An Experimental and Clinically Controlled Study of the Prevention of Dental Caries Using 1.23% Fluoride Gel in Elderly Patients

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Aim: To describe the enamel and dentin fluoride mineralization process in practical application and assess the fluoride gel (NaF 1.23%) effectiveness in dental caries prevention for elderly patients. 

Materials and Methods: Two different types of study were applied: (a) experimental study of fluoride mineralization of enamel and dentin in vitro; (b) clinical controlled interventional studies of the effectiveness in dental caries prevention using 1.23% fluoride gel. Experimental research was performed in laboratory conditions. Teeth of the elderly extracted due to dental diseases served as research objects. Enamel surface and dental root surface were examined under a scanning electron microscope (SEM) before and after demineralization with 37% phosphoric acid within 15 s, as well as after remineralization with toothpaste and 1.23% fluoride gel. Controlled clinical research included 218 older people divided into two groups (intervention group, n = 106; control group, n = 112). In the intervention group, the application of the gel lasts 4 min in the morning for 18 months. The control group received adult P/S toothpaste and a P/S toothbrush. The DIAGNOdent device was used to assess damage both before and after demineralization. For the clinical evaluation of dental caries, international caries detection and assessment system (ICDAS) has been used. Decay missing-filled index (DMFT), effective index (Ef-I), and intervention index (In-I) were determined. Statistical data were analyzed using Mann–Whitney U test and χ² test. Differences were considered significant at P < 0.05.

Results: An SEM image of the enamel surface and dental root surface after teeth remineralization with fluoride gel shows a hard enamel surface without cracks, even in color and structure. After brushing with toothpaste, numerous cracks remain on the surface of the enamel, and the surface layer of the enamel with a depth of 9.64 microns remains damaged without remineralization. After 18 months of intervention, the rate of dental caries in the control group increased from 42.1% to 68.8%, and in the intervention group it increased from 30.8% to 17.0%. A comparison of the 1.23% fluoride gel with toothpaste shows that the former exhibits performance in protecting teeth from decay and it is 108.2% more effective than the latter.

Conclusions: Practical experiments proved the function of remineralizing the enamel and dentin of 1.23% fluoride gel on the teeth of the elderly. Intervention research has proven the performance of preventing dental decay from 1.23% fluoride gel for the elderly in question.

Keywords: Aged, dental caries, fluorides, oral health, tooth diseases

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**INTRODUCTION**

Older adult care policy includes daily oral care. In this respect, dental caries is a major problem.[1] Dental caries is a common disease worldwide and in Vietnam (more than 93% of the population).[2] As with the young, the elderly also suffers from oral pathological signs, but at a more serious level. For them, this disease is often accompanied by at least one systemic disease that creates the necessity for additional oral treatment, which is even more difficult.[3,4] The main changes in the oral tissues due to the aging process include changes of tissues (of teeth, teeth surrounding tissues, oral mucosa) and changes of function (saliva, taste, chewing, and swallowing functions). The current state of dental caries in the elderly, missing teeth due to dental caries, particularly untreated caries teeth, was very high in terms of indicator value.[5] In many communities, the tooth deficiency indicator represents ⅓ or more of a person’s total SMT indicator. On average, each elderly person has 15.2 teeth that require treatment, specific instructions for routine treatment, or instructions for preventive therapy of weak teeth (filling decay teeth, cervical tooth wear, dental trauma).[6]

Dental caries is usually classified by the “site and size” method, Pitts diagnosis threshold, or the ICDAS.[6] Dental caries is diagnosed by various methods with different standards and thresholds of diagnosis, such as vision checking, film-plaque biting, electric caries monitor (ECM), fluorescent laser diagnosis (DIAGNOdent), digital imaging fiber-optic transillumination (DIFOTI), or quantitative light fluorescence (QLF).[8,9]

In the treatment of dental caries at an early stage, it is possible to completely restore the enamel structure by remineralization methods. The WHO offers methods to prevent caries, including fluoride, pitting and fissure sealants, balanced nutrition, oral hygiene instructions, and antibacterial measures.[10]

In general, the function of fluoride itself and 1.23% fluoride gel, in particular, in the prevention and treatment of dental caries and its usefulness in reducing incidence and seriousness have been known and continuously emphasized.[11,12] It was found that fluoride is capable of increasing the enamel strength, protecting teeth from the destruction of minerals, and boosting their remineralization.[13,14] These studies, however, presented several restrictions, such as failure to propose an ideal use (with high effectiveness, safety, and simple application) and determine an optimal dose for each phase of dental caries.

An understanding of the pathological signs for dental caries, its related issues, and characteristics of enamel and dentin fluoride absorbability in the elderly is necessary to recommend fluoride using methods for dental caries prevention. The statistics on the effectiveness of dental caries prevention with 1.23% fluoride gel compared with fluoride-containing toothpaste requires further examination to establish a strategy for preventing and effectively treating dental caries in the elderly.

To date, no systematic research on 1.23% fluoride gel application in dental caries prevention for the elderly has been performed in Vietnam. Also, no studies are available on enamel emulation and dentin floor mineralization as an empirical experiment. Therefore, a study of dental caries prevention with 1.23% fluoride gel for the elderly people in HaiPhong city was conducted. This study aimed at describing the process of fluoride remineralization of enamel and dentin under the action of fluoride gel (NaF 1.23%) in vitro, as well as at evaluating the effectiveness of fluoride gel (NaF 1.23%) in preventing caries among elderly patients.

**MATERIALS AND METHODS**

Two different types of study were applied: (a) experimental study of fluoride mineralization of enamel and dentin in vitro; (b) clinical controlled interventional studies of the effectiveness of prevention of dental caries using 1.23% fluoride gel (study period from January 2016 to December 2017). The research was carried out at Hanoi Medical University School of Odonto-Stomatology.

**EXPERIMENTAL STUDY OF FLUORIDE MINERALIZATION OF ENAMEL AND DENTIN IN VITRO**

Empirical research was performed in laboratory conditions. Teeth of the elderly (≥60 years old) extracted due to periodontal diseases served as a research object. A total of 20 molars were selected with decayed teeth without break (the crown and root remain intact, DIAGNOdent indicator of ≤13).

The study did not examine teeth with cavities as defined by ICDAS, with broken crowns or ruptured roots and teeth with DIAGNOdent indicator >13.

To avoid bacterial development, the removed teeth were placed for seven days at 4°C in tap water with thymol crystals dissolved in 4 mL of alcohol. The surface of all teeth was cleaned with a pumice stone suspension; then, the teeth were flushed with running water and dried with a towel. Teeth were demineralized using 37% phosphoric acid in 15s. After demineralization, all samples were thoroughly rinsed with distilled water. Exposure windows (5 × 10 mm) were created on the enamel surface of the crown (5 mm above the crown–root junction) and on the root (5 mm below the crown–root junction). For the remineralization procedure, teeth were randomly divided...
into two groups of 10 each. A dental cleaner was applied to the enamel in the exposure windows: 1.23% fluoride gel in group 1, and adult P/S toothpaste in group 2. In both groups, exposure to the tested brushing agents was performed twice a day for 18 days, with the duration of exposure being 5 min.

The enamel surface and dental root surface were examined with an SEM both before and after demineralization, as well as after remineralization with toothpaste and 1.23% fluoride gel.

**CLINICALLY CONTROLLED INTERVENTION RESEARCH FOR ASSESSMENT OF DENTAL CARIES PREVENTION EFFICIENCY BY 1.23% FLUORIDE GEL**

The sample for intervention research included 218 elderly people (the study group, \( n = 106 \); the control group, \( n = 112 \)).

Inclusion criteria were elderly people from Haiphong city with at least 10 healthy teeth who have agreed to voluntarily participate in the research.

Exclusion criteria were elderly people with fluoride allergy, undertaking treatment with fluoride cross-reaction drugs such as Chlorhexidine, suffering from any acute body disease, practicing betel chewing habit that decolorizes enamel, and those who failed to answer the research questions (the deaf-and-dumb, psychopathic patients, etc.).

In the study group, the 1.23% fluoride gel was applied according to an established schedule, namely, 4 min in the morning once a week for 18 months. The control group used standard adult P/S toothpaste and P/S toothbrush twice a day.

The DIAGNOdent device was employed to assess the damage both before and after demineralization. An examination lamp mirror was used to observe every tooth directly without natural light or additional illumination. For the clinical assessment of dental caries, the ICDAS standard (International Standard for the Detection and Evaluation of Caries) was used. DMFT, Ef-I, and In-I were determined.

**DATA PROCESSING AND STATISTICS**

Statistical data were entered into EPI DATA 3.1 software, and they were analyzed by SPSS 20.0 program using the medical statistical method. The results of the clinical study were assessed using the Mann–Whitney U test and \( \chi^2 \) test. Differences were considered significant at \( P < 0.05 \).

**ETHICS**

All participants were informed about the purpose of the study and the procedures that will be used. The informed consent to participate in the study was obtained from all subjects. The examination process ran with proper bacteria sterilization to avoid any negative consequences. During the research, any unintended examination was conducted. Patients with serious dental decay received dental treatment free of charge. The control and study groups were treated in a similar way, but the control patients underwent no assessment upon the completion of the research. All the procedures have been performed as per the ethical guidelines laid down by the Declaration of Helsinki. The authors declare that the work is written with due consideration of ethical standards. The study was conducted in accordance with the ethical principles approved by the Ethics Committee of Hanoi Medical University (Protocol № 6 of 13.01.2016).

**RESULTS**

**FLUORIDE REMINERALIZATION OF ENAMEL AND DENTIN IN VITRO**

Before demineralization, all teeth show DIAGNOdent factor within normal limitation (≤13, non-carious), and average measured DIAGNOdent value is 5.95 ± 2.70. After demineralization with 37% phosphoric acid within 15 s, all teeth show DIAGNOdent factor within carious limitation D1 (DIAGNOdent factor ranges between 14 and 20), and average value becomes 17.6 ± 3.20. This fact means all teeth get dental caries in level D1, corresponding with carious code 1 of ICDAS clinically.

Microscope pictures showed that the normal enamel surface is smooth, and it is rather hard to detect enamel pillar surfaces and borders between enamel pillars. Just endpoints of the enamel pillars can be seen occasionally. The enamel pillars lie close to each other with a certain space between the pillars. The bodies of enamel pillars contain enamel crystals and organics [Figure 1A].

After demineralization, the enamel surface becomes rough and uneven [Figure 1B]. Enamel crystals are dissolved in an acid environment, leaving fissures on the surface. The demineralized area shows an unordered

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Figure 1: Dental surface of normal (A) and demineralized (B) teeth (zoom scale ×1000)
surface, whereas the enamel face is demineralized more actively (zoom scale ×1000). A surface layer of enamel is faded to expose the damaged enamel layer beneath. The picture shows a cauliflower-shaped form [Figure 1B].

Usually, the dental root surface on microscope pictures is rather smooth, solid in color and density [Figure 2]. After demineralization, the structure of demineralized dentin color is obviously damaged. The density of the enamel tubes is changed, forming many areas with different appearances, which shows different demineralization effects [Figure 3].

After applying toothpaste P/S, many enamel crystals are not remineralized and they expose fissures on the enamel surface in zoom scale ×1000 [Figure 4]. On the longitudinal capture of the dental crown, an enamel surface layer with a depth of 9.64 μm remains damaged without remineralization [Figure 5].

After 1.23% fluoride gel application, the enamel surface becomes smooth, solid, with no fissure observed [Figure 6]. Longitudinal capture shows that enamel pillars were remineralized completely. The remineralization layers get the most thickness of 44.9 μm in zoom scale ×1000 [Figure 7].

After applying toothpaste P/S, the root surface shows an incomplete remineralized structure, demonstrating many fissures and cavities [Figure 8]. Longitudinal capture shows that the thickness of the damaged
non-remineralized enamel layer becomes 18.0 μm in zoom scale ×1000 [Figure 9].

After fluoride application, the root surface showed a solid appearance in color and structure; no damaged structure of the enamel tube was revealed [Figure 10]. On the longitudinal capture of the root surface, 1.23% fluoride gel forms a smooth layer of minerals, covering the root surface with a thickness of up to 3.7 μm [Figure 11].

**Effectiveness of preventing dental caries by 1.23% fluoride gel**

Among the 218 elderly people, the age group of 65–74 years accounts for the highest rate (40.3%), followed by the group of 60–64 years (33.2%), and the lowest one is the group ≥75 years (26.5%). In both study and control groups, the female rate is higher than the male rate; the group of 65–74-year-olds occupies the highest rates in both, and the group ≥75 years is the lowest. There is no statistically significant difference between the control and intervention groups.

Before the intervention, the dental caries rate of the control group was 42.1%. This figure reached 48.0% after six months, 63.4% after 12 months, and 68.8% after 18 months of the intervention. The effective factor decreased to 63.4%. In the study group, the dental caries rate after 6, 12, and 18 months of the intervention decreased gradually from the initial rate of 30.8% to 28.9%, 25.4%, and 17.0%, respectively. The effective factor increased up to 44.8%.
The treatment effectiveness in the study group increased by 108.2% compared with the control one. Intervention effective factor difference between both groups represents a statistically significant difference [Table 1].

Dental caries rate differences after 6, 12, and 18 months between the study and control groups comprise the statistically significant differences [Figure 12].

An analysis of intervention effectiveness per decay teeth averaged by time, after 18 months of the intervention: The number of decayed teeth in the control group increases from 1.4 to 1.9; effective factor decreases by 35.7%, whereas that of the study group presents a strong decrease, from 1.2 to 0.6 with a 50.0% increase for effective factor. Intervention efficiency per caries tooth on average among both groups was 85.7%. Differences in efficacy factors between age groups, gender and between the two groups include statistically significant differences [Table 2].

The rate of tooth-root decay increased from 28.3% to 39.9%, with a 38.9% decrease in effective factors. The rate of tooth-root decay in the intervention group decreased from 16.4% to 7.6%; the effectiveness factor increased by 53.7%. Intervention effectiveness for dental root caries between the intervention and the control groups increased by 92.5%. The difference in the intervention effectiveness factor between both groups is statistically significant [Table 3].

After 18 months of the intervention, the DMFT index of the control group decreased from 3.8 to 6.8, resulting in an effective factor decrease of 78.9%. In the study group, this factor increased from 3.7 to 5.2, representing an effective decrease of 40.5%. The difference in the intervention index between the two categories is statistically significant [Table 4].

The DMFT indices for both groups increase compared with the pre-intervention, where the DMFT index for the control group has a larger increase compared with the other group. Differences in post-intervention DMFT scores between the two groups after 6, 12, and 18 months exhibit statistical significance [Figure 13].

Thus, 1.23% fluoride gel helps reduce the average of decayed teeth from 1.2 down to 0.8 after six months, 1.0 after 12 months, and 0.6 after 18 months. The intervention efficiency between the fluoride group and the toothpaste group for the average of decayed teeth increases by 40.5%, 45.2%, and 85.7% after 6, 12, and 18 months, respectively. The DMFT score for the toothpaste group is higher than the other group. The effectiveness of the intervention between the two groups for DMFT increases by 7.3% after six months, 9.7% after 12 months, and 38.4% after 18 months.

**DISCUSSION**

**ENAMEL AND DENTIN FLUORIDE REMINERALIZATION**

In this post-deminalization study, the teeth show the mean value of the DIAGNOdent factor 17.6 ± 3.20. DIAGNOdent factor was lower than that of Hai’s study[15] (22.8 ± 4.83). The reason can be the difference in the tooth search sample. Research by Hai selects the permanent teeth of children who are 7–13-years-old. As minerals lack time to fill enamel piers, the spaces...
of enamel piers relative to that of older people are immature and phosphoric acid can absorb and damage minerals during demineralization.

In SEM images after demineralization with phosphoric acid, the enamel surface was rough and the enamel cracks were clearly visible. The damaged structure of the de-mineralized enamel tubes was clearly visible on the root surface of the tooth. This changed the color and density of enamel tubes. This result is similar to that of Talaat et al.\(^16\) and Gonçalves et al.\(^17\) although they applied other processes to demineralize enamel in the course of their research. The SEM images of the enamel surface and dental root surface after teeth remineralization with 1.23%
fluoride gel show a hard enamel surface without cracks, solid in color and structure. This results in a successful remineralization of the enamel surface and dental roots. After brushing with toothpaste, numerous cracks remain on the surface of the enamel; the surface layer of the enamel with a depth of 9.64 microns remains damaged without remineralization. On the surface of the root of the tooth, numerous cracks and cavities with incomplete remineralized tubular structures of the enamel are found; the thickness of the damaged non-mineralized enamel layer reaches 18.0 microns.

The results of this study are consistent with the results of several other authors, who have shown that 1.23% fluoride gel applied after mechanical damage to teeth shows lower demineralization (less depth of enamel corrosion) when immersed in an acidic environment than teeth applied with other control agents.\[18\] Thus, the data obtained in this study demonstrate that 1.23% fluoride gel is effective in remineralizing demineralized enamel and dentin damage in practical applications.

**Elderly Dental Caries Prevention Effectiveness with 1.23% Fluoride Gel**

After 18 months of the intervention, the rate of tooth decay in the control group increased from 42.1% to 68.8%; in the study group, it decreased from 30.8% to 17.0%.

Research results indicate that the longer the intervention period, the lower the dental caries rate, clearly proving the effectiveness of 1.23% fluoride. However, the research did not identify an optimal intervention time to completely clear the tooth decay. Such a period can be difficult to suggest, because many studies show that fluoride can completely restore dental damage only in the early stages (corresponding to ICDAS codes 1 and 2); however, for severe cavity-forming dental damage, fluorine can only slow the spread of such damage.\[19,20\]

A comparison of 1.23% fluoride gel with toothpaste shows that the first shows performance in tooth protection that is 108.2% more effective than the previous. Some studies have shown that fluoride helps protect people of all ages from dental caries and reduces the incidence and risk of dental caries by 17%–29%.\[21,22\]

Effectiveness analysis of dental caries intervention after 18 months showed an increase in the number of decayed teeth in the control group from 1.4 to 1.9, and a decrease in Ef-I to 35.7%. The study group demonstrated a strong decrease in the number of caries teeth from 1.2 to 0.6 and an increase in Ef-I to 50.0%. After 18 months, the efficacy of the intervention in terms of caries, on average between the control and experimental groups, rises up to 85.7%.

Thus, 1.23% fluoride helps reduce tooth decay and moderate tooth decay for the study group during the research period. The intervention effective factor between the intervention and control groups gradually increases with time, proving the performance of 1.23% fluoride gel in protecting teeth from harmful elements. This increases the effectiveness of dental caries prevention compared with usual toothpaste.

According to this research, the dental root caries rate undergoes significant changes as well. After the intervention, the dental root caries rate of the control group increases up to 39.3% from a pre-intervention rate of 28.3%, whereas the rate in the study group decreases from 16.4% to 7.6% after 18 months. The intervention effectiveness between the two groups also increases by 92.5% after 18 months, proving a better performance of 1.23% fluoride gel in protecting teeth against the usual toothpastes. Numerous research also demonstrates the same performance of 1.23% fluoride gel in the prevention of tooth decay.\[18–22\] Research by Magalhães\[23\] in Brazil within three years of using a 5% varnish fluoride (four times/year) and 38% silver diamine fluoride (once a year) in two groups of elderly people in combination with toothpaste 5,000 ppm daily showed that both contributed to a 64% and 71% reduction in dental root caries rates, respectively.

The DMFT index in both groups rose relatively to the preliminary intervention. However, the control group factor increased more strongly than the study group factor, with a statistically significant difference (\(P < 0.05\)).

Addressing dental caries in the elderly is undoubtedly an important task of modern dentistry. The relationship between oral pathology and many systemic diseases is now evident. Thus, the possibility of improving oral health may have important systemic implications for the body, for the prevention of diseases, and, consequently, for the quality of life of individuals.\[24\]
This study demonstrated the preventative value of fluoride gel and its effect on the reduction of caries and its roots in older people. It was found that the use of 1.23% fluoride gel reduces the incidence of dental caries and has a positive effect in preventing dental caries in the elderly.

Over the past few years, the use of toothpastes containing tin fluoride has been discussed. Concerns have been raised about the health risks of this chemical, but studies have shown it to be safe. Stannous fluoride has been reported to perform well in the remineralization of enamel, even in demineralized areas or when dentinal tubules are blocked.[25] Therefore, studies on the effectiveness of stannous fluoride toothpastes in preventing caries in the elderly, particularly in combination with fluorinated gel, would be of great interest.

This study was limited to older patients residing in the Hanoi area. Only P/S brand dental cleaners were used and the fluorinated gel was used as recommended by the manufacturer. However, findings on the efficacy of 1.23% fluoride gel in caries prevention are well correlated with other studies in other age groups and regions. The data obtained from this study can be used as a basis for developing practical recommendations for oral care in elderly patients.

**CONCLUSION**

Practical experience performed has proven the function of remineralizing the enamel and dentin of 1.23% gel flour on the teeth of the elderly.

Intervention research has proven the performance of preventing dental caries by 1.23% fluoride gel for the elderly. Applying 1.23% fluoride gel is a preventive medical method that can be adopted in medical centers, local and primary. As such, this methodology should be applied to oral and dental care programs.

Further research should aim at finding the safest, easiest, and most efficient way to use 1.23% fluoride gel for caries prophylaxis in the elderly. It is necessary to determine the optimum period of using fluorinated gel, the frequency of its application, and the exposure time. The optimum dose for each stage of dental caries must be established. In addition, studies on the efficacy of 1.23% fluoride gel in combination with various toothpastes, such as those containing stannous fluoride, are required.

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**CONFLICTS OF INTEREST**

There are no conflicts of interests.

**AUTHORS’ CONTRIBUTION**

All authors contributed to the study conception, design, definition of intellectual content, investigation, and article writing.

**ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT**

All the procedures have been performed as per the ethical guidelines laid down by the Declaration of Helsinki. The authors declare that the work is written with due consideration of ethical standards. The study was conducted in accordance with the ethical principles approved by the Ethics Committee of Hanoi Medical University (Protocol № 6 of 13.01.2017).

**PATIENT DECLARATION OF CONSENT**

All participants were informed about the purpose of the study and the procedures that will be used. The informed consent to participate in the study was obtained from all subjects.

**DATA AVAILABILITY STATEMENT**

Data will be available on request.

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Ngoc, et al.: Dental caries prevention with 1.23% fluoride gel

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