 2016]. The placement of a preformed stainless-steel crown following SDF treatment has been suggested as another method to restore the tooth and is referred to as SMART Hall. There are, however, no current clinical trials or studies with follow-up to support the efficiency of these “smart” techniques [Hu et al., 2018].

4.12. Introduction to Nano Silver Fluoride (NSF)

Since one of the studies done on the use of nano silver (Santos et al., 2014) has already been mentioned in this review, it is of benefit to describe the most recent literature published on the use of nano silver particles in the treatment of caries. A recent systematic review of 3 studies has shown high arrest rates in dental caries in children using nanosilver fluoride in comparison to placebo [Shetty et al., 2024]. One of the included studies was the double-blind clinical trial by Tirupathi et al. (2019), which evaluated the caries arrest rate of SDF in comparison to nano silver-incorporated sodium fluoride (NSSF). 50 children were included in the study, with a total of 159 carious teeth. After and throughout one year, the authors reported no significant difference in the caries arrest rate of SDF compared to NSSF. It was therefore concluded that the annual application of NSSF is almost equal to 38% SDF in effectiveness in treating caries.

NSSF has advantages over SDF that it does not cause dark staining owing to the lack of oxidation at the caries surface. NSSF has no metallic taste, does not cause painful ulcerations, and is relatively economical. The authors, therefore, recommend its use in children [Tirupathi et al., 2019]. Silver nanomaterials have also been incorporated in other products like resin in pits and fissure sealants or glass ionomer. The concise review done by Yin et al. (2020) concluded that silver nanomaterials have similar properties to SDF in caries arrest and prevention however only few clinical studies are currently available with the majority being in-vitro studies. Hence further clinical research is required before silver nanomaterials can be implemented in healthcare [Yin et al., 2020].

4.13. SDF use during COVID-19 pandemic

Lastly, SDF application has been described in several studies as one of the non-aerosol-generating procedures during the COVID-19 pandemic. Its use has been recommended in dental practice due to its non-invasive nature to minimize viral transmission associated with aerosols and to increase safety among patients and professionals in an otherwise risky dental setting [Mallineni et al., 2020; Gao et al., 2021; Al Masri et al., 2021].

5. Aim of the study

Given the limited research on SDF use in Europe, this study aims to evaluate the clinical effectiveness of SDF treatment among children and to assess the acceptance among both dentists and parents of pediatric patients undergoing SDF treatment in a university dental clinic in Germany.

6. Materials and Methods

6.1. Ethical approval

Ethical approval to conduct the study was obtained from the Research Ethics Committee of the University of Greifswald under protocol number BB-142/20. The study was done according to the declaration of Helsinki [World Medical Association, 2013].

6.2. Study design

This study consisted of two components: a retrospective analysis and a cross-sectional analysis based on a designed questionnaire.

6.3. Retrospective analysis

Electronic records of all patients treated with SDF at the Paediatric Dentistry Department in the University of Greifswald were retrospectively collected from SDF application and up to 2 years afterward to evaluate the outcome of SDF treatment.

6.4. Inclusion criteria

- Paediatric patients treated with SDF at the University of Greifswald Paediatric Dentistry Department between January 2017 and February 202.
- Patients who had attended at least one follow-up appointment (until February 2022).
- Patients without baseline clinical or radiographic signs/symptoms of pulpal/periapical pathology.
- Only patient records with sufficient documentation were included.

6.5. Clinical procedure

The SDF product used was Riva Star® (SDI Limited, Victoria 3153, Australia), and the application followed manufacturer's instructions (see 6.6). The treatment was performed in a chairside setting by 8 dentists, 5 of whom were paediatric dental specialists and 3 were postgraduate paediatric dentistry (PD) students with at least 2 years of working experience, all trained in treating children with SDF following a standard protocol.

6.6. SDF application protocol

Figure 4. Clinical set up for SDF application using Riva Star® showing SDF and Potassium Iodide capsules.

The following are the main steps in the application of SDF according to manufacturer's instructions:

1. The tooth is first cleaned to remove debris and optimize SDF penetration.
2. Isolation with petroleum jelly, cotton rolls, or gingival barrier resin is done to protect soft tissues.
3. A maximum of 1 drop of SDF product should be used per patient/visit.
4. The tooth is dried with the 3-way syringe and SDF solution is applied directly on the caries lesion with a micro-brush for 1 minute if possible.
5. Excess unreacted SDF can be cleaned with cotton rolls or allowed to air dry.
6. If the child cooperates well, a subsequent application of the second bottle; potassium iodide solution is done to lower the risk of black staining.
7. Follow-up within 2–4 weeks is recommended to evaluate the inactivation of caries, especially with deeper dentinal lesions.

6.7. Outcomes

Recorded data comprised demographics (age, gender, address, medical status) and clinical baseline findings ($d_3$mft/s-D_3MFT/S index, clinical diagnosis, severity level of carious lesions using ICDAS index, radiographic and pulpal status, etc.). Outcome measures were assessed according to the last follow-up session using criteria modified from Innes et al. (Table 1) [Innes et al., 2006].

Table 1. Assessment criteria for the outcome analysis of treated teeth considering the two indications for SDF use.

Success

Dental caries

- Caries arrested (hardness/softness; lesion feels hard on gentle probing; characteristic SDF discoloration/black staining reported) and no further treatment required.
- Caries arrested and tooth restored.
- No clinical signs or symptoms of irreversible pulpal pathology.
- Tooth exfoliated without minor or major failure.

Dentin hypersensitivity (due to MIH)

- Reported reduced MIH hypersensitivity, tooth not restored.
- Reported reduced MIH hypersensitivity, tooth then restored.

Minor Failure

Dental caries

- Caries progression (hardness/softness; soft/leathery lesion on gentle probing; partially achieved/no reported SDF discoloration/black staining).
- Signs or symptoms of reversible pulpitis treated without requiring pulpotomy or extraction.

Dentin hypersensitivity (due to MIH)

- Hypersensitivity persisted and required other treatment without pulpotomy or extraction.

Major Failure

- Signs or symptoms of reversible pulpitis (no spontaneous pain) requiring pulpotomy.
- Signs or symptoms of irreversible pulpitis (spontaneous/persistent pain) or dental abscess requiring pulpectomy or extraction.

Data collection was based on the documentation obtained from the dental records. Data were collected and decoded by the main investigator (RA) and reviewed by at least one co-investigator each time in a standardised manner using a Microsoft Excel (2020) spreadsheet prepared for the purpose of this study with the below-mentioned variables (Table 2).

Table 2. Summary of the variables used in this study.

Variable	Description	Variable type
Patient number	Patient number in the clinic's software	Interval
Gender	Patient gender	Nominal
Age	Patient age at the time of SDF treatment	Ratio
Address	Patient address to show the distance travelled to the University clinic	Nominal
Medical conditions	Presence of any medical conditions	Nominal
Dentition	Primary/Permanent teeth involvement	Nominal
Anterior/Posterior	Anterior/Posterior teeth involvement	Nominal
Number of teeth	Number of teeth treated with SDF	Ratio
Diagnosis	Dental Caries, Early Childhood Caries (ECC), Molar Incisor Hypomineralization (MIH)	Nominal
Pulpal involvement	Pulpal status of the teeth involved	Nominal
Radiographic findings	To evaluate pulpal involvement or apical radiolucency	Nominal
DMFT/DMFS	DMFT/S Index based on (decayed, D), missing (missing, M) and filled (filled, F) Teeth (teeth, T) or surface (surface, S) in the permanent dentition	Ratio
dmft/dmfs	DMFT/S Index based on (decayed, D), missing (missing, M) and filled (filled, F) Teeth (teeth, T) or surface (surface, S) in the primary dentition	Ratio
ci/CI	Initial caries index	Ratio
Child's cooperation	Assessed using Frankl's behavioral Rating Scale to describe patient's compliance during SDF treatment.	Interval
Complications	Any complications reported during the SDF treatment	Nominal
Operator	Pediatric specialist, dentist, or post-graduate student	Nominal
Indications	Reason for choosing SDF treatment	Nominal

6.8. *Cross-Sectional Questionnaire-Based Analysis*

In order to assess the acceptability of SDF treatment in children, questionnaires were developed for both dentists and parents. These questionnaires were initially pilot tested with two paediatric dentists and five parents to ensure clarity and suitability for the intended audience. The pilot testing did not reveal any significant design flaws and the parents who participated did not report any difficulties in answering the questions. Minor adjustments were made to the structure, language and format of the questionnaires.

Study sample

- Parents' questionnaire: the sample size was calculated according to the initial results of the retrospective analysis (see Results 7.1). By assuming that around 400 patients received SDF annually, the sample size was calculated with population size = 400, confidence level 95% and a margin of error 20%, which, in turn, resulted in at least 23 participants to be included. Adding loss of responses due to missing data in the questionnaires (about 30%), a total sample size of 30 parents was determined.
- Dentists' questionnaire: all identified dentists using SDF at the University of Greifswald Paediatric Department were invited to participate in the study.

Survey questions

They surveys were written in German language and only participants who accepted participating in the study were included.

- Parents/caregivers

The primary investigator (RA) screened regular clinic attendees to identify eligible participants who are parents of patients scheduled to be treated with SDF and sequentially recruited 30 participants based on the inclusion criteria. Parents first received verbal and written information about the aim of the study and were informed that

participation was voluntary. Only parents who completed both the baseline and follow-up questionnaires were included in the study.

Two questionnaires were administered to parents after obtaining signed informed consent - one before and one week after SDF application. The first questionnaire consisted of 12 questions designed to collect demographic information (age, gender, education level) and to assess parents' perceptions of the SDF procedure in terms of their child's comfort, behaviour during application and treatment duration. These aspects were rated on a 10-point Likert scale, with 10 being "very satisfied". The follow-up questionnaire consisted of 14 open-ended and Likert scale questions. The first question was whether the parents had noticed any dark staining on the treated teeth and, if so, their opinion of it. Answers ranged from 'very acceptable' to 'very unacceptable'. Secondary questions explored parents' views on three key aspects of the treatment: aesthetics, pain/complaints and SDF as a treatment option for carious lesions. Some of the key statements included

1. **I feel the need for an aesthetic restoration as soon as possible.**
2. **I regret going for this treatment due to its dark discoloration of the teeth.**
3. **Toothbrushing has become much easier after the application of SDF.**
4. **I think SDF is a good treatment option to stop caries and I would consider this treatment again.**

- Dental practitioners

The dental practitioners included in the study were pediatric specialists or general dentists working at the Preventive and Pediatric Dentistry Department at the University of Greifswald. Also including the post-graduate students undergoing a 3-year Master (M.Sc.) program in Pediatric Dentistry. The procedures performed by the students are done under the supervision of specialists. The M.Sc. program includes a theoretical part along with practical training on all pediatric-related management techniques whether chair-side, under conscious sedation or general anesthesia. Among these procedures is the off-label use of SDF in children.

The questionnaire included 4 fill-in items regarding dentists' experience and qualifications and 12 Likert-scale statements aimed at exploring dentists' acceptance and experience with SDF. Possible responses ranged from "totally agree" to "totally disagree". To explore acceptance, dentists were asked if they considered SDF a good treatment option for ECC or avoided it due to the associated black staining. Some of the main statements included:

1. **I believe SDF is a good alternative to treating early childhood caries**.
2. **I use SDF for treating anxious children with caries.**
3. **I consider SDF before restorative therapy or general anesthesia.**
4. **I confidently use SDF based on the researched evidence for its effectiveness.**
5. **I had an experience with parents rejecting SDF treatment due to aesthetics.**

6.9. Statistical Analysis

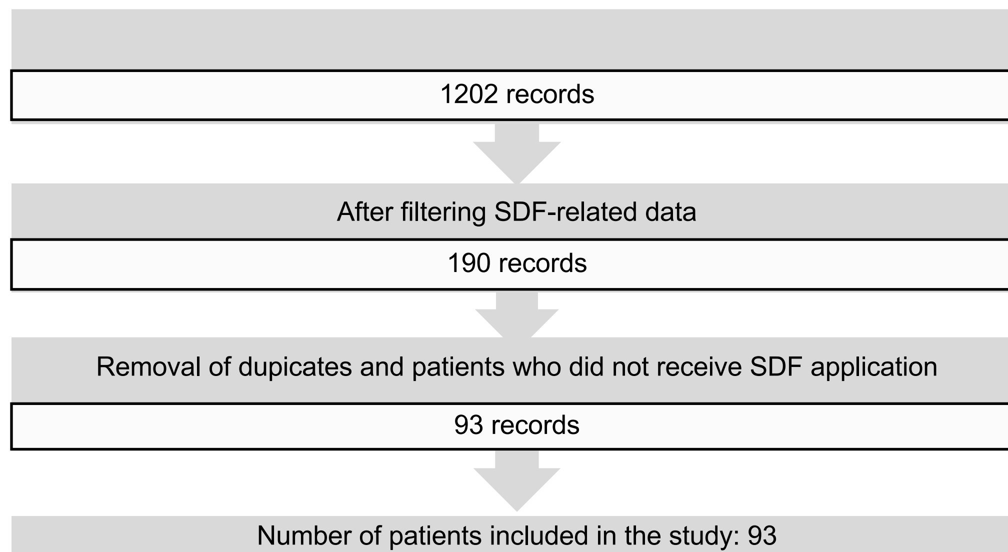
A Microsoft Excel (2020) spreadsheet including all variables required (Table 2) was designed for the purpose of this study. Patients' data were collected from the electronic patients' clinical records software (DAMPSOFT GmbH) and encoded. Statistical analysis was carried out using SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Mac, Version 25.0. Armonk, NY, USA: IBM Corp.). Descriptive statistics were applied to describe patient characteristics and conditions of treated teeth. Chi-square statistics were used to test relationships between categorical variables. Survival analysis using the Mantel–Cox method and a Kaplan–Meier curve was used to report mean time until treatment failure as well as the Log-rank test. A Mann–Whitney U test was performed to test the differences in the acceptance of SDF treatment. The level of significance was set at 0.05.

7. Results

7.1. Patient profiles and characteristics

Data from 1202 patients were initially retrieved and then filtered according to the inclusion criteria. Only patients with sufficient documentation who had attended at least one follow-up appointment were included. Resulting in a total of 93 patients collected for this study (Figure 5).

Figure 5. Flow diagram showing the retrieval process of the study sample.



The demographics and clinical characteristics are presented in Table 3. Patients' age ranged from 1 to 17 years (±5.3 years). A sum of 455 teeth were treated with an average of 4.9 teeth per patient. Most of the treated teeth were primary teeth (n = 418; 92%). Only 41 patients (44%) had a recent radiograph available within the last year, almost all (93%) showing carious lesions at the dentin level (ICDAS 4–6). A total of 52% of the patients had a very negative or negative cooperative level. Dental caries was the main reported diagnosis (98.2%), along with a few cases of hypersensitivity due to MIH (n = 8; 1.8%). Patients' mean d_3mft/D_3MFT was 6.3/2.5. The patients were treated by a postgraduate paediatric dentistry student (46.2%) or by a paediatric dental specialist (53.8%). Regarding the side effects of SDF application, only a few cases of sensitivity (7.5%) were

reported during the application of the product. Other than the black staining of the carious lesions (98%), no adverse effects were reported in this study.

Table 3. Demographics and clinical characteristics of the study sample.

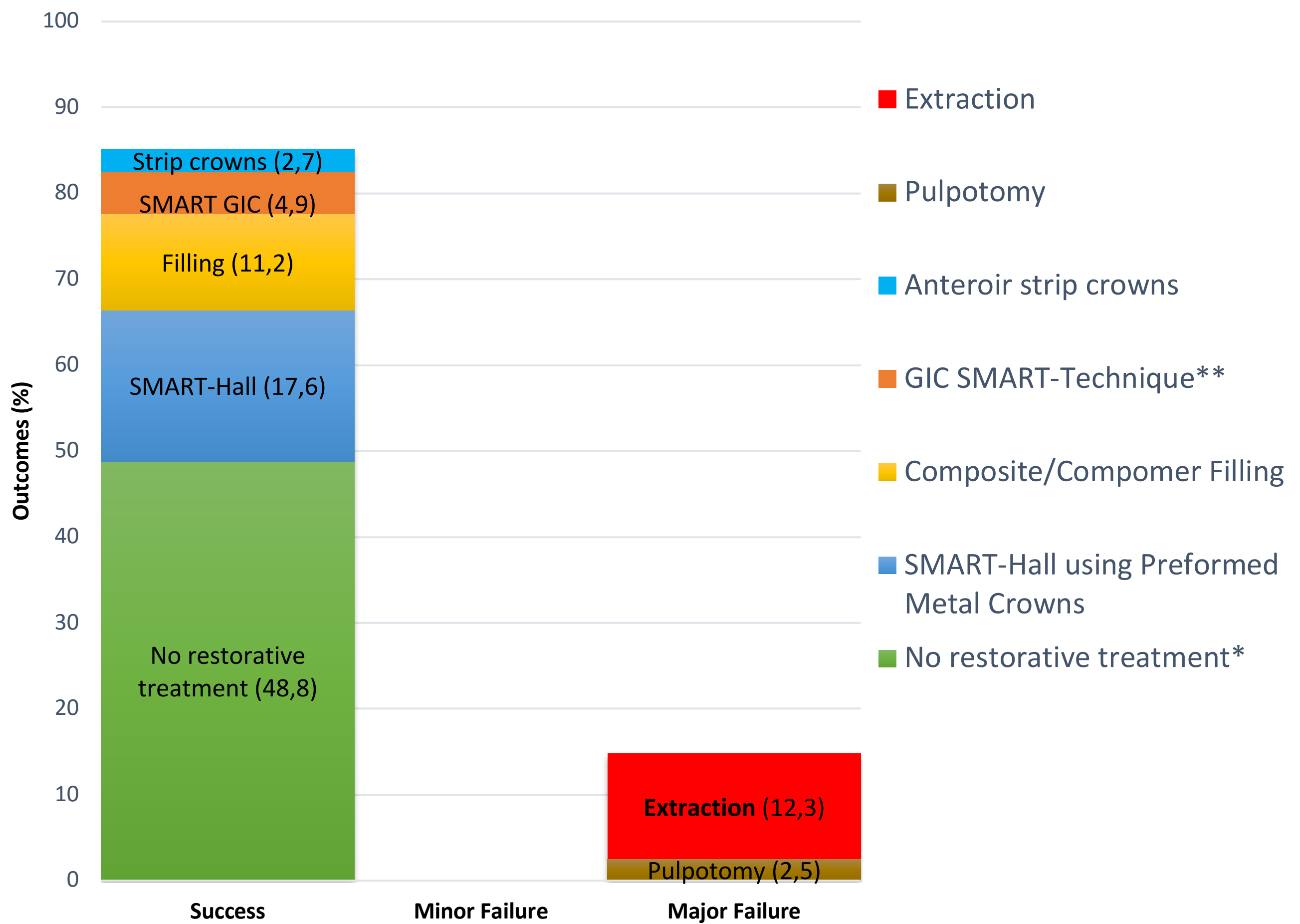
Characteristics (*n* = 93)		
Age, mean (SD)		5.3 years (2.9)
Gender, *n* (%)	Female	45 (48.4)
	Male	48 (51.6)
Address, n (%)	State local	90 (97)
	Non-local	3 (3)
Caries experience, mean (SD)	$d_3$mft	6.3 (4.1)
	d_3t	4.9 (3.9)
	D_3MFT	2.5 (3.7)
	D_3T	1.6 (2.8)
Medical history, *n* (%)	Medically unfit	13 (14)
	Medically fit	80 (86)

SD = standard deviation; d = decay; missing; f = filled; t = teeth.

7.2. Clinical efficacy and indication

The clinical efficacy of SDF treatment was evaluated according to the success/failure criteria (Figure 6). Patients were followed up for 2 years after SDF application (19.9; SD = 10.5 months). Overall, SDF treatment showed a success rate of 84.2%. There were 5 teeth (1.1%) presenting with minor failures and 67 teeth (14.7%) with major failures (p = 0.001). SDF was mainly used in primary and permanent carious teeth (n = 447). A few hypersensitive MIH permanent first molars (n = 8) were also treated with SDF. Out of the eight treated teeth, five required further restorative therapy due to persistent hypersensitivity, and one was extracted due to poor prognosis as part of a full mouth rehabilitation under general anaesthesia. Excluding MIH, carious treated teeth showed a success rate of 85.2%. Carious lesions were arrested and regularly checked up without further restorative treatment in two-thirds (57.2%) of the treated teeth. The other 42.8% of teeth were restored after lesion inactivation.

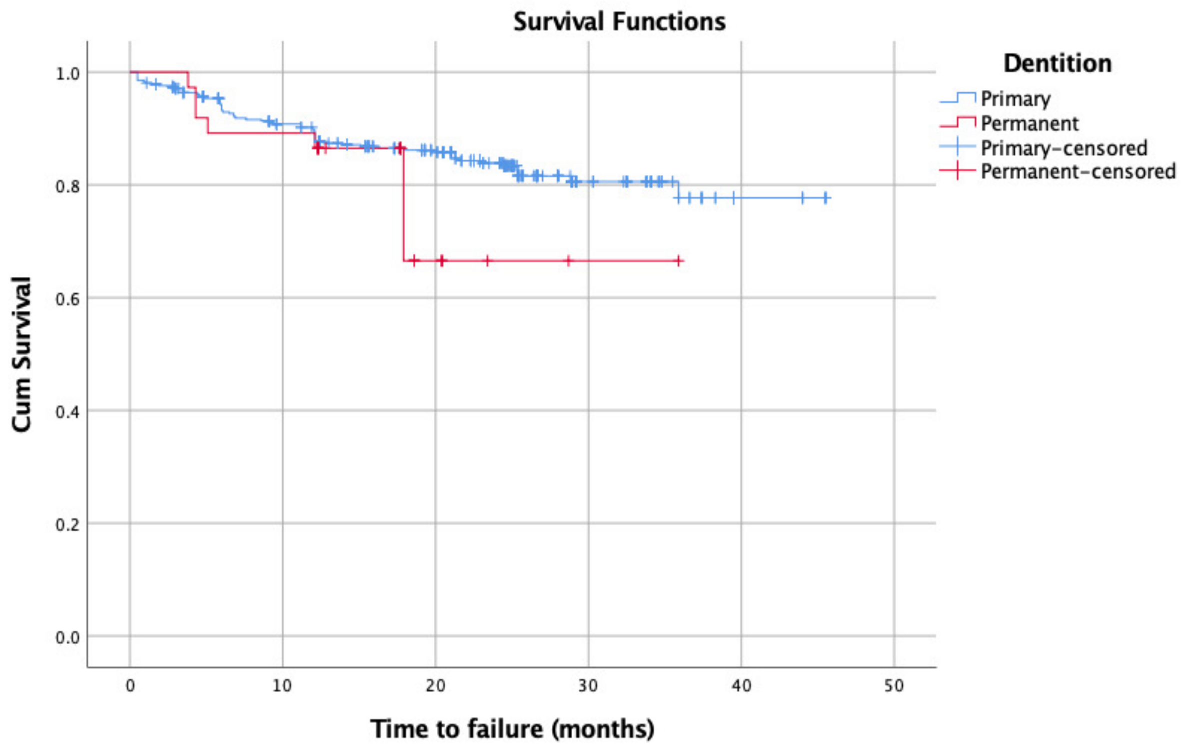
Figure 6. Treatment outcome of SDF-treated teeth due to dental caries only.



*Caries arrested; no signs/symptoms of irreversible pulpal pathology. Oral hygiene follow-ups done including bacterial plaque disclosing, tooth-brushing training, fluoride use, and application according to age, parental/patient active involvement, motivation, and reinforcement, etc. **Glass Ionomer Cement (GIC): Silver Modified Atraumatic Restorative Treatment (SMART).

Survival time for treated teeth was calculated from the first SDF application until the last check-up visit or until failure was reported. The mean survival time for primary and permanent teeth was 38.8 months (95% confidence interval 37.2 to 40.3) and 28.3 months (95% confidence interval 23.7 to 32.8), respectively. The log-rank test was done to compare the primary and permanent teeth in terms of time until failure and a Kaplan-Meier curve was created (Figure 7). No significant difference between both groups was found ($p = 0.19$). The results also showed no statistically significant difference when success/failure rates were compared according to several factors such as patient compliance, gender, primary/permanent dentition, or medical condition ($p > 0.05$).

Figure 7. Kaplan–Meier survival curve showing survival time of SDF-treated teeth until failure.



7.3. *Parents' acceptance and satisfaction*

Parents of regular patients attending for treatment were surveyed at the SDF application visit as well as at the follow-up visit. A total of 42 responses were initially collected. 30 participants then completed the follow-up questionnaire and were included in the study. The participating parent was mainly the child's mother (n = 27; 90%), with an average age of 37 years (±6.4 SD). SDF treatment was applied to the anterior teeth of 2 children (6.7%), the posterior teeth of 15 children (50%), and both the anterior and posterior teeth of 13 children (43.3%). The educational backgrounds of the parents ranged from secondary school (5%) to postgraduate education (19%), with roughly 46% having completed vocational training or an apprenticeship. The primary reason for the dental visit was dental caries (63%), followed by routine check-ups (27%) and pain (10%).

At the first visit, 70% of parents reported initial acceptance of the procedure, particularly regarding their child's comfort during the treatment. At the follow-up, 80% of parents observed dark staining on the treated teeth, yet approximately 70% rated the treatment as either very acceptable or acceptable. Notably, satisfaction was significantly higher for posterior teeth (95.2%) compared to anterior teeth (36.4%; $p < 0.001$). When asked about the necessity for aesthetic restorations, 43.3% of parents agreed while around 93% disagreed with the statement that they regretted the treatment due to the discoloration. Also, 97% agreed that they would support using SDF to halt caries progression. In general, parents expressed a high level of acceptance for the SDF treatment of caries (Table 4).

Table 4. Parents' acceptance of dark staining associated with SDF treatment.

	Anterior teeth	Posterior teeth
	n (%)	**n (%)**
1 (Very acceptable)	2 (18.2)	13 (61.8)
2 (Acceptable)	2 (18.2)	7 (33.4)
3 (Fair)	0 (0)	1 (4.8)
4 (Unacceptable)	4 (36.3)	0 (0)
5 (Very unacceptable)	3 (27.3)	0 (0)

Likert Scale (1–5) from very acceptable to very unacceptable of dark discoloration.

7.4. Dentists' experience and knowledge

Questionnaires were distributed to all dentists (n=18) working at the Department of Pediatric Dentistry at Greifswald University from November to December 2020. All the questionnaires distributed were filled out giving a response rate of 100%. The same questionnaire was also created as an online survey using Google Forms, to facilitate the distribution, and sent out via E-mail to more dentists working at the forementioned department (n=11). A total of 9 responses were collected giving a response rate of 82%.

In total, 27 responses were obtained. Among these, 56% (n=15) were pediatric specialists, 11% (n=3) dental practitioners, and 33% (n=9) post-graduate students, all practicing in the aforementioned department. Around 30% (n=8) of the participating dentists had more than 10 years of dental experience, 33% (n=9) more than 5 years of experience, and 37% (n=10) more than 2 years of experience. All of which had at least some experience with SDF use.

The majority of the participants (n=23; 85%) consider the use of SDF as a good treatment option for ECC, and 67% (n=18) would prefer it over other treatment options for children with ECC.

SDF is also considered an option by most participants (n=22; 81%) for treating caries in anxious children as it may gradually help improve patient behaviour. All participants, except one (96%) who "somewhat disagrees", believe that SDF can also be used to arrest caries until a restorative therapy is delivered or to "buy time" before the child is treated under general anesthesia.

Around 60% (n=16) agree that they confidently use SDF based on the evidence in research behind its effectiveness, and 52% (n=14) confidently use SDF based on their clinical experience. Table 5 shows a summary of the main findings obtained from the questionnaire.

Table 5. Dentists' opinions of SDF treatment.

Questionnaire Item		*n* (%)
Find SDF a good alternative to the treatment of early childhood caries.	Totally agree	20 (74.1%)
	Somewhat agree	3 (11.1%)
	Neither	3 (11.1%)
	Somewhat disagree	1 (3.7%)
	Totally disagree	0 (0%)
Prefer SDF over other options for the treatment early childhood caries.	Totally agree	9 (33.3%)
	Somewhat agree	9 (33.3%)
	Neither	8 (29.6%)
	Somewhat disagree	1 (3.7%)
	Totally disagree	0 (0%)
Use SDF treatment for anxious children with caries.	Totally agree	10 (37%)
	Somewhat agree	12 (44.4%)
	Neither	3 (11.1%)
	Somewhat disagree	0 (0%)
	Totally disagree	2 (7.4%)
Consider SDF before restorative therapy or general anesthesia.	Totally agree	21 (77.8%)
	Somewhat agree	5 (18.5%)
	Neither	0 (0%)
	Somewhat disagree	1 (3.7%)
	Totally disagree	0 (0%)
Confidently use SDF based on the researched evidence for its effectiveness.	Totally agree	16 (59.3%)
	Somewhat agree	9 (33.3%)
	Neither	2 (7.4%)
	Somewhat disagree	0 (0%)
	Totally disagree	0 (0%)
Had an experience with parents rejecting SDF treatment due to aesthetics.	Totally agree	1 (3.7%)
	Somewhat agree	9 (33.3%)
	Neither	6 (22.2%)
	Somewhat disagree	9 (33.3%)
	Totally disagree	2 (7.4%)

8. Discussion

8.1. Discussion of the methods

In this study, a retrospective analysis was implemented. Thus, data collection was based on the documentation recorded by the dentists in patient records. Although this could be considered a limitation to the study, it is noteworthy to emphasize that patient documentation at the Department of Pediatric Dentistry is done in a standardized manner using pre-set texts for each procedure, and with the possibility to add other comments and notes according to each case. Likewise, data collection for the purpose of this study (post-graduate research) was done using a systematic process, and in a standardized manner under constant guidance. Only data from patients with sufficient information were collected and in case of missing data (e.g.: child behavior level), the reported percentages were adjusted.

8.2. Study sample and characteristics

This study explored the use of SDF in terms of clinical efficacy (2-year follow-up) and acceptance by the dentists and parents of paediatric patients treated in Germany in a specialised university dental setting. SDF was primarily used to arrest active carious lesions in young patients (mean age = 5.3 years) presenting with high caries risk and experience (d_3mft/D_3MFT = 6.3/2.5) and low cooperation levels.

In Germany, 3-year-old children have a mean d_3mft level of 0.48 for the whole population [Basner et al., 2018]. Whereas in our study, the treated children showed around 13 times higher levels of caries experience than the average. Looking at the “d_3” component of the index alone shows that 78% of primary teeth are left untreated. In such cases, restorative therapy can only be delivered under dental general anaesthesia (DGA) due to the increased treatment need and the low cooperation at a young age. While treatment under DGA has shown high success rates in the medium term and improved oral health-related quality of life, it involves complications and risks, especially in young patients, that should be carefully considered. In addition to the economic burden placed on public health

systems due to the increased resources required. [Al-Eheideb et al., 2003; Spera et a., 2017; FDA Drug Safety Communication, 2016].

8.3. Discussion of the main results

In alignment with recent guidelines and evidence-based practices, this study employed non- or minimally invasive treatment strategies, particularly the use of SDF [Phantumvanit et al., 2018; Crystal et al., 2017b]. More than 450 teeth were treated, mostly being primary teeth (92%). After a 2-year follow-up, the success rate for carious teeth treated with SDF was high (> 85%). These results are in the range of international data, considering that several systematic reviews and an umbrella review have documented caries arrest rates for primary teeth ranging between 51% and 91% [Zaffarano et al., 2022; Seifo et al., 2019; Chibinski et al., 2017; Gao et al., 2016]. These studies compared the effectiveness of SDF with placebo, fluoride varnish, or atraumatic restorative treatments, considering factors such as treatment of anterior and posterior teeth, application frequency, and varying SDF concentrations, which account for the range in reported rates. Despite this variability, all reviews strongly support the effectiveness of SDF in arresting caries in children [Crystal and Niederman, 2019]. Consistent with this, the current study found that 57.2% of successfully treated teeth required no further treatment, while the remaining 42.8% were restored in follow-up visits, mostly using GIC (SMART technique) or the Hall technique (SMART-Hall).

Conversely, teeth classified as failures were those that exhibited pathological signs or symptoms indicating irreversible pulp deterioration. A significant number of these teeth required pulpotomy or extraction under dental general anesthesia (DGA). On average, the time from SDF application to DGA treatment was approximately 10.7 months or nearly a year. Even in such cases, SDF can be viewed as beneficial for delaying the need for DGA, allowing time to schedule the procedure and postulating that this delay potentially might have reduced the risks associated with performing DGA on young children [FDA Drug Safety Communication, 2023].

The use of SDF in dentistry is generally regarded as a safe procedure [Crystal, Niederman., 2019]. In the present study, apart from the dark staining of carious lesions,

no other adverse effects were observed. However, 7.5% of patients (7 individuals) experienced sensitivity during the application of the SDF solution. Most of these cases involved children under the age of 5 who exhibited a negative or very negative level of cooperation, which may explain their discomfort and adverse perception of the treatment.

The questionnaire administered to the dentists treating the patients in this study yielded a high response rate of 93%. The majority of respondents recognized SDF as a practical treatment option for ECC, especially for young children who experience dental anxiety or exhibit low compliance, as the procedure is straightforward. Similar perspectives have been noted among dental professionals in the UK [Seifo et al., 2020]. Moreover, nearly all participants reported using SDF to delay restorative procedures or treatments under general anesthesia, a practice also observed in surveys of pediatric dentists in the US [Antonioni et al., 2019].

Dark staining caused by SDF has been identified by many practitioners as a major barrier to its use [Seifo et a., 2020; Alajlan et al., 2020; Vollú et all., 2019; Magno et al., 2019]. In this study, a few dentists reported parents declining the treatment due to aesthetic concerns. Since SDF is relatively new in Germany, parental acceptance and satisfaction were explored through surveys conducted before and after treatment. Parents generally showed high acceptance, particularly for posterior teeth, and were satisfied with the short procedure time and child comfort. Similar findings were seen in U.S. studies [Clemens, Gold and Chaffin, 2018; Cernigliaro et al., 2019], whereas a study in Saudi Arabia reported higher disapproval [Alshammari et al., 2019], likely influenced by cultural perceptions since perception of aesthetics and beauty is subjective. Factors such as education, culture, and the child's cooperation level also impact acceptance [Magno et al., 2019]. Interestingly, acceptance increased when SDF helped avoid more invasive procedures like general anesthesia [Crystal et al., 2017].

Lastly, further research is needed to develop a clear treatment plan following SDF treatment. This includes longitudinal studies evaluating the success rates and longevity of direct restorative treatment after SDF application, such as GIC sealants and preformed metal crowns or the further inactivation of caries with multiple SDF applications

9. Strengths and Limitations

- To our knowledge, this is the first study to assess the use of SDF in Germany. The results support recent clinical research on SDF's effectiveness while offering new insights into its practical application and acceptance by healthcare providers and caregivers in the region.
- Evidence reported in this study corresponds to data from patients who were monitored for at least two years, strengthening the study's credibility and reflecting real-world clinical outcomes.
- The study's findings should be considered alongside its limitations. The effectiveness of SDF was evaluated through a retrospective analysis, which differs from a clinical trial and may not provide fully comparable results. Nevertheless, this approach captures long-term outcomes and prognoses for the treated teeth. One advantage of the retrospective method is that practitioners were unaware of being part of a study, reducing potential bias. The evaluation of treatment success was based on strict criteria, categorizing outcomes as either successful or minor/major failures.
- Dental professionals surveyed were affiliated with a university pediatric dentistry setting, which may limit the generalizability of the findings. Since SDF is not widely used in German dental clinics, future research should include practitioners from private clinics, where attitudes toward SDF may differ, and parents from varied clinical settings to provide a broader perspective.

10. Conclusion

In this study SDF was found to be effective in the long-term in treating young children with high caries risk and treatment needs with low compliance, which was perceived as an acceptable treatment by dental practitioners and parents equally. Treatment acceptance was higher in the posterior than in the anterior teeth among the parents and the dental practitioners treating these patients had an overall high level of knowledge and acceptance of the SDF material and its use. The disposal of such information benefits decision-making and treatment planning in the clinical practice. We can, therefore, conclude that, with proper diagnosis and sufficient awareness of dentists and parents, SDF can be beneficial for at-risk patients whose treatment could otherwise be very challenging.

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12. Publication

The results of this work have been published in a peer-reviewed article in the international open-access journal “Medicina” with an impact factor of 2.948 (2021).

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Article

Silver Diamine Fluoride Renaissance in Paediatric Dentistry: A 24-Month Retrospective and Cross-Sectional Analysis

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Abstract: *Background and Objectives:* Silver diamine fluoride (SDF) has been incorporated into the treatment of dental caries in children, mainly in countries with high caries prevalence. In Europe, however, SDF started to gain popularity during the COVID-19 pandemic. This study aimed to investigate the efficacy of SDF and to evaluate dentists'/parents' acceptance of SDF use in paediatric patients treated in a German university setting. *Materials and Methods:* A retrospective analysis of all patients treated with SDF between 2017 and 2020 was carried out. Only teeth with no reported clinical/radiographic evidence of irreversible pulpal inflammation were included. The outcome measures were success, minor failures (caries progression, reversible pulpitis) and major failures (irreversible pulpitis, abscess). The treatment acceptance by dentists and the parents of SDF-treated children was cross-sectionally evaluated using questionnaires. Descriptive statistics and Kaplan–Meier survival analysis were performed. *Results:* A total of 93 patients (mean age 5.3 ± 2.9 years) with 455 treated teeth (418 primary/91.9%; 37 permanent/8.1%) were included and followed up for up to 24 months (19.9 ± 10.5 months). SDF was used for dental caries (98.2%) and hypersensitivity relief on MIH teeth (1.8%). Most teeth did not show any failure (total success 84.2%). A total of 5 teeth (1.1%) showed minor failures, and 67 teeth (14.7%) showed major failures ($p = 0.001$). Success/failure rates were not affected by patient compliance, gender, dentition, or operator ($p > 0.05$). In total, 30 questionnaires were collected from parents (mean age 36.8 ± 6.4 years). SDF was applied on anterior ($n = 2/6.7\%$), posterior ($n = 15/50\%$) and anterior/posterior teeth ($n = 13/43.3\%$). At the 1-week follow-up, 80% of parents noticed black teeth discoloration. Treatment satisfaction was higher for posterior (95.2%) than for anterior teeth (36.4%; $p < 0.001$). In the 27 responses from clinicians, SDF was generally considered a viable option in paediatric dentistry ($n = 23$; 85%). *Conclusions*: SDF was found to be effective and well-accepted by parents and dentists for caries inactivation in a paediatric dentistry German university setting.

Keywords: dental caries; silver diamine fluoride; treatment outcome; paediatric dentistry; parents

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1. Introduction

Dental caries in children remain a global oral health issue to this day. Multiple risk factors have been associated with this issue, such as poor oral hygiene and dietary habits as well as altered oral bacterial flora. The increasing prevalence, especially in countries with low socio-economic status, present as a burden and challenge to its management. Hence, biological-based minimally invasive treatment strategies have been widely advocated in the recent literature [1]. First developed in the late 1960s, silver diamine fluoride (SDF) has been a research topic of interest, particularly in the last decade [2]. It has been thoroughly investigated and several systematic reviews have demonstrated its effectiveness in arresting

caries in primary teeth, showing up to 91% success rates with biannual application [3–5]. This led the World Health Organisation to list it as an essential medicine for the treatment of carious lesions [6]. SDF has been largely researched in countries with high caries prevalence and regions with limited access to dental care [7–9].

The growing evidence on its effectiveness has led to its adoption worldwide including, but not limited to, in Australia, Brazil, Hong Kong, Japan, and the United States [10]. On the other hand, in Europe, treatment with SDF has been very limited due to the lack of national guidelines and its restricted off-label use. It has been proposed as an alternative option for young children presenting with high caries levels or low cooperation for invasive restorative therapy. In this regard, the European Organisation for Caries Research (ORCA), the European Federation of Conservative Dentistry (EFCD) as well as the German Association of Conservative Dentistry (DGZ) published, in a recent consensus statement, a recommendation of high-strength that SDF can be successfully used in the treatment of ECC [11]. SDF became further widespread during the COVID-19 pandemic, as it is considered as a non-invasive, non-aerosol-generating procedure [10,12].

Considering the lack of research on SDF use in Europe, this study aimed to investigate the clinical efficacy and acceptance by dentists and parents of paediatric patients treated with SDF application in Germany in a university dental setting.

2. Materials and Methods

2.1. Ethical Approval and Study Outline

Ethical approval was obtained from the Research Ethics Committee of the University of Greifswald under protocol number BB-142/20. This study comprised two different designs: a retrospective analysis and a cross-sectional questionnaire-based analysis.

2.2. Retrospective Analysis

Electronic records of all patients treated with SDF at the Preventive and Paediatric Dentistry Department in the University of Greifswald, Germany were retrospectively collected and followed up to evaluate the effectiveness of SDF treatment.

Study sample and inclusion and exclusion criteria

All patients, irrespective of age or health status, without baseline clinical or radiographic signs/symptoms of pulpal/periapical pathology, who were treated with SDF at the University of Greifswald Paediatric Department between January 2017 and February 2020, and who had attended at least one follow-up appointment (until February 2022), were included in the study. Patient records with insufficient documentation were excluded.

Clinical procedure

The SDF product used was Riva Star® (SDI Limited, Victoria 3153, Australia), which includes two bottles that are applied sequentially: bottle/step 1 corresponds to 38% SDF solution and bottle/step 2 contains potassium iodide (KI) solution (to lower the risk of black staining). The tooth is first cleaned, and debris removed. Soft tissues are protected using cotton rolls and petroleum jelly. SDF solution is then applied on the carious lesion using a micro brush after drying the tooth. The treatment was performed in a chairside setting by 8 dentists, 5 of whom were paediatric dental specialists and 3 were postgraduate paediatric dentistry (PD) students with at least 2 years of working experience, all following the department's standard protocol for caries management in children and trained in treating children with SDF.

Outcomes

Recorded data comprised demographics (age, gender, address, medical status) and clinical baseline findings ($d_3$mft/s-D_3MFT/S index, clinical diagnosis, severity level of carious lesions using ICDAS index, radiographic and pulpal status, etc.). Outcome measures were assessed according to the last follow-up session using criteria modified from Innes et al. (2006) (Table 1) [13]. Data collection was based on the documentation obtained

from the dental records. Documentation following treatment at the Preventive and Paediatric Dentistry Department was completed in a thorough and standardised manner using pre-set text for each procedure with the possibility to add or change notes when needed. Only patients with the sufficient documentation necessary for the study were included. Similarly, data were collected and decoded by the main investigator (RA) and reviewed by at least one co-investigator each time in a standardised manner using a Microsoft Excel (2020) spreadsheet prepared for the purpose of this study with the above-mentioned variables.

Table 1. Assessment criteria for the outcome analysis of treated teeth considering the two indications for SDF use.

Success
Dental caries • Caries arrested (hardness/softness; lesion feels hard on gentle probing; characteristic SDF discoloration/black staining reported) and no further treatment required. • Caries arrested and tooth restored. • No clinical signs or symptoms of irreversible pulpal pathology. • Tooth exfoliated without minor or major failure. Dentin hypersensitivity (due to MIH) • Reported reduced MIH hypersensitivity, tooth not restored. • Reported reduced MIH hypersensitivity, tooth then restored.
Minor Failure
Dental caries • Caries progression (hardness/softness; soft/leathery lesion on gentle probing; partially achieved/no reported SDF discoloration/black staining). • Signs or symptoms of reversible pulpitis treated without requiring pulpotomy or extraction. Dentin hypersensitivity (due to MIH) • Hypersensitivity persisted and required other treatment without pulpotomy or extraction.
Major Failure
• Signs or symptoms of reversible pulpitis (no spontaneous pain) requiring pulpotomy. • Signs or symptoms of irreversible pulpitis (spontaneous/persistent pain) or dental abscess requiring pulpectomy or extraction.

2.3. Cross-Sectional Questionnaire-Based Analysis

Questionnaires were created to assess dentists' and parents' acceptance of SDF treatment in children. The created questionnaires were first pilot tested with two paediatric dentists and five parents to ensure that they were comprehensible and acceptable to the target groups. No major flaws in the design of the questionnaires were revealed and the participating parents did not report any difficulty in answering the questions. Minor changes regarding the questionnaire structure, language, and format were made.

Sample size calculation

For the dentists' questionnaire, all identified dentists using SDF at the University of Greifswald Paediatric Department were invited to participate in the study. However, for the parents' questionnaire, the sample size was calculated according to initial results of the retrospective analysis (see Section 3.1). By assuming that around 400 patients received SDF annually, the sample size was calculated with population size = 400, confidence level 95% and a margin of error 20%, which, in turn, resulted in at least 23 participants to be included. Adding loss of responses due to missing data in the questionnaires (about 30%), a total sample size of 30 parents was determined.

Study participants

Parents/caregivers

The main investigator (RA) screened regular clinic attendees for eligible patients and consecutively recruited 30 participants according to the inclusion criteria. Only parents

whose children were to be treated with SDF and who fully completed the first and follow-up questionnaires were included.

After obtaining a signed informed consent form, two questionnaires were distributed to the parents before and after one week of SDF application. The first questionnaire included a 12-item fill-in and Likert-scale questions covering participants' demographics and assessing parents' perception of the SDF procedure performed in terms of child comfort and behaviour during application and treatment duration. Meanwhile, the follow-up questionnaire consisted of 14-item fill-in and Likert-scale questions. The primary survey question was whether dark staining on the treated teeth was noticed by the parents or not, and if noticed, their opinion about it. Possible responses ranged from "very acceptable" to "very unacceptable". The secondary questions further explored parents' opinion of 3 main aspects related to the treatment: aesthetics, pain/complaints and SDF as a treatment option of carious lesions.

Dental practitioners

The dentists surveyed included paediatric dental specialists and post-graduate PD students all treating children on a regular basis. The questionnaire included 4 fill-in items regarding dentists' experience and qualifications and 12 Likert-scale statements aimed at exploring dentists' acceptance and experience with SDF. Possible responses ranged from "totally agree" to "totally disagree". To explore acceptance, dentists were asked if they considered SDF a good treatment option for ECC or avoided it due to the associated black staining.

2.4. Statistical Analysis

Statistical analysis was carried out using SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Mac, Version 25.0. Armonk, NY, USA: IBM Corp.). Descriptive statistics were applied to describe patient characteristics and conditions of treated teeth. Chi-square statistics were used to test relationships between categorical variables. Survival analysis using the Mantel–Cox method and a Kaplan–Meier curve were used to report mean time until treatment failure as well as the Log-rank test. A Mann–Whitney U test was performed to test the differences in the acceptance of SDF treatment. The level of significance was set at 0.05.

3. Results

3.1. Patient Profiles and Characteristics

The dental records of 1202 patients were initially retrieved. The data were filtered and assessed according to the inclusion criteria. In total, 93 patients had sufficient documentation and attended at least one follow-up appointment. The demographic and clinical characteristics are presented in Table 2.

Table 2. Demographics and clinical characteristics of the study sample.

Characteristics (n = 93)		
Age, mean (SD)		5.3 years (2.9)
Gender, n (%)	Female	45 (48.4)
	Male	48 (51.6)
Caries experience, mean (SD)	$d_3$mft	6.3 (4.1)
	d_3t	4.9 (3.9)
	D_3MFT	2.5 (3.7)
	D_3T	1.6 (2.8)
Medical history, n (%)	Medically unfit	13 (14)
	Medically fit	80 (86)

SD = standard deviation; d = decay; m = missing; f = filled; t = teeth.

The patients' age ranged from 1 to 17 years (±5.3 years). A sum of 455 teeth were treated with an average of 4.9 teeth per patient. Most of the treated teeth were primary teeth (n = 418; 92%). Only 41 patients (44%) had a recent radiograph available within the last year, almost all (93%) showing carious lesions at the dentin level (ICDAS 4–6). A total of 52% of the patients had a very negative or negative cooperative level. Dental caries was the main reported diagnosis (98.2%), along with a few cases of hypersensitivity due to MIH (n = 8; 1.8%). Patients mean $d_3$mft/D_3MFT was 6.3/2.5. The patients were treated by a postgraduate paediatric dentistry student (46.2%) or by a paediatric dental specialist (53.8%). Regarding the side effects of SDF application, only a few cases of sensitivity (7.5%) were reported during the application of the product. Other than the black staining of the carious lesions (98%), no adverse effects were reported in this study.

3.2. Clinical Efficacy and Indication

After 2 years of SDF application (19.9; SD = 10.5 months), follow-up data were collected, and the outcome of the treatment was evaluated according to the success/failure criteria (Table 3). The SDF treatment showed an overall success rate of 84.2%. There were 5 teeth (1.1%) presenting with minor failures and 67 teeth (14.7%) with major failures (p = 0.001). Besides dental caries, SDF was also used in the treatment of MIH-associated hypersensitivity in permanent first molars. Out of the eight treated permanent first molars, five required further restorative treatment due to persisted hypersensitivity, and one was extracted under general anaesthesia. Excluding MIH, the success rate of treated teeth due to dental caries was 85.2% with around two-thirds (57.2%) of carious teeth arrested, but not restored. The other 42.8% of teeth were restored after lesion inactivation.

Table 3. Treatment outcome of SDF-treated teeth due to dental caries only.

Outcomes *n* (%)		**Treatments Performed**	***n* (%)**
Success * 381 (85.2)	No restorative treatment performed 218 (57.2)	Further follow-ups **	218 (48.8)
	Further restorative treatment performed 163 (42.8)	SMART-Hall using PMC	79 (17.6)
		Filling (Composite/Compomer)	50 (11.2)
		SMART-Technique with GIC	22 (4.9)
		Anterior strip crowns	12 (2.7)
Minor Failure	Caries progression/Secondary caries 0 (0)		
Major Failure 66 (14.8)	Irreversible pulpitis/Abscess 66 (100)	Extraction	55 (12.3)
		Pulpotomy	11 (2.5)
Total			447

* Caries arrested; no signs/symptoms of irreversible pulpal pathology. ** Oral hygiene follow-ups involve bacterial plaque disclosing, tooth-brushing training, fluoride use, and application according to age, parental/patient active involvement, motivation, and reinforcement, etc. Glass Ionomer Cement (GIC): Silver Modified Atraumatic Restorative Treatment (SMART). SMART-Hall: after SDF application, teeth are restored using preformed metal crowns (PMC).

After SDF application, the mean survival time for primary and permanent teeth was 38.8 months (95% confidence interval 37.2 to 40.3) and 28.3 months (95% confidence interval 23.7 to 32.8), respectively (Figure 1). The log-rank test was run to compare the primary and permanent dentition in terms of time until failure. No significant difference between both groups was found (p = 0.19). The results of the study were not statistically significant when success/failure rates were compared according to patient compliance, gender, dentition, or medical condition ($p > 0.05$).

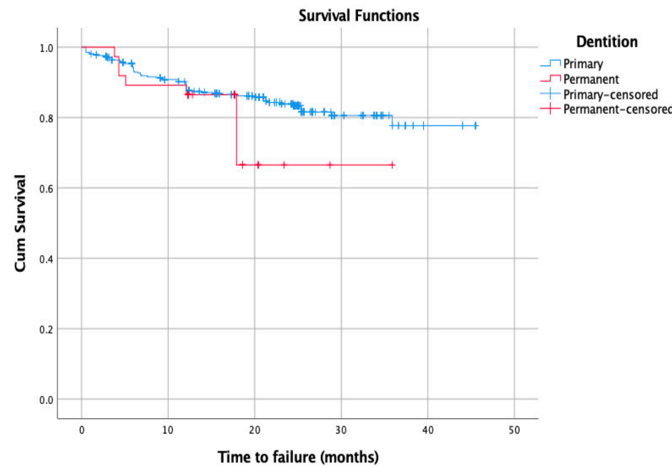

Figure 1. Kaplan–Meier survival curve showing survival time of SDF-treated teeth until failure.

3.3. Parents' Acceptance and Satisfaction

Initially, 42 responses were collected. In total, 30 participants fully completed the follow-up questionnaire and were included in the study. The participant parent was mainly the mother of the child (n = 27; 90%) with a mean age of 37 years (±6.4 SD). SDF treatment was used on anterior teeth in 2 children (6.7%), posterior teeth in 15 children (50%), and both anterior and posterior in 13 children (43.3%). The parents had varying educational backgrounds from secondary school (5%) up to postgraduate studies (19%), with around 46% of parents having completed an apprenticeship, i.e., a vocational training programme. Among other reasons like regular check-up (27%) and pain (10%), the main reason behind the dental visit was dental caries in 63% of the participants.

At the first visit, there was an overall acceptance (70%) of the procedure in terms of child comfort. At the follow-up, 80% of the parents noticed dark staining on the treated teeth but around 71% assessed the treatment received as very acceptable or acceptable. However, satisfaction with treatment was higher for posterior teeth (95.2%) than for anterior teeth (36.4%; $p < 0.001$). When asked about the need for an aesthetic restoration, 43.3% responded with 'agree'. Around 93% responded with 'disagree' when asked if they regret receiving the treatment due to its discoloration and 97% chose 'agree' for using SDF to arrest caries. Overall, there was high acceptance of SDF treatment of caries among the participating parents (Figure 2).

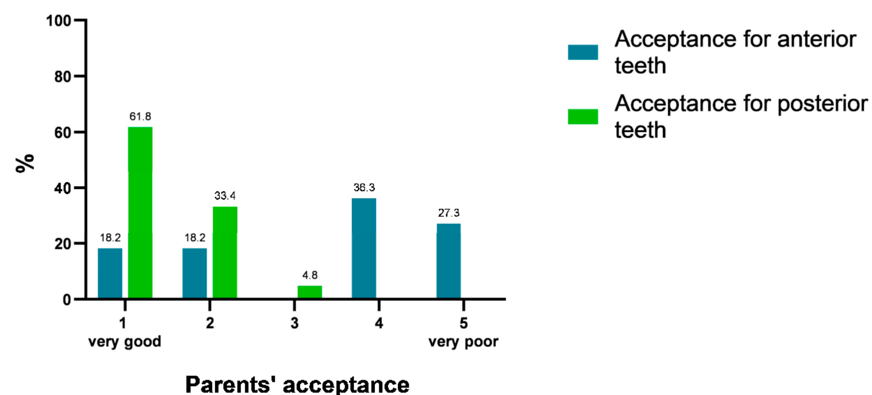

Figure 2. Parents' acceptance of dark staining associated with SDF treatment. Likert Scale (1–5) from very good to very poor acceptance of dark discoloration.

3.4. Dentists' Experience and Knowledge

In total, 27 responses were obtained. Among these, 56% (n = 15) were paediatric specialists, 11% (n = 3) dental practitioners, and 33% (n = 9) post-graduate students, all treating paediatric patients on a regular basis.

All participants in this study, expect one, confirmed their awareness of the SDF protocol. Around 60% (*n* = 16) of the respondents agreed that they confidently use SDF based on the researched evidence for its effectiveness. The importance of obtaining a consent form from the parents was also confirmed by all participants.

Most of the participants (*n* = 23; 85%) consider the use of SDF as a good treatment option for ECC, and 67% (*n* = 18) would prefer it over other treatment options for children with ECC, as well as for the treatment of carious lesions in anxious/low cooperative children (*n* = 22; 81%). All participants, except one (96%) who "somewhat disagrees", believe that SDF can be considered as an interim procedure to arrest carious lesions and win time until a restorative therapy can be delivered or until the child can be treated under general anaesthesia. Table 4 shows a summary of the main findings obtained from the questionnaire.

Table 4. Dentists' opinions of SDF treatment.

Questionnaire Item		*n* (%)
Find SDF a good alternative to the treatment of early childhood caries.	Agree	20 (74.1%)
	Somewhat agree	3 (11.1%)
	Neither	3 (11.1%)
	Somewhat disagree	1 (3.7%)
	Disagree	0 (0%)
Prefer SDF over other options for the treatment early childhood caries.	Agree	9 (33.3%)
	Somewhat agree	9 (33.3%)
	Neither	8 (29.6%)
	Somewhat disagree	1 (3.7%)
	Disagree	0 (0%)
Use SDF treatment for anxious children with caries.	Agree	10 (37%)
	Somewhat agree	12 (44.4%)
	Neither	3 (11.1%)
	Somewhat disagree	0 (0%)
	Disagree	2 (7.4%)
Consider SDF before restorative therapy or general anesthesia.	Agree	21 (77.8%)
	Somewhat agree	5 (18.5%)
	Neither	0 (0%)
	Somewhat disagree	1 (3.7%)
	Disagree	0 (0%)
Confidently use SDF based on the researched evidence for its effectiveness.	Agree	16 (59.3%)
	Somewhat agree	9 (33.3%)
	Neither	2 (7.4%)
	Somewhat disagree	0 (0%)
	Disagree	0 (0%)
Had an experience with parents rejecting SDF treatment due to aesthetics.	Agree	1 (3.7%)
	Somewhat agree	9 (33.3%)
	Neither	6 (22.2%)
	Somewhat disagree	9 (33.3%)
	Disagree	2 (7.4%)

4. Discussion

This study explored the use of SDF in terms of clinical efficacy (2-year follow-up) and acceptance by the dentists and parents of paediatric patients treated in Germany in a specialised university dental setting. SDF was primarily used to arrest active carious lesions in young patients (mean age = 5.3 years) presenting with high caries risk and experience ($d_3$mft/D_3MFT = 6.3/2.5) and low cooperation levels.

Regarding the caries experience of treated patients ($d_3$mft/D_3MFT of 6.3/2.5), these figures are particularly high in comparison to average values for children in primary and permanent dentition in Germany. For 3-year-olds, a weighted mean $d_3$mft value of 0.48 has

been reported [14]. However, in the present study, this group presented almost 13 times higher $d_3$mft levels than the average value for the whole population. In addition, for the whole sample the "d_3/D_3" component of the $d_3$mft/D_3MFT index corresponded to 78% in primary teeth and 65% in permanent teeth of the whole caries experience. Considering the high treatment need of the whole sample, as well as the limited ability to cooperate with dental procedures at a young age, without SDF, the only likely treatment option would have been treatment under dental general anaesthesia (DGA). Although the clinical success of dental procedures under DGA is considered very high in the medium-term, this procedure increases the health risk for young patients as well as the economic burden for public health systems [15–17].

The selected caries management modality in this study followed recent guidelines and evidence-based recommendations on the use of non/minimally invasive treatment modalities like SDF [18,19]. In total, 455 teeth were treated, most of which were primary teeth (92%). An overall success rate of 84.2% of SDF-treated teeth after 2-year follow-up was observed. Excluding MIH teeth, the success rate of treated teeth increases to 85.2%. Several systematic reviews and an umbrella review have reported caries arrest rates ranging from 51% to 91% in primary teeth [20–23]. The studies included assessed the effectiveness of SDF in arresting carious lesions in children in comparison to a placebo, fluoride varnish, or the use of atraumatic restorative treatment, including anterior and posterior teeth, annual or biannual application and with varying concentrations of SDF. This explains the wide range reported according to each study and its setting. However, all systematic reviews agree that there is strong evidence for the efficacy of SDF in arresting carious lesions in children [24]. Similarly, the present study reported that 57.2% of the successfully SDF-treated carious teeth did not require any further treatment/restoration. The rest (42.8%) were further restored at subsequent visits mostly with GIC (SMART-Technique) or the Hall technique (SMART-Hall).

On the other hand, carious teeth categorised under failure were teeth that developed pathological signs/symptoms of irreversible pulp deterioration. Many of these teeth had to be treated with pulpotomy/extraction under DGA. The mean time after SDF application until DGA treatment was almost 1 year (10.7 months). So, even in these cases, SDF may be considered beneficial to buy time until an appointment for DGA could be arranged or to reduce the implied risks of DGA at young ages [17].

In this study, SDF was mainly used for the treatment of carious lesions; however, attempts to reduce dental hypersensitivity using SDF were also seen in a few cases of MIH. Since SDF is a dentin-desensitizing agent, its use in reducing dentin hypersensitivity associated with MIH is not novel [25]. The number of MIH-treated teeth in this study was small (n = 8) and most teeth required further restorative treatment to reduce hypersensitivity. In addition, due to the per se limitations of retrospective analyses, the severity of hypersensitivity and the degree of MIH could not be accurately reported in this study. It is therefore difficult to draw conclusions on the effectiveness of SDF in MIH-diagnosed teeth. However, one clinical trial has recently reported significant reductions in hypersensitivity following the application of SDF and SMART sealants on MIH teeth for up to one year [26].

Other than the dark staining of the carious lesions, no adverse effects were reported. In seven patients (7.5%), sensitivity upon application of the SDF solution was reported. Most of these patients were under 5 years of age and with a very negative or negative level of cooperation. This could explain the difficulty faced by the child receiving the treatment and perceiving it negatively. While SDF is biocompatible and safe to use [21], its direct application to vital pulp has been shown to cause pulpal necrosis [27]. Therefore, correct diagnosis is imperative prior to treatment with SDF in deep carious lesions.

A high response rate of 93% was obtained from the questionnaire distributed to the dentists who treated the patients in this study. Most participants considered SDF a viable treatment option for ECC, especially for young children presenting with dental anxiety and low compliance, since it is a simple procedure. Dental professionals in the UK have also reported similar views [28]. Also, almost all participants used SDF to buy time prior to

restorative therapy or treatment under DGA. This opinion was also reported in a survey of paediatric dentists in the US [29]. Similar minimally invasive procedures for the treatment of caries in children, such as the Hall technique using preformed metal crowns and non-restorative caries control, were also found to be easy procedures for dentists and favoured by the children [30].

However, the dark staining side effect associated with SDF was reported by many practitioners as the main barrier to its use [28,31–33]. In this study, few dentists reported parents rejecting this treatment option due to aesthetic concerns. It was, therefore, crucial to explore parents' acceptance and satisfaction with SDF, since this product has been recently introduced and is not the most common treatment modality in Germany. Parents of treated children were surveyed prior to and after the application of SDF. Overall, parents showed a high acceptance of the procedure in terms of treatment time and child comfort and the majority assessed the treatment received as satisfactory with higher acceptance rates for posterior than for anterior teeth. A similar pattern was found in other studies that interviewed parents in the U.S. regarding their opinion of the discoloration following treatment with SDF [34,35], whereas a study from Saudi Arabia showed high disapproval rates, although the parents were interviewed and presented with photos and scenarios without the actual use of SDF [36]. It is important to note that the perception of aesthetics and beauty is subjective and influenced by several factors such as age, level of education and culture [37]. Child-related factors, such as the location of the tooth and cooperation level of the child, also play a role. One study reported high disapproval rates; however, when more advanced behavioural techniques such as DGA were avoided by treatment with SDF, the acceptance rates increased [38].

The results reported in this study should be interpreted alongside its limitations. The effectiveness of SDF treatment was evaluated by performing a retrospective analysis. While comparing results from a retrospective study to those of a clinical trial cannot be considered completely valid, the findings from this study represent long-term outcomes and the prognosis of the treated teeth after SDF application. An advantage of such a study is that the patients recruited have been regularly treated and the results are then assessed without pressure on practitioners being aware of participating in a clinical study. In addition, the analysis was carried out under the strict evaluation of the treated teeth using pre-set criteria determining the levels of success, minor or major failures. The surveying of dental professionals included participants employed or part of a post-graduate program at a university paediatric dentistry department; this may pose a concern as the findings cannot be generalised.

Lastly, future efforts should aim to incorporate different remineralising agents in addition to fluorides. A proactive action could be necessary to reduce the incidence of caries in children using products, such as substances based on biomimetic hydroxyapatite, that are showing similar potential in remineralisation [39]. Also, further research is needed to develop a clear treatment plan following SDF treatment. This includes longitudinal studies evaluating the success rates and longevity of direct restorative treatment after SDF application, such as GIC sealants and preformed metal crowns or the further inactivation of caries with multiple SDF applications.

5. Conclusions

To the best of our knowledge, this is the first time the use of SDF has been assessed in Germany. The findings of this study give an overview of the treatment of SDF in children and its acceptance by parents and dental practitioners. SDF was found to be effective in treating young children with high caries risk in the long-term, which was perceived as acceptable by dental practitioners and parents equally. We can, therefore, conclude that, with proper diagnosis and sufficient awareness of dentists and parents, SDF can be particularly beneficial for at-risk patients whose treatment could otherwise be very challenging.

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Data Availability Statement: The data are contained within the article. Further inquiries can be directed to the corresponding author.

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