

Evaluation of Remineralization Potential of Remin Pro Forte vs Remin Pro on White Spot Lesions: A Randomized Clinical Trial

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ABSTRACT

Aim: This study was conducted to evaluate the remineralization potential of Remin Pro Forte vs Remin Pro remineralizing agents on white spot lesions (WSLs) post-orthodontic treatment.

Materials and methods: Twenty patients with post-orthodontic WSLs were divided into the following two equal groups based on treatment ($n = 10$): (1) A 3-month program of hydroxyapatite, fluoride, xylitol, ginger, curcuma-containing cream (Remin Pro Forte) as intervention group; (2) A 3-month cream regimen including hydroxyapatite and fluoride, xylitol (Remin Pro) as control group. The main outcomes including caries regression (assessed by ICDAS II), mineral content (assessed by VistaCam iX camera), and color of WSLs (assessed by digital image analysis by Adobe photoshop) were measured at the time of enrollment and 1, 2, and 3 months afterward. Mann-Whitney test used to compare between tested groups. The statistical significance was set at $p < 0.05$.

Results: Both Remin Pro Forte and Remin Pro elicited much better caries regression and significantly higher mineral content in WSLs over a 3-month period ($p < 0.05$). However, the difference in mineral content of WSLs between groups did not reach statistical significance ($p = 0.414$). In both experimental groups, the appearance of WSLs improved significantly ($p < 0.05$).

Conclusion: Both Remin Pro Forte and Remin Pro were successful in reducing caries, increasing mineral content, and enhancing the appearance of demineralized enamel, indicating that both products could be suggested for post-orthodontic WSL management.

Clinical significance: Natural herbal products could be employed as remineralizing agents and included into tooth preventive measures. It is a less harmful alternative to traditional chemical remineralization methods.

Keywords: Caries regression, Color improvement, ICDAS II, Post-orthodontic treatment, Remineralization, Remin pro, Remin Pro Forte, VistaCam iX, White spot lesions.

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INTRODUCTION

For centuries, dental caries has been a serious public health issue due to its multifactorial nature. White spot lesions are opaque, white lesions caused by demineralization beneath the enamel's surface. The post-orthodontics WSLs occur in 5–97% treated patients, with the buccal surfaces of the maxillary incisors are the most commonly affected.¹ Fixed orthodontic appliance not only makes routine oral hygiene more difficult but also increases the number of plaque retention sites and the accumulation of food particles and *Streptococcus mutans* colony forming units on tooth surfaces that are ordinarily less vulnerable to caries development. White spot lesions can appear around the brackets within a month of their placement, however, typical caries take at least 6 months to occur.² The focus of modern dentistry aims to treat non-cavitated caries lesions with a noninvasive remineralization approach to impede disease progression and improve esthetics, strength, and function.³ The process of supplying calcium, phosphate, and fluoride ions from the surrounding oral environment to the tooth to convert ion deposition into crystal gaps in demineralized enamel is known as remineralization. Remineralization occurs when the enamel or dentine crystals recrystallize at a higher pH of 7.5–8.5 in the existence of salivary calcium and phosphate. Remineralizing agents should ideally precipitate quickly on partially demineralized tooth structure and change into a more stable, acid-resistant apatite than the hard tissue they replace.⁴

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Recent release of Remin Pro, a remineralizing cream including fluoride, hydroxyapatite, and xylitol. Hydroxyapatite has been shown to fill worn enamel, fluoride occluding dentinal tubules, and xylitol is an antibacterial substance.⁵ This material was claimed to be effective in inhibition of enamel demineralization, and the promotion of enamel subsurface lesions remineralization.⁶ Ginger

rhizome (*Zingiber officinale* Roscoe, Zingiberaceae) is a natural herbal with antimicrobial, antifungal activities on oral cavity pathogens, showing no toxicity, and considered as “generally recognized as safe” in the Food and Drug Administration of the USA.^{7,8} The ginger remineralization tendency obtained was probably due to the antimicrobial properties and the high fluoride and calcium content.⁹ Turmeric, one of the antioxidant plants, is commonly used as a spice, colorant, and preservative. It contains the natural phenol curcuma, which has a wide range of biological properties. Curcuma can have anti-caries effect restraining the bacterial activity.¹⁰ Remin Pro Forte, a new formulation of Remin Pro, was recently introduced with the same constituents as Remin Pro: fluoride, hydroxyapatite, xylitol, and two natural ingredients (ginger and curcuma) with antibacterial and anticariogenic effects against *S.mutans*, which has been confirmed in the scientific literature. With a limited evidence-based information in the literature, it was ascertained that a randomized clinical trial would be beneficial to test the null hypothesis that there would be no difference in remineralization potential between Remin Pro Forte and Remin Pro on WSLs post-orthodontic treatment after 1, 2, and 3 months.

MATERIALS AND METHODS

Tested Materials

The following materials were used in this study:

- *Remin Pro*: A remineralizing cream enriched with sodium fluoride (1,450 ppm), hydroxyapatite and xylitol (VOCO GmbH, Cuxhaven, Germany).
- *Remin Pro Forte*: A remineralizing cream enriched with sodium fluoride (1,450 ppm), hydroxyapatite, xylitol, ginger extracts and curcuma (VOCO GmbH, Cuxhaven, Germany).

Study Design

The trial was done in the Conservative Dentistry Department, Outpatient Clinic of Faculty of Dentistry, Cairo University, Egypt, and was designed to be randomized, two parallel arms, and double blinded. The trial was reviewed and approved by the Cairo University Faculty of Dentistry Research Ethics Committee (Approval No. CREC19758), and it adhered to the ethical norms of the institution’s research committee as well as the Helsinki declaration of 1964 and its subsequent amendments. The Clinical Trials Registry was used to register the study (No. NCT04017884).

Sample Size Calculation

A power analysis was carried out to guarantee that there was enough power to apply a statistical test of the research hypothesis to compare caries regression of Remin Pro Forte to Remin Pro in the remineralization of WSLs following orthodontic treatment. According to Kamh et al.,¹¹ the score A probability for Remin Pro (control) caries regression was (0.2), while the score B probability was (0.66) with effect size $w = 0.71$ ($n = 16$). When utilizing an alpha level of 0.05 (5%) and a power of 80, Remin Pro Forte’s predicted likelihood of caries regression was (0.3) for score A and (0.69) for score B, with an effect size of 0.83 ($n = 17$). The sample size was expanded by 20% to account for potential dropouts during intervals of follow-up, resulting in a total of (40) lesions, with (20) in each group. The Chi-squared test was performed to computed sample size using G*power 3.1.9.2.

Eligibility Criteria

Patients were selected for this clinical research from the outpatient clinic of the Department of Conservative Dentistry, Faculty of

Dentistry, Cairo University with the following inclusion criteria: Participants should be from 12 to 25 years, no systemic disease or concomitant medication affecting salivary flow, and patients with two or more teeth with WSLs, following orthodontic treatment subjects underwent routine periodontal care. The exclusion criteria excluded patients with any of the following conditions: Patients with enamel hypoplasia or fluorosis and tetracycline staining, periodontal pocket of 3 mm or greater, dentin caries, and reduced salivary flow or significant tooth wear.

The study’s aims were clearly described, and the patients signed an informed consent in simple Arabic language prior to the start of the investigation.

Intervention Application

A total of 20 eligible participants were randomized to one of two groups and were given different treatment regimens. Using the Random Sequence Generator, a computer-generated database of random integers was used to randomize the data. Randomness and Integrity Services Ltd (<https://www.random.org/>). The allocated groups’ information was recorded on cards that were placed in envelopes that are consecutively numbered, opaque, and securely closed. After the participant had been subjected to baseline evaluations by the primary investigator and his/her compliance with the inclusion criteria was confirmed, and an impartial third party was responsible for allocation assignment disclosure.

Patients in group I were assigned to use (Remin Pro forte, VOCO GmbH, Cuxhaven, Germany) according to manufacture instructions: A pea-sized amount of the cream was used and was allowed to remain on the teeth for at least three minutes twice daily after conventional tooth brushing. Patient was advised to spit out the remaining amount to avoid swallowing excessive fluoride and to wait for 30 minutes after the treatment before rinsing or eating or drinking.

Patients in group II were instructed to use (Remin Pro, VOCO GmbH, Cuxhaven, Germany) under the identical settings as patients in group I. A plastic syringe was used to standardize the amount of cream applied by all patients. According to American Dental Association in 2014,¹² the pea-sized amount of toothpaste is approximately (0.25 gm) which was equivalent to 0.25 mL. Therefore, 0.25 mL of plastic syringe was filled by Remin Pro or Remin Pro Forte cream according to the patients’ groups. All patients in the intervention and control groups were advised to use a soft-bristled toothbrush twice daily. The patients were urged to avoid any additional fluoride products and limit their use of sugary and acidic foods and beverages.⁶

Outcomes Assessment

The patients were assessed at baseline (T0) and intervals of 1 (T1), 2 (T2), and 3 (T3) months later. The primary outcome measures were caries regression, changes in mineral content, and WSL color change. Before the clinical examination, adhesive remnants left after orthodontic brackets debonding were removed with a low-speed carbide finishing bur, and under a dental operating light, adhesive removal was deemed complete when the tooth surface felt smooth and appeared to be free of adhesive.

For patient assessment baseline photographic records were captured under fixed conditions using (Canon EOS 6D) camera with Lens Canon 100 mm f/2.8 L Macro IS (20.2 MP DX with a CMOS sensor, DIGIC 5+ image processor, 4.5 FPS continuous shooting, 1080/30p video record, Japan) and Dr Eye’s kit mirror. The camera was set to manual with an aperture of f/22, and the same focal

length (35 mm), shutter speed (1/125) of a second, and sensor adjustment (ISO 200), to ensure reproducible conditions, Light was supplied by twin flash attached to the camera with an adjustable arm at 45° angulation, one on each side of the camera, all images were taken with the same magnification ratio 1:1.

Caries Regression Assessment

It was done by photographic image records and performing International Caries Detection and Assessment System (ICDAS II) scoring on WSLs on the image records. Images were captured under the same fixed conditions used at baseline photographic records taken by (Canon EOS 6D) camera and was saved in JPEG format. Photos were opened in Adobe Photoshop, version 7.0 (Adobe Systems, San Jose, California, United States) and image edge enhancement was accomplished by filtering the photographs and applying brush strokes with highlighted edges. After 1, 2, and 3 months, the remineralizing cream had an effect on the increase or decrease of codes. If a lesion no longer met the lesion criteria, it was given a score of 0 (sound enamel).¹³

Color Improvement Assessment

It was performed by photographic image records taken with the same fixed conditions used at baseline photographic records taken by (Canon EOS 6D) camera and were saved in JPEG format and analyzed by Adobe photoshop, version 7.0, software (Adobe Systems, San Jose, California, United States) by incorporation of the Commission Internationale de l'Eclairage (CIE) system in the form of L^* , a^* , and b^* obtained by the software. The L , a , and b values of the designated area were measured, and histogram data were collected. Then ΔE , which indicates the overall color difference according to the CIE system, was calculated as follows:

$$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$$

Even though all efforts to standardize the photos have been made, some variability in the photographs cannot be avoided totally. As a result, a strategy must be devised to eliminate as many differences as possible. A grey card was used in the professional photography throughout the study for this reason.¹⁴

Mineral Content Assessment

The buccal surfaces of the teeth were examined and evaluated by Light induced fluorescence intraoral camera (VistaCam iX, DürrDental, Bietigheim-Bissingen, Germany) with a special head for capturing fluorescent photographs in accordance with the manufacturer's instructions. The fluorescent pictures were graded from green (a wavelength of about 510 nm) to red (680 nm wavelength), with numeric score spanning between 0 and 3 indicating the severity of the lesion. According to the manufacturer, a score of 0–1.0 indicates intact tooth enamel, while a score of 1.0–1.5 indicates initial stage enamel caries. The maximum value for each WSL was reported between 1.0 and 1.5, which matched the lowest mineral content (Fig. 1).⁶

Statistical Analysis

Statistical analysis was performed with IBM® SPSS® (version 26. SPSS Inc., IBM Corporation, Armonk, NY, USA). Data presented as mean, standard deviation (SD), frequency (n), percentage, median, minimum, and maximum when appropriate. Data explored for normality using Shapiro–Wilk test. International Caries Detection and Assessment System II and mineral content data showed a non-normal distribution. Mann–Whitney test used to compare

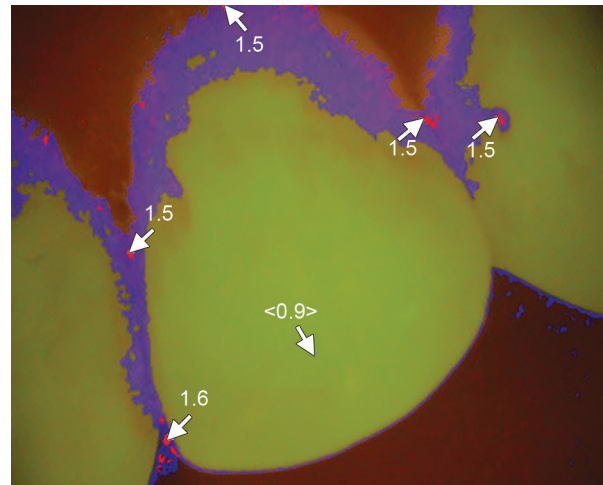


Fig. 1: An image taken from an initial caries lesion by VistaCam iX in DBSWIN software

between tested groups. While Friedman test used to for comparison between tested periods followed by pairwise comparison with Dunn Bonferroni correction. For ΔE , repeated measure ANOVA used to show the effect of different groups and periods. Followed by pairwise comparison with Tukey HSD. The significance level was set at $p < 0.05$.

RESULTS

Caries Regression

The intragroup comparison within both Remin Pro and Remin Pro Forte groups showed statistically significant difference between follow-up periods ($p < 0.001$). On the other hand, the intergroup comparison showed that there was no difference between Remin Pro and Remin Pro Forte groups at baseline, both groups showed 100% of score 2 at ($p = 1.00$). After 2 Months, Remin Pro group showed 25% for score 2, 70% for score 1 and 5% for score 0, while Remin Pro Forte showed 60% for score 2, and 40% for score 1 with significant difference between tested groups ($p = 0.046$). (Table 1).

Table 2 showed the descriptive analysis (mean, standard deviation) for caries regression of WSLs in the study groups at baseline (T0) and three months after the remineralization therapy was completed (T3).

Color Improvement

The intragroup comparison within both groups showed that, there was statistically significant difference between follow-up periods, as Remin Pro group showed a significant decrease in ΔE after 3 months follow-up ($p = 0.028$), the same resulted for Remin Pro Forte group with a significant decrease in ΔE after 3 months follow-up ($p = 0.01$). On the other hand, intergroup comparison showed that after 1 month and 2 months there was no statistically significant difference, while at baseline and after 3 months there was statistically significant difference between both groups as Remin Pro group (12.33 ± 1.99) showed higher significant ΔE compared to Remin Pro Forte (10.98 ± 1.79) at $p = 0.031$ (Table 3).

Mineral Content

The intragroup comparison within both groups showed that there was statistically significant difference between follow-up periods, as Remin Pro group showed a significant rise in mineral content after 2 months in comparison to baseline and one month ($p < 0.001$). For Remin Pro Forte the mineral content was improved significantly

Incipient Caries Remineralization by Remin Pro Forte vs Remin Pro

Table 1: Frequency, percentage and *p*-value of ICDAS II score for caries regression

			Remin Pro		Remin Pro Forte		<i>p</i> -value
			<i>N</i>	%	<i>N</i>	%	
ICDAS II scoring	Baseline	0	0	0.0%	0	0.0%	1.00 NS
		1	0	0.0%	0	0.0%	
		2	20	100.0%	20	100.0%	
	1 month	0	0	0.0%	0	0.0%	0.183 NS
		1	7	35.0%	2	10.0%	
		2	13	65.0%	18	90.0%	
	2 months	0	1	5.0%	0	0.0%	0.046*
		1	14	70.0%	8	40.0%	
		2	5	25.0%	12	60.0%	
	3 months	0	9	45.0%	4	20.0%	0.183 NS
		1	11	55.0%	16	80.0%	
		2	0	0.0%	0	0.0%	

*Significant at *p* <0.05; NS, non-significant at *p* >0.05

Table 2: The mean and standard deviation (SD) values of ICDAS II scoring for caries regression

Variables	ICDAS II scoring				<i>p</i> -value
	Pro		Pro Forte		
	Mean	SD	Mean	SD	
Baseline	2.00	0.00	2.00	0.00	1 NS
After 1 month	1.65	0.49	1.90	0.31	0.062 NS
After 2 months	1.20	0.52	1.60	0.50	0.021*
After 3 months	0.55	0.51	0.80	0.41	0.096 NS
<i>p</i>	<0.001*		<0.001*		

*Significant at *p* <0.05; NS, non-significant at *p* >0.05

Table 3: Mean and standard deviation (SD) values for color improvement

ΔE			Remin Pro	Remin Pro Forte	<i>p</i> -value
	Baseline	Mean	14.33	12.77	0.015*
		SD	2.22	1.63	
		Median	14.02	12.66	
		Minimum	11.34	10.34	
		Maximum	18.72	15.89	
	1 month	Mean	13.53	12.33	0.060 NS
		SD	2.16	1.74	
		Median	13.39	12.34	
		Minimum	10.67	9.68	
		Maximum	17.55	15.42	
	2 months	Mean	12.89	11.69	0.068 NS
		SD	2.23	1.75	
		Median	12.90	11.72	
		Minimum	10.01	9.04	
		Maximum	16.78	14.91	
	3 months	Mean	12.33	10.98	0.031*
		SD	1.99	1.79	
		Median	12.43	10.68	
Minimum		9.96	8.43		
Maximum		15.65	14.22		

*Significant at *p* <0.05, NS, non-significant at *p* >0.05

Table 4: Mean, standard deviation (SD) values for mineral content

			Baseline	1 month	2 months	3 months	p-value
Mineral content	Remin Pro	Mean	1.5	1.4	1.3	1.2	<0.001*
		SD	0.0	0.0	0.0	0.0	
		Median	1.5	1.4	1.3	1.2	
		Minimum	1.4	1.3	1.2	1.1	
		Maximum	1.5	1.4	1.3	1.2	
		Rank	b	b	a	a	
	Remin Pro Forte	Mean	1.5	1.4	1.3	1.1	
		SD	0.0	0.0	0.1	0.1	
		Median	1.5	1.4	1.3	1.2	
		Minimum	1.4	1.3	1.2	0.9	
		Maximum	1.5	1.4	1.4	1.3	
		Rank	a	ab	bc	c	

*Significant at $p < 0.05$, NS, non-significant at $p > 0.05$
Different letters within each row indicate significant difference

after 2 months compared to baseline only ($p < 0.001$) while the intergroup comparison showed no statistically significant difference between both groups (Table 4).

Over a period of 3 months, both Remin Pro Forte and Remin Pro produced significantly better caries regression and a significantly greater increase in mineral content of WSLs ($p < 0.05$). The difference in mineral content between groups of WSLs failed to reach statistical significance ($p = 0.414$). Both experimental groups demonstrated a substantial improvement in the appearance of WSLs ($p < 0.05$).

DISCUSSION

This clinical trial examined the remineralization capability of two remineralizing drugs, Remin Pro Forte and Remin Pro, on WSLs in youths following orthodontic treatment. Remin Pro® (RP) (VOCO GmbH, Cuxhaven, Germany) is cream enriched with hydroxyapatite, fluoride, and xylitol; this product has shown a sufficient capacity to remineralize the enamel's structure.^{6,15} The hydroxyapatite and fluoride act as an ion reservoir that can be incorporated into the enamel structure.

Remin Pro Forte was newly introduced and suggested by the manufacture due to its content of hydroxyapatite (calcium and phosphate), fluoride, and xylitol with the addition of two natural products (ginger and curcuma). Scientific literature has confirmed the antimicrobial potential against oral microorganisms (especially against *S. mutans*) of ginger extracts and curcuma. In this study, a 3-month treatment term was chosen because, in the majority of instances, WSLs diminish rapidly within the first 3 months after appliance removal.¹⁶

In this study, caries regression assessment was carried out by using ICDAS II criteria for smooth surface lesions as it can record the severity and incidence of the caries¹⁷ promoting preventative therapies globally that support the remineralization of non-cavitated lesions.¹⁸ The use of colored photographs to assess enamel demineralization appears to be more reliable than direct clinical inspection with the naked eye.¹⁹ In this study, a combination of both methods was used by performing ICDAS II scoring on WSLs on the photographic image records.¹² Color evaluation with a colorimeter or spectrophotometer and digital image analysis with Adobe Photoshop produce numeric values, rendering the

procedure objective, measurable, reproducible, and statistically analyzable.^{20,21} In this study, colorimetric analysis with adobe photoshop version 7.0 (Adobe Systems, San Jose, California, United States) and digital photographic camera was used. Also, VistaCam iX was used in this study to obtain fluorescence images for mineral content assessment. This fluorescence camera, according to a prior study, offers excellent reproducibility and efficiency when it comes to detecting caries during different stages of the disease.²²

On comparing the changes in the ICDAS II scores at 2 months, it was found that the mean percentage change in ICDAS II scores for the two remineralizing agents used (Remin Pro Forte and Remin Pro) was statistically significant, since most of the cases in Remin Pro group recorded score 1 (70%), while most of the cases in Remin Pro Forte group scored 2 (60%). Remin Pro contains hydroxyapatite structured from fluoride, calcium, and phosphate, and it can fill minor surface enamel defects. One limitation of using photographs is that the ICDAS scores must be evaluated after the tooth surface has been air dried. As a result, proper distinction of ICDAS I and ICDAS II scores would be impossible, as the only difference between scores 1 and 2 is whether the tooth is dry or wet, therefore, in this study's investigation, each WSL was photographed twice with the first photograph was taken of wet tooth surface and the second photograph was taken after prolonged air-drying (5 s) for proper differentiation between ICDAS score 1 and 2.

Regarding the impact of the two remineralizing agents on the color change of the WSL, during the study, both groups (Remin Pro and Remin Pro forte) demonstrated a considerable improvement in the color of WSLs with a significant decrease in ΔE after 3 months follow-up period ($p = 0.028$ and $p = 0.01$, respectively). This observation can be linked to the efficacy of of Remin Pro, Remin Pro Forte in remineralizing WSLs. However, at 3 months, the difference between groups was statistically significant, in which Remin Pro Forte group showed higher color improvement compared to Remin Pro group. This finding may be related to the ginger natural product in Remin Pro Forte as the remineralization obtained and substitution of lost minerals was probably due to the antimicrobial properties and the high fluoride and calcium content of ginger. Also, it has a positive effect on saliva and apatite stimulation, minerals enhancing the color regression of the WSLs.²³

The mineral content was increased in the Remin Pro Forte and Remin Pro groups throughout the trial with mean change in mineral content (1.1 ± 0.1 and 1.2 ± 0.0 , respectively). These results revealing these materials' remineralizing capacity, presumably due to hydroxyapatite's transport of calcium and phosphate ions with greater efficacy. The findings of this study are consistent with several *in vivo* studies by Heravi et al.,⁶ Kamh et al.,¹¹, Ebrahimi et al.,²⁴ Kiriştioglu et al.,²⁵ Esparza et al.,²⁶ who showed significant area reduction, improved color appearance and increased mineral content for WSLs by Remin pro remineralizing agent.

Ebrahimi et al.²⁴ reported a significant area reduction of WSLs in all groups; Remin Pro and Mi paste plus, except for the comparator group, and a significant increase was observed in terms of mineral content for Remin Pro as well as MI Paste Plus groups only. Heravi et al.⁶ reported that MI Paste Plus or Remin Pro substantially reduced the area of demineralized enamel, increased the mineral constituents, and improved the appearance compared with control group over a 12-week period.

While the results of this study were in conflict with results of Youssef et al.²⁷ who reported that Remin Pro and Complete Care failed to enhance lesion appearance and oral health in comparison to resin infiltration. The difference may be due to different remineralization therapy period which was performed for 7 consecutive days, while in this study, it was performed for 3 months. The amount of remineralizing agent used and its proximity to the demineralized surface of the tooth are other factors to consider. It was not specified how much Remin Pro cream was used, but it was applied chairside with a polishing brush and low-speed handpiece for five minutes. These steps were done daily three times for 7 days, while in this study Remin Pro was applied according to manufacture instructions that recommend pea-sized amount applied by a finger or brush and to leave for 3 min twice daily.

This clinical investigation had a few shortcomings. The inability to control patients' compliance optimally is one of the primary difficulties. An experiment was conducted to overcome the compliance barrier by providing the patients with instructions on cream technique, standardizing the time and amount of cream applied by the plastic syringe, and using the brushing diary as a way to monitor their actual protocol compliance. In this investigation, the null hypothesis was accepted. After orthodontic treatment, there was no significant difference between the remineralization capability of Remin Pro and Remin Pro Forte on WSLs.

CONCLUSION

Under the limitation of the following trial, it can be concluded that the use of Remin Pro Forte compared to Remin Pro twice daily for three months was beneficial in caries regression, color improvement and increasing the mineral content of WSLs post-orthodontic treatment. After orthodontic therapy, either Remin Pro Forte or Remin Pro can be prescribed to improve the mineral characteristics and improve dental esthetics in individuals with severe initial white lesions.

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This research received no external funding. All procedures in this study were carried out in compliance with the institutional research committee's ethical standards as well as the 1964 Helsinki statement and its subsequent amendments.

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