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Research Article

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Comparative Evaluation of Giomer Varnish Versus Fluoride Varnish As Desensitizing Agents Among a Group of Children with Molar Incisor Hypomineralization: A Randomized Clinical Trial

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ABSTRACT

Background: Dentin hypersensitivity in children with Molar incisor hypo mineralization (MIH) causes transient sharp pain, adversely affecting oral health- related quality of life (OHRQoL). This research aimed to illustrate the effect of Giomer varnish versus Fluoride varnish on hypersensitivity in children with MIH over 4 weeks.

Methodology: Eighty-four children from 8 to 10 years old with a molar incisor hypomineralized hypersensitive permanent first molar were enrolled in the randomized controlled trial study, randomly allocated into two groups, Group I is the experimental group; subjects received Giomer varnish PRG BARRIER COAT as a desensitizing agent. While, group II is the control group, subjects received BIFLOURID 10 varnish as a desensitizing agent. SCHIFF scale was used to assess hypersensitivity to evaporative stimulus while the WONG-BAKER face pain rating scale was used to assess hypersensitivity to thermal and evaporative stimulus. OHRQoL was evaluated before and after treating hypersensitivity using the Arabic version of the Child Perception Questionnaire from 8 to 10 years, with follow up period 4 weeks.

Results: The statistical analysis revealed significant changes between the two groups for the evaluation of pain to evaporative stimulus using face pain rating scale after first week a statistically significant improvement in hypersensitivity was shown in the experimental group. Another significant difference arose between groups in first and second weeks in group 1 after evaluating pain to evaporative stimulus using SCHIFF scale. Evaluating pain response to thermal stimulus showed significant difference in favor to experimental group immediately, and a week after treatment. Regarding OHRQoL, a significant difference between two groups was also noticed with greater improvement in the experimental group.

Conclusions: The Giomer varnish showed significantly greater immediate and sustained reduction in dentin hypersensitivity to both evaporative and thermal stimuli compared to the BIFLOURID varnish, improving Oral Health Related Quality of Life (OHRQoL), Therefore the newly introduced Giomer varnish could be a promising desensitizing agent for children suffering from increased hypersensitivity due to MIH.

Keywords: Hypersensitivity, Molar Incisor Hypomineralization, varnish, desensitizing agents, oral health-related Quality of life, pediatric dentistry.

This clinical trial was registered at [ClinicalTrials.gov] under registration number [NCT05542667] on [13/9/2022].

BACKGROUND

Enamel formation is a very sensitive biological process, and any disturbance to the ameloblasts, the cells that produce enamel, can trigger an enamel defect. This may result in fragile and underdeveloped enamel or a normal volume of enamel with inadequate mineralization, depending on the stage of the ameloblasts' life cycle disrupted. When discussing insufficient mineralization, it can incorporate enamel defects like Molar Incisor Hypomineralization (MIH), Hypomineralized Second Primary Molar (HPSM), and Deciduous Molar Hypomineralization (DMH) [1].

In comparison with sound teeth, those with enamel defects demonstrate poorly defined prism sheaths and a diminished content of hydroxyapatite crystals. Consequently, the hypomineralized enamel exhibits lower mechanical characteristics, such as elasticity and hardness, than normal enamel. Additionally, the enamel affected by these conditions demonstrates higher levels of proteins, including serum albumin, alpha-1 antitrypsin, antithrombin III, type I collagen, and ameloblastin, which hinder the growth of hydroxyapatite crystals, leading to reduced enamel quality minerals [1].

The prevalence of Molar Incisor Hypomineralization differs but approximately 27.4% of all individuals with MIH will require intervention to restore teeth for daily functional use. Therefore, with approximately 5 million new cases of MIH identified/diagnosed annually, there are approximately 240 million existing MIH cases without treatment; many are untreated, in countries with lower socioeconomic status with a global incidence of MIH equal to approximately 14.2% [2].

Hypersensitivity, decay following eruption, and other dental problems that are associated with MIH present a variety of difficult clinical challenges. Furthermore, children with MIH experience poor aesthetics and impact their health and well-being through reduced quality of life (QoL). There are a number of challenges involved in treating MIH-affected teeth for clinicians, such as how to manage pain, what restoration material to use, and where to finish the borders of the restoration [3].

Casein-derived products, as well as fluoride varnishes (FVs), are now regarded as an effective protective and reparative measure when treating MIH. Fluoride Varnish promotes enamel remineralization through the encouragement of calcium and phosphate ions from within the tooth, which increases enamel resistance to caries and sensitivity, while also creating a temporary barrier on the surface of each compromised site to slow enamel degradation and enhance the uptake of fluoride by the tooth's enamel over time[4].

Casein phosphopeptide-amorphous calcium phosphate (CPP-ACP), which are casein-derived materials, have also been found useful for managing MIH. With respect to the management of MIH, CPP-ACP maintains a sufficient level of calcium and phosphate ions at the surface of the tooth such that the remineralization process is optimized and ongoing enamel breakdown is prevented. Together, casein-derived products and FVs will provide a complete approach to halting the progression of MIH and assisting with the restoration of the structural integrity of affected teeth [4].

One of the newest treatment options, S-PRG/Giomer technology, is an approach that features multi-ionic trilaminar glass particles, called S-PRG (surface pre-reacted glass-ionomer “PRG”). As a xerogel, its outer porous layer helps release multiple ions, including fluoride, strontium, silicate, aluminum, boron, and sodium. In the commercial market, it's introduced as PRG Barrier Coat, a light-cured varnish used as an adhesive coating layer. When smeared to the enamel surface, it's principally used as a dentin hypersensitivity material and to remineralize areas prone to dental caries [5].

Molar Incisor Hypomineralization is considered a challenge for patients, parents, and even pediatric dentists. Many treatment options have been proposed, including Giomer varnish, which is a newly introduced product to the market and has shown many superior results. Due to its superior properties, it requires further research, especially regarding its use in pediatric dentistry, as there are currently only a few studies conducted on pediatric patients. The manufacturer introduced the PRG BARRIER COAT as a desensitizing agent. Therefore, this study focused on comparing the effects of the newly introduced Giomer varnish versus the conventionally used fluoride varnish in treating hypersensitivity in MIH patients.

MATERIALS AND METHODS

Study design

This was a randomized, double-blind, two-parallel-arm clinical trial at Cairo University's Faculty of Dentistry. The research plan adhered to the guidelines instructed in the Consolidated Standards of Reporting Trials (CONSORT) statement (**Figure 1**).

The following published trial adheres to the CONSORT guidelines for reporting.

Ethical approval and trial registration

The Ethical Committee, Faculty of Dentistry, Cairo University, revised and approved the work protocol for its scientific content and compliance with research ethics and human subject

regulations (Code: 17123). This clinical trial was registered at [ClinicalTrials.gov] under registration number [NCT05542667] on [13/9/2022].

Sample size calculation

A power analysis was organized to have adequate power to employ a statistical test of the null hypothesis that there is no difference between tested groups. By assuming α level of (0.05) i.e. power=80% and an effect size (d) of (0.682) estimated based on the findings of past research [1] and on expert's opinion; the predicted sample size (n) was found to be 35 cases/group (a total 70 cases). Sample size was raised by (20%) to account for possible dropouts to be 42 cases/group (a total 84 cases). Sample size calculation was conducted *via* PS Power and Sample Size Calculations version 3.1.2.

Participant eligibility criteria

All participants were examined and enrolled in this study according to predetermined inclusion and exclusion criteria was demonstrated in **Table (1)**

Recruitment and informed consent

Personal, dental, and medical histories of each participant were recorded prior clinical exams. All participants had comprehensive study information about goals, methods, potential benefits/risks, expected duration of participation, and safety measures. Guardians of the eligible subjects were then needed to sign an Arabic informed consent, authorized by Cairo University's Faculty of Dentistry Research Ethical Committee (REC), describing the trial's ethical considerations and confirming voluntary contribution.

Group allocation

Contributors were randomized into two groups - Group I (PRG barrier coat) and Group II (Bifluorid 10 Varnish).

Randomization

The subjects were randomly assigned to receive the treatment, either Giomer varnish or Fluoride varnish. using a random order generator (<http://www.random.org/>) to apply random

sequencing of the patients into the intervention's groups with allocation ratio 1:1 according to block randomization.

Allocation concealment

Folded papers carrying information about which intervention to be used and to which tooth, were packed in opaque sealed envelopes. Then, these envelopes were delivered to the operator by the patients.

Blinding

Double- blinded study, the operator could not be blinded due to the nature of the study, but Participants and the statistician were blinded towards agents used in the study to avoid reporting bias.

The CONSORT flow diagram illustrates the numbers of participants assessed for recruitment, eligibility, allocation, randomization, and analysis (**Figure 1**).

Materials

The materials applied in this study were Giomer varnish, PRG Barrier coat by Shofu PRG Barrier Coat (Shofu Inc., Kyoto, Japan) and Fluoride varnish, Biflourid 10 by Voco Bifluorid 10 (VOCO GmbH, Cuxhaven, Germany). A full detailed description of the materials is illustrated in **Table (2)**

Clinical procedure

Patients' preparation

Personal info including name, age, phone number, address, medical history, and dental history were collected by the operator from each patient in special forms. History of chief complaint was obtained.

The teeth were examined tentatively *via* a diagnostic mirror and probe for existence of extensive caries, large or old restoration, pulp exposure, and soft tissue. Tooth mobility as well as percussion and palpation were done to confirm that no mobility or pain on palpation were

present, as well as no or slight discomfort on percussion. Visual inspection of the face and neck was performed to exclude the presence of any swellings.

Teeth with a final diagnosis of Molar Incisor Hypomineralization were chosen for the study based on the History of chief complaint reporting pain with hot or cold stimulus. All harms and benefits of the treatment were explained to the parents and post -treatment instructions were explained and informed consent was signed. After enrollment of patients, pre-clinical intra-oral photographs were taken prior to treatment (**Figure 2**).

Dentin hypersensitivity assessment

Evaporative stimulus

All included teeth were assessed for pain due to an evaporative stimulus applying a triple syringe (**Figure 3**). The air is focused perpendicular to the teeth and persists about 2 mm away for 3 seconds. Children are instructed to raise their fingers or hands if they experience any distress, and then the pain response is estimated using the Schiff scale demonstrated in **Figure (4)** and Wong-Baker Faces Pain Scale illustrated in **Figure (5)** [6].

Thermal stimulus

An anesthetic carpule, refrigerated at 4°C for at least 24 hours, was put in contact with the tooth for 1 to 5 seconds (**Figure 3**), depending on the child response. Pain was assessed with Wong baker FACES scale (**Figure 5**) [7].

Oral health-related quality of life assessment

Oral health-related quality of life was evaluated in this study by employing the Arabic version of CPQ from 8 to 10 years (**Figure 6**).

Preparation phase

Prohylaxis

Pre-treatment prophylaxis was performed *via* a fluoride-free paste (Quartz, Dharma Research Inc., USA) applied with a nylon polishing brush (Microdont, São Paulo, SP, Brazil) attached to a low-speed handpiece (Contra T4 HP, Sirona, Germany). The tooth surfaces were

then thoroughly cleaned with an air–water spray and gently dried with cotton pellets to get rid of debris and moisture, confirming optimal surface preparation.

Isolation

Isolation was performed *via* rubber dam application on selected molar (KSK molar clamp no 202, Dentsply, Japan) (**Figure 3**).

Treatment phase

Material application

For Group I, Giomer varnish was applied once during the initial treatment visit. One drop of PRG Coat Barrier ACTIVE was added to the container supplied in the kit containing PRG Coat Barrier BASE. The components were mixed using the disposable mixing tip provided by the manufacturer. A thin layer was then applied and set undisturbed for 3 seconds as stated by the manufacturer's guidelines. Finally, the varnish was light-cured using a Woodpecker curing light (Woodpecker Medical Instrument Co., Guilin, China) (**Figure 7**) [7].

For Group II (control group), the seal of the single-use Bifluorid 10 vial was pierced via a Micro-Tim brush. A thin layer of the varnish was then employed with a microbrush over four sessions, at a frequency of one session per week. The varnish was left undisturbed for 10–20 seconds and subsequently air-dried, as stated by the manufacturer's guidelines (**Figure 8**). Reapplication of the varnish at each weekly follow up visits according to manufacturer instructions [7].

Patients are to be instructed not to brush or eat hard food for at least 4 hours after varnish application. And restricted from eating any staining food for 3 to 4 days after application of the varnish.

Any other dental problems rather than teeth involved in the study were treated during the follow-up period, including any extractions, restorations, pulp treatment, and full coverage. These treatments were done in both groups for all participants.

Outcomes measures

Primary outcome

Pain to evaporative stimulus was measured used SCHIFF scale and Wong baker face pain rating tool at baseline, 1 week, 2 weeks, 3 weeks and 4 weeks.

Secondary outcomes

Pain to thermal stimulus was rated using Wong baker face pain rating scale at baseline, 1 week, 2 weeks, 3 weeks and 4 weeks. OHRQoL was evaluated *via* CPQ8-10 at baseline and 4 weeks.

Follow up procedures

Patients were recalled each week to assess dentin hypersensitivity under standard conditions and intra-oral clinical photographs were taken at each follow up visit.

Statistical analysis:

Statistical analysis was conducted with SPSS 27®, Microsoft Excel 2016, and Graph Pad Prism®. All results were verified for normality using Shapiro Wilk Normality test Kolmogorov tests. Which illustrated that all data except age originated from non-parametric origin. Comparison between both groups was done *via* Mann Whitney test, while comparison between different intervals was carried out with Friedman test and subsequently Dunn`s test multiple comparisons. In age, comparison between groups was done with independent tests. In categorical results, all comparisons were accomplished *via* Chi square test and fishers exact test. The significant level was determined to be at $P \leq 0.05$.

RESULTS

Baseline data

Demographic data of the groups were presented in [Tables 3 and 4]. Comparison between groups revealed that both groups were demographically comparable, with no statistically significant changes in sex distribution, age, or tooth numbers. (all $p > 0.05$).

Primary outcome

Absence of sensitivity to evaporative stimulation (SCHIFF SCALE)

Comparison between groups regarding thermal sensitivity to evaporative stimulation showed that both groups started with identical baseline values, with no significant difference ($P = 0.939$). Immediately after treatment, sensitivity decreased in both groups, but the difference remained non-significant ($P = 0.065$), despite lower mean scores in Group I. A significant intergroup difference appeared at 1 and 2 weeks ($P = 0.002$ and $P = 0.006$), with the experimental group showing a markedly greater reduction in sensitivity. By 3 and 4 weeks, Group I continued to demonstrate lower scores than Group II; conversely, these differences were no longer statistically meaningful ($P = 0.117$ and $P = 0.088$). Overall, the experimental group showed a faster and more pronounced early reduction in thermal sensitivity, while both groups exhibited a gradual decline over time.

Within both groups, thermal sensitivity showed a highly significant reduction over time ($P < 0.0001$). In Group I, SCHIFF scores dropped rapidly after treatment and remained consistently low throughout follow-up, with no further significant changes between post-treatment time points. Group II also showed a significant gradual decrease over time, but the reduction was less marked and sensitivity remained higher than in Group I at most evaluations. Overall, both groups improved significantly, with a faster and more stable response observed in the experimental group.

All of these findings are illustrated in **Table (5)**

Absence of pain to evaporative stimulus using face pain rating scale

Comparison between groups regarding evaporative stimulation sensitivity (Face Rating Scale) showed no significant difference at baseline ($P = 0.343$), indicating comparable initial pain levels. Immediately after treatment, a significant intergroup difference emerged ($P = 0.032$), with Group I showing lower pain scores than Group II. This significant advantage for Group I persisted at 1 and 2 weeks ($P = 0.017$ and $P = 0.042$), while at 3 and 4 weeks no significant differences were observed, although Group I consistently maintained lower scores.

In both groups, there was a significant decrease in pain to thermal stimulation with time ($P < 0.05$). For Group I, there was a rapid decrease following treatment which was maintained consistently without any significant difference between the post-treatment follow-up period. There was a progressive yet significant reduction in Group II, however, with relatively higher pain scores than Group I at each follow-up point. Statistical data illustrated in Table (6).

Secondary outcomes

Pain response to thermal stimulation (using only Face rating scale)

Using the Mann-Whitney test to compare intergroup differences at the start of the study, we found that there were no statistical differences in tooth sensitivity between groups ($P = 0.450$). Similarly, tooth sensitivity did not differ between groups immediately after treatment ($P = 0.128$). However, there was a statistically significant difference at one week ($P = 0.028$) and at four weeks ($P = 0.011$) with consistently lower ratings reported for the experimental group compared to the control group. Differences in tooth sensitivity were not statistically significant between groups at two and three weeks, although the experimental group had lower mean tooth sensitivity ratings than the control group.

The intra-group analysis conducted using the Friedman test showed a statistically significant decrease in tooth sensitivity across all groups at all time points ($p < 0.0001$). The experimental group showed an immediate decrease in tooth sensitivity after treatment that continued to decrease over time and remained low at all follow-up visits. The control group

also showed a significant gradual reduction over time, but the improvement was less pronounced and sensitivity levels remained higher compared to the experimental group at most time points. All these findings demonstrated in **Table (7)**

Oral health-related quality of life:

Comparison between groups regarding changes in OHRQoL showed that, at the 1st visit, there were no remarkable changes between either groups in oral symptoms, functional limitation, or emotional well-being ($P > 0.05$). However, Group I showed significantly better outcomes in social well-being ($P = 0.001$) and a significantly lower total CPQ score ($P = 0.02$) compared with Group II, indicating an overall better QoL early in the study. At the last visit, no significant differences were initiated between groups in functional limitation, oral symptoms, or emotional well-being ($P > 0.05$), while Group I continued to show significantly better social well-being ($P = 0.003$) and a reduced total CPQ score ($P = 0.003$), reflecting a sustained overall advantage in OHRQoL in the experimental group.

Within both groups, OHRQoL improved significantly from the 1st to the last visit ($P < 0.001$). In Group I, all domains and the total CPQ score showed a marked reduction, indicating a strong overall improvement. Similarly, Group II demonstrated significant improvements across all domains, although the degree of improvement was slightly greater in the experimental group.

Inter group and intra group comparisons shown in **Tables (8 and 9)**

DISCUSSION

Molar incisor hypomineralization has received extensive global attention, with numerous studies indicating a rising prevalence of the condition. One of the most common complaints associated with MIH is hypersensitivity; therefore, this study was conducted. It specifically focused on children aged 8 to 10 years, as previous research has shown that hypersensitivity is notably higher among 8-year-olds, especially in their molars [8-11].

Hypersensitivity was assessed in this study using an evaporative stimulus. According to a published paper, the evaporative method is the most preferred approach for provoking pain in patients with dentin hypersensitivity, as the pain intensity is elevated with the air test among the tactile tests [12].

Pain from evaporative and thermal stimuli was estimated *via* the Wong-Baker FACES Pain Rating Scale. This tool is considered the easiest for children to use when expressing their pain. Additionally, high reproducibility and clinical utility have been reported for the Wong-Baker scale. The SCHIFF scale was used to measure tooth sensitivity to evaporative stimulus in this study. Previous studies indicate that the SCHIFF scale shows higher sensitivity and specificity than other assessment scales [8, 12-14].

The current study looked at the OHRQoL of children who had MIH. Dantas-Neta and Portella et al. found that MIH negatively affected the OHRQoL of affected children, in that they had lower OHRQoL scores than children without MIH. Furthermore, Gutiérrez et al. showed that moderate to severe MIH causes a greater negative impact on QoL than mild MIH. A systematic review regarding the effects of MIH on OHRQoL corroborates these studies and demonstrates the effect MIH has on the OHRQoL of children with MIH [15-20].

The most utilized tool for the assessment of OHRQoL in children is the Child Perception Questionnaire (CPQ), however, previous work has validated the Arabic language version of the CPQ for 8- to 10-year-old children as being both valid and reliable making it appropriate for this population. Hence, the Arabic version was used in the present study [21].

The follow-up period within this randomized clinical trial was one month; one month is the usual interval to evaluate desensitizing agents in clinical trials because it allows an adequate amount of time for the mechanisms of action of these products (e.g. occlusion of dentinal tubules, remineralization) to occur, while at the same time allowing for the assessment of early clinical results [22-24].

Statistical analysis of evaporative stimuli using the Schiff scale revealed that there are significant statistical differences in post-treatment hypersensitivity between the two groups. The first treatment delivered higher initial levels of hypersensitivity to group I participants compared to group II participants and was followed by a period of gradual decrease. Groups I and II both maintained decreased levels of hypersensitivity throughout the duration of the study.

These findings align with a randomized controlled trial in 2021 comparing the PRG barrier coat to Biflourid 10 fluoride varnish, which also indicated that the Giomer varnish resulted in an immediate reduction in hypersensitivity this could be related to the bioactive nature of GIOMER varnish which is attributed to existence of PRG particles these particles serving as filler to occlude dentinal tubules [7].

In this study on pain response to evaporative stimuli using face pain rating scales, our statistical results demonstrated a significant alteration between both groups, with the experimental group (Group I) demonstrating a greater reduction in dentin hypersensitivity. Ravishankar supported this study findings in their published clinical trial in 2018, which compared the effectiveness of the PRG barrier coat to two other desensitizing agents. They used an evaporative stimulus similar to this study. As their findings were similar to ours, they provide support for the PRG barrier coat's ability to provide an immediate reduction in dentinal hypersensitivity with the effect lasting one month at follow up; the time period of their study and our study were both the same[7].

Additionally, a different study also produced similar findings, indicating that the long-term benefit of Giomer varnish may be due to its resinous composition that makes it more resistant to pH loss and to mechanical removal from the occluded dentinal tubules by brushing [24].

The results showed significant statistical changes in response to pain stimuli from baseline to the end of the study among participants in both groups. The results are comparable

with those of research that were done in April 2025; PRG Barrier Coat showed the fastest effect on hypersensitivity among all other desensitizers. Moreover, it was able to maintain lower levels of hypersensitivity in the course of thermal test possibly because of the bioactive S-PRG fillers used in it. They ensure ion release that leads to dentinal tubule occlusion and potential remineralization effects. These results further validate the findings of this study [25].

Supporting the results of our study a 2026 review stated that PRG barrier coat helped in Molar incisor hypo mineralization with dentin hypersensitivity due to role of bioactive potential S-PRG (surface pre-reacted glass particles)filler on dental tissues [2]

Furthermore, a controlled clinical trial published in 2023 compared the effects of Biflourid 10 to another sodium fluoride varnish in reducing dentin hypersensitivity. Biflourid 10 demonstrated a significant change in the reduction of dentin hypersensitivity in intragroup comparisons between follow-up visits, aligning with the results of our study. This indicates that Bifluorid 10 effectively decreases hypersensitivity and maintains its effect over the follow-up period, this could be related to multiple application of varnish [27].

This study evaluated OHRQoL, showing that the total CPQ score was drop in the experimental group (Group 1) than in Group 2, indicating better quality of life post-treatment. This aligns with findings from a German trial on children with MIH and hypersensitivity, which showed a significant decrease in CPQ scores after treatment using the same questionnaire. These results suggest that treating hypersensitivity can improve children's OHRQoL [19].

LIMITATIONS

The limitations of this paper include the fact that the severity of Molar Incisor Hypomineralization was not taken into consideration, as mild cases were compared to severe cases. Additionally, the follow-up period needs to be extended. The questionnaire used was challenging for some children to answer, and the application of rubber dams without anesthesia

caused discomfort for most patients. Furthermore, postoperative instructions were not provided to guardians in written form; some guardians forgot the instructions.

RECOMMENDATIONS

We recommend that future researchers increase the follow-up period, assess retention for both varnishes, compare fluoride release between the two varnishes, subdivide groups according to severity, simplify the questionnaire, provide written postoperative instructions for guardians, and explore alternative methods for isolation that do not involve rubber dams.

CONCLUSIONS

Depending on this research's outcomes, the resulting conclusions can be drawn both varnishes could be used as desensitizing agents for non-carious MIH molars. The newly introduced varnish (PRG BARRIER COAT VARNISH) showed immediate relief for hypersensitivity compared to fluoride varnish. Even after 4 weeks follow up period, both varnishes sustained their effect on decreasing hypersensitivity in MIH patients. PRG BARRIER COAT varnish could be a better option for pediatric patients because it is only applied once and has better scent and taste compared to fluoride varnish. Pain to both thermal stimulus and evaporative stimulus was reduced in both groups after application of desensitizing agents. OHRQoL of all patients improved by decreasing hypersensitivity.

DECLARATIONS

Ethics approval and consent to participate

This work was authorized by the Research Ethics Committee of Cairo University, Cairo, Egypt (Approval No. 17123). The research was carried out in accordance with the Declaration of Helsinki and relevant institutional policies. Written informed consent was acquired from the legal guardians of all contributing children before to inclusion in the work.

Trial registration

This clinical trial was recorded at [clinical trial.gov] under registration number [NCT05542667] on [13/9/2022].

Consent for publication

Not applicable.

Availability of data and materials

The datasets analyzed and/or generated during this work are available from the corresponding author upon reasonable request.

Competing interests

The authors report no conflicts of interest.

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Authors' contributions

E.K.H.S (Ethar Khaled Hassan Swidan) conceived and formulated the study, gathered the data, performed the clinical procedures, interpreted the results, and drafted the manuscript. H.M.E.A (Hala Mohy El Din Abbas) contributed to conceptualization, methodology, supervision, validation, and critical revision of the manuscript through review and editing. S.H.E.S (Shereen Hassan El Shamy) contributed to the methodology, supervision, validation, and critical revision of the manuscript through editing and review. All authors have reviewed the final form of the manuscript and approve of being responsible for all components of the study.

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Authors' information

Not applicable.

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Table (1): Inclusion and exclusion criteria

Inclusion criteria for participants	Exclusion criteria for participants
1. Patients aged between 8 and 10 years old with MIH affected teeth according to European Academy of Pediatric Dentistry diagnostic criteria. 2. Systemically healthy. 3. Cooperative patients who will comply with follow-up visits.	1. Undergoing desensitizing treatments in the last 3 months 2. Occlusal problems such as bruxism. 3. Cognition problems. 4. Who used any type of analgesics before treatment. 5. Undergoing orthodontic treatment.
Inclusion criteria for teeth	Exclusion criteria for teeth
1. At least one first molar or one incisor erupted in the oral cavity exhibiting molar incisor hypomineralization. 2. Teeth representing molar incisor hypomineralization are sensitive.	1. Enamel defects, such as enamel hypoplasia, amelogenesis imperfecta, and dental fluorosis. 2. Carious teeth.

Table (2): Materials used in the trial

Material	Specification	Composition	Manufacturer	LOT#
PRG Barrier Coat	BioSmart Light Cured Protective Shield with bioactive S-PRG filler technology	Base: S-PRG filler based on fluoroboroaluminosilicate glass, distilled water, Methacrylic acid monomer, and others. Active: Phosphonic acid monomer, Methacrylic acid monomer, Bis-MPEPP, Carboxylic acid monomer, TEGDMA, Polymerization initiator, and others.	SHOFU, Kyoto, Japan	04230
Biflourid 10	Fluoride varnish (Desensitizing agent) containing 5% NaF (22,600 ppm fluoride) + 5% CaF ₂	Active: Sodium fluoride 5%, Calcium fluoride 5%, Synthetic resin base (transparent varnish matrix), solvent system (organic solvents), flavoring agents. Key feature: dual fluoride release (immediate + long-term)	VOCO GmbH, Cuxhaven, Germany	2345240

1. Bis-MPEPP: 2,2-bis (4-methacryloxy polyethoxyphenyl) propane
2. TEGDMA: Triethylene glycol dimethacrylate
3. NaF: Sodium fluoride
4. CaF₂: Calcium flouride

Table (3): Demographic data of both groups.

		Group I Experimental	Group II Control	P value
Age M ± SD		8.93 ± 0.89	9.12 ± 0.86	0.32
Tooth number N (%)	16.00	11 (26.2%)	15 (35.7%)	0.61
	26.00	10 (23.8%)	12 (28.6%)	
	36.00	11 (26.2%)	8 (19.0%)	
	46.00	10 (23.8%)	7 (16.7%)	
Sex N(%)	Male	19 (45.2%)	16 (38.1%)	0.51
	Female	23 (54.8%)	26 (61.9%)	

Table (4): Dental examination of both groups.

		Minimum	Median	Maximum	Mean	Standard Deviation	P value
DMF	Group I Experimental	0.00	1.00	4.00	1.02	1.12	0.26
	Group II Control	0.00	0.00	3.00	0.83	1.15	
def	Group I Experimental	0.00	2.50	7.00	2.71	1.93	0.23
	Group II Control	0.00	2.00	10.00	2.31	2.53	
dmf	Group I Experimental	0.00	0.00	0.00	0.00	0.00	0.32
	Group II Control	0.00	0.00	1.00	0.02	0.15	

Table (5): Comparison between groups regarding tooth Evaporite stimulus using SCHIFF scale.

Evaporite stimulus using SCHIFF scale	Group I (Experimental)		Group II (Control)		P value
	Min / Max (Median)	M ± SD	Min / Max (Median)	M ± SD	
Before TTT	1 / 3 (2)	1.90 ± 0.79 ^a	1 / 3 (2)	1.90 ± 0.91 ^a	0.939
After TTT	0 / 3 (1)	1.02 ± 0.84 ^b	0 / 3 (1)	1.45 ± 1.02 ^{ab}	0.065
After 1 week	0 / 3 (0)	0.45 ± 0.80 ^b	0 / 3 (1)	1.14 ± 1.12 ^{bc}	0.002 *
After 2 weeks	0 / 3 (0)	0.43 ± 0.70 ^b	0 / 3 (1)	1.02 ± 1.07 ^{bc}	0.006 *
After 3 weeks	0 / 2 (0)	0.48 ± 0.67 ^b	0 / 3 (0.5)	0.90 ± 1.12 ^{bc}	0.117
After 4 weeks	0 / 2 (0)	0.43 ± 0.67 ^b	0 / 3 (0)	0.86 ± 1.09 ^c	0.088
P value	<0.0001*		<0.0001*		

*Significant difference as $P \leq 0.05$.

Means with different superscript letters were significantly different as $P < 0.05$.

Table (6): Comparison between groups regarding sensitivity to evaporative stimulation (Face rating scale).

pain response to the evaporative stimulation (Face rating scale)	Group I (Experimental)		Group II (Control)		P value
	<i>Min / Max (Median)</i>	<i>M ± SD</i>	<i>Min / Max (Median)</i>	<i>M ± SD</i>	
Before TTT	1 / 5 (2)	2.50 ± 1.13 ^a	1 / 5 (3)	2.76 ± 1.32 ^a	0.343
After TTT	0 / 4 (1)	1.10 ± 1.25 ^b	0 / 5 (1)	1.88 ± 1.71 ^b	0.032*
After 1 week	0 / 4 (1)	0.93 ± 1.05 ^b	0 / 5 (1.5)	1.76 ± 1.64 ^b	0.017*
After 2 weeks	0 / 4 (1)	0.90 ± 1.08 ^b	0 / 5 (1)	1.62 ± 1.59 ^b	0.042*
After 3 weeks	0 / 4 (1)	0.98 ± 1.09 ^b	0 / 5 (1)	1.52 ± 1.70 ^b	0.277
After 4 weeks	0 / 4 (0.5)	0.83 ± 1.10 ^b	0 / 5 (1)	1.48 ± 1.71 ^b	0.142

*Significant difference as $P \leq 0.05$.

Means with different superscript letters were significantly different as $P < 0.05$.

Table (7): Comparison between groups regarding tooth sensitivity to thermal stimuli using face rating scale

thermal stimulus (face pain rating scale)	Group I (Experimental)		Group II (Control)		P value
	Min / Max (Median)	M ± SD	Min / Max (Median)	M ± SD	
Before TTT	1 / 5 (2)	2.43 ± 1.47 ^a	1 / 5 (2)	2.21 ± 1.44 ^a	0.450
After TTT	0 / 4 (1)	1.26 ± 1.33 ^b	0 / 5 (1.5)	1.76 ± 1.54 ^{ab}	0.128
After 1 week	0 / 4 (0)	0.62 ± 1.15 ^b	0 / 5 (1)	1.33 ± 1.68 ^b	0.028*
After 2 weeks	0 / 5 (0)	0.90 ± 1.25 ^b	0 / 5 (0.5)	1.33 ± 1.71 ^b	0.406
After 3 weeks	0 / 5 (0)	0.67 ± 1.12 ^b	0 / 5 (0)	1.05 ± 1.43 ^b	0.245
After 4 weeks	0 / 5 (0)	0.57 ± 1.11 ^b	0 / 5 (1)	1.31 ± 1.55 ^b	0.011
P value	< 0.0001*		< 0.0001*		

*Significant difference as $P \leq 0.05$.

Means with different superscript letters were significantly different as $P < 0.05$.

Table (8): Comparison between groups regarding patients oral health related quality of life.

		Group I (Experimental)		Group II (Control)		P value
		Min/Max (Median)	Mean $\pm$ SD	Min/Max (Median)	Mean $\pm$ SD	
1st visit	oral symptoms	0.40 / 3.00 (1.80)	1.78 $\pm$ 0.75	0.00 / 3.00 (2.00)	1.70 $\pm$ 0.89	0.996
	functional limitation	0.00 / 3.00 (1.00)	1.07 $\pm$ 0.73	0.00 / 3.40 (1.10)	1.35 $\pm$ 0.88	0.143
	emotional well being	0.00 / 4.00 (0.80)	1.05 $\pm$ 0.93	0.00 / 3.80 (1.20)	1.35 $\pm$ 0.91	0.116
	social well being	0.00 / 2.50 (0.60)	0.77 $\pm$ 0.69	0.10 / 2.60 (1.35)	1.28 $\pm$ 0.71	0.001*
	CPQ sum	0.80 / 8.70 (4.65)	4.67 $\pm$ 2.04	2.10 / 8.80 (5.50)	5.69 $\pm$ 1.70	0.02*
Last visit	oral symptoms	0.00 / 2.40 (1.00)	1.03 $\pm$ 0.53	0.00 / 2.60 (1.20)	1.11 $\pm$ 0.73	0.434
	functional limitation	0.00 / 2.00 (0.60)	0.66 $\pm$ 0.53	0.00 / 2.60 (0.80)	0.92 $\pm$ 0.72	0.130
	emotional well being	0.00 / 2.20 (0.60)	0.69 $\pm$ 0.62	0.00 / 2.40 (0.90)	0.84 $\pm$ 0.66	0.250
	social well being	0.00 / 1.90 (0.40)	0.52 $\pm$ 0.52	0.00 / 2.00 (0.90)	0.90 $\pm$ 0.60	0.003*
	CPQ sum	0.00 / 5.30 (2.90)	2.90 $\pm$ 1.33	0.40 / 5.80 (3.85)	3.78 $\pm$ 1.27	0.003*

*Significant difference as $P \leq 0.05$.

Table (9): Comparison between 1st and last visit patient oral health related quality of life score within each group.

		1st visit		Last visit		P value
		Min/Max (Median)	Mean $\pm$ SD	Min/Max (Median)	Mean $\pm$ SD	
Group I (Experimental)	Oral symptoms	0.40 / 3.00 (1.80)	1.78 $\pm$ 0.75	0.00 / 2.40 (1.00)	1.03 $\pm$ 0.53	<0.001*
	Functional limitation	0.00 / 3.00 (1.00)	1.07 $\pm$ 0.73	0.00 / 2.00 (0.60)	0.66 $\pm$ 0.53	<0.001*
	emotional well being	0.00 / 4.00 (0.80)	1.05 $\pm$ 0.93	0.00 / 2.20 (0.60)	0.69 $\pm$ 0.62	<0.001*
	Social well being	0.00 / 2.50 (0.60)	0.77 $\pm$ 0.69	0.00 / 1.90 (0.40)	0.52 $\pm$ 0.52	<0.001*
	CPQ sum	0.80 / 8.70 (4.65)	4.67 $\pm$ 2.04	0.00 / 5.30 (2.90)	2.90 $\pm$ 1.33	<0.001*
Group II (Control)	Oral symptoms	0.00 / 3.00 (2.00)	1.70 $\pm$ 0.89	0.00 / 2.60 (1.20)	1.11 $\pm$ 0.73	<0.001*
	Functional limitation	0.00 / 3.40 (1.10)	1.35 $\pm$ 0.88	0.00 / 2.60 (0.80)	0.92 $\pm$ 0.72	<0.001*
	Emotional well being	0.00 / 3.80 (1.20)	1.35 $\pm$ 0.91	0.00 / 2.40 (0.90)	0.84 $\pm$ 0.66	<0.001*
	Social well being	0.10 / 2.60 (1.35)	1.28 $\pm$ 0.71	0.00 / 2.00 (0.90)	0.90 $\pm$ 0.60	<0.001*
	CPQ sum	2.10 / 8.80 (5.50)	5.69 $\pm$ 1.70	0.40 / 5.80 (3.85)	3.78 $\pm$ 1.27	<0.001*

*Significant difference as $P \leq 0.05$.

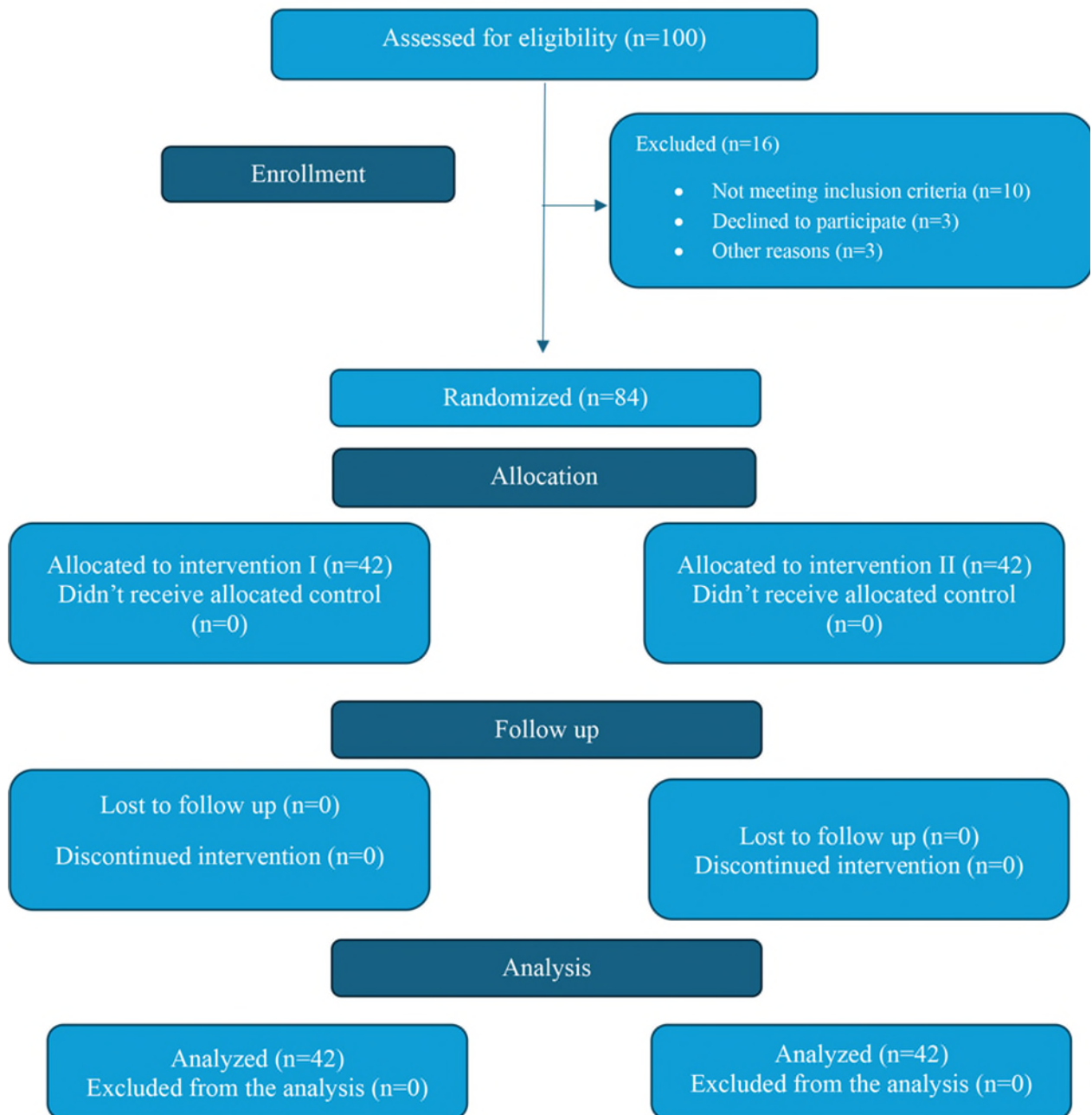


Figure (1) CONSORT flow diagram.



Figure (2): Intra oral clinical photos.

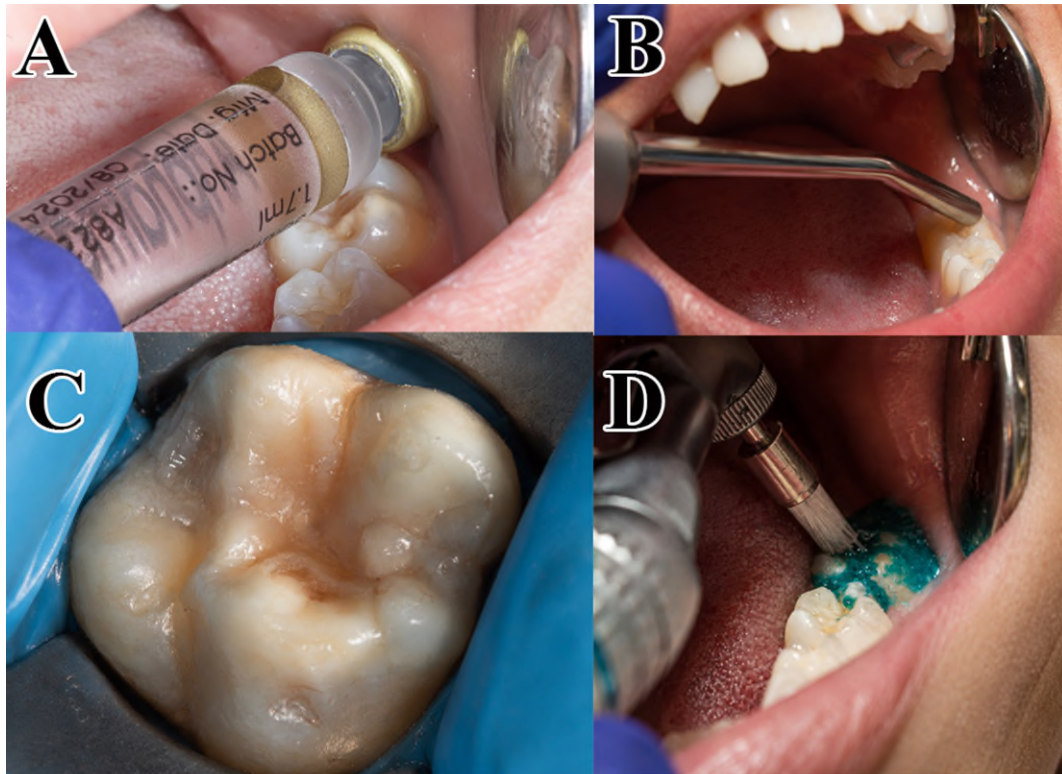


Figure (3): Stimuli application and tooth preparation **A:** using thermal stimulus, **B:** using evaporative stimulus, **C:** rubber dam application, **D:** cleaning tooth.

0 'subject does not respond to air stimulus',

1 'subject responds to air stimulus but does not request discontinuation of stimulus'

2 'subject responds to air stimulus and requests discontinuation or moves from stimulus'

3 'subject responds to the air stimulus, considers stimulus to be painful and requests discontinuation of the stimulus'

Figure (4): SCHIFF scale

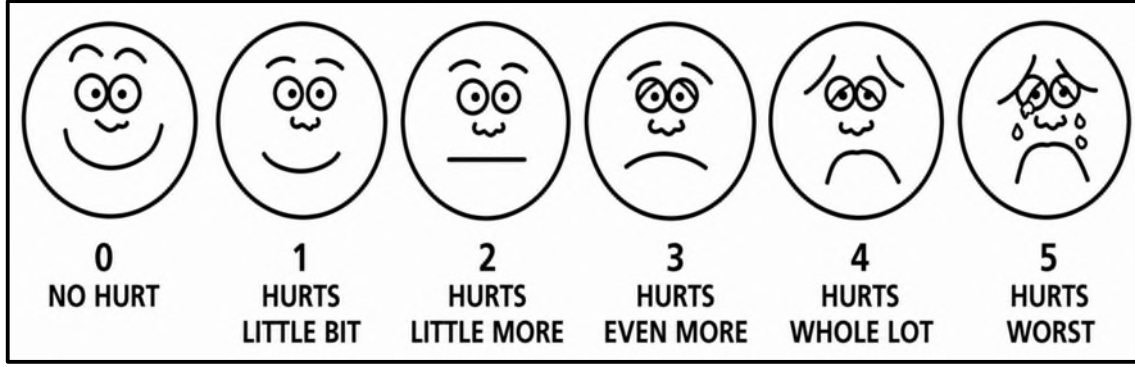


Figure (5): Wong baker face pain rating scale

1	كان عندك ألم في أسنانك أو فكك
2	كان عندك مناطق (قرح) مؤلمة في فكك
3	كان عندك ألم في أسنانك عندما تشرب المشروبات الباردة أو عندما تأكل الأكلات الساخنة
4	التصق الطعام في أسنانك
5	كان عندك رائحة فم كريهة
6	أخذت وقتاً أطول من غيرك لتناول وجبتك بسبب أسنانك أو فكك
7	كان عندك صعوبة في مضغ أو قطع أطعمة كالتفاح و الذرة و اللحم بسبب أسنانك أو فكك
8	كان عندك صعوبة في تناول الأطعمة التي تحبها بسبب فكك أو أسنانك
9	كان عندك صعوبة في نطق بعض الكلمات بسبب أسنانك أو فكك
10	كان عندك صعوبة في النوم ليلاً بسبب أسنانك أو فكك
11	تضيق بسبب أسنانك أو فكك
12	أحسست بالانحباط بسبب أسنانك أو فكك
13	كان عندك خجل بسبب أسنانك أو فكك
14	كنت مهتماً برأي الأشخاص الآخرين في أسنانك أو فكك
15	كنت قلقاً من أن مظهرك لا يبدو جميلاً كالآخرين بسبب أسنانك أو فكك
16	تغيب عن المدرسة بسبب أسنانك أو فكك
17	كان عندك صعوبة في حل واجباتك المدرسية بسبب أسنانك أو فكك
18	كان عندك صعوبة في الانتباه في المدرسة بسبب أسنانك أو فكك
19	لم ترغب في الكلام أو القراءة بصوت عالي في الفصل بسبب أسنانك أو فكك
20	حاولت أن لا تبتسم أو تضحك عند وجودك مع الأطفال الآخرين بسبب أسنانك أو فكك
21	لم ترغب في الكلام مع الأطفال الآخرين بسبب أسنانك أو فكك
22	لم ترغب أن تكون مع الأطفال الآخرين بسبب أسنانك أو فكك
23	تجنب الأنشطة الرياضية و التوادي بسبب أسنانك أو فكك
24	ضايقتك الأطفال أو أطلقوا عليك أسماء بسبب أسنانك أو فكك
25	سألك الأطفال أسئلة عن أسنانك أو فكك

Figure (6): Arabic version of child perception questionnaire.

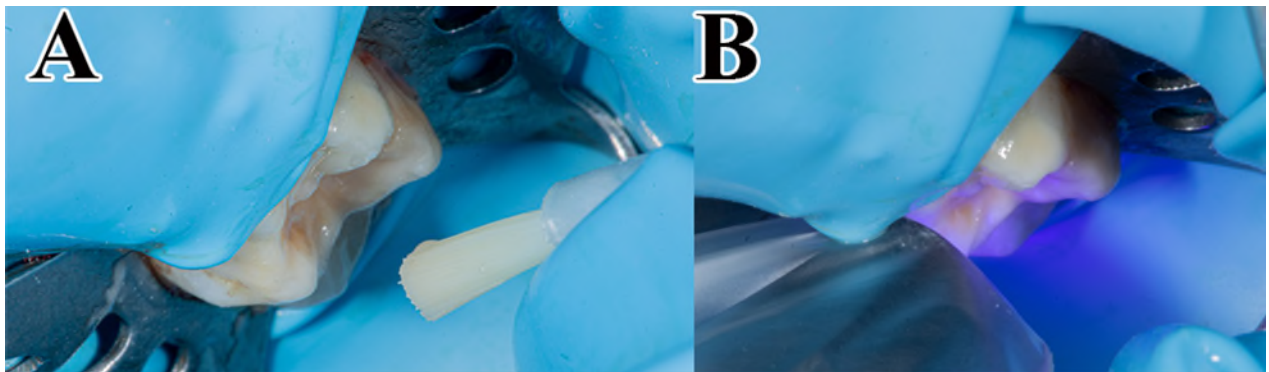


Figure (7): Giomer varnish application on upper permanent first molar, A: application of Giomer varnish with its applicator, B: light curing of the varnish.

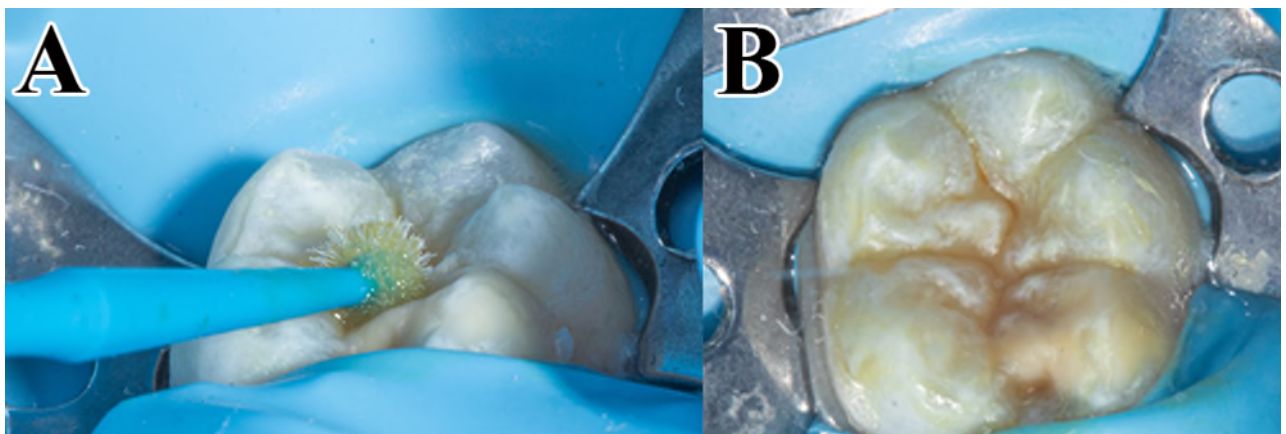


Figure (8): Bifluorid 10 varnish application on a lower first permanent molar, A: fluoride varnish application with micro brush, B: Yellowish discoloration of the tooth after application of fluoride varnish.