

“Evaluation Of Clinical Efficacy And Tooth Sensitivity Of PAP Based Teeth Whitening Pen”. - An Observational Study.

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Abstract

Aim: To observe and evaluate the efficacy of PAP based teeth whitening pen on teeth whitening and sensitivity after 14 days of application.

Methods and material: After obtaining ethical approval(SVIEC/ON/DENT/SRP/231801), the study included 15 volunteers who provided consent and had yellowish teeth with a shade darker than A2. Preoperative shade L*, a*, b* coordinates were recorded using a DSLR camera following oral prophylaxis. The volunteers were given a teeth whitening pen and instructed to use it twice a day after brushing their teeth. After a two-week period, the participants returned for evaluation, which involved recording the postoperative shade L*, a*, b* coordinates, documenting any sensitivity experienced during the use of the teeth whitening pen, and assessing patient satisfaction.

Statistical analysis: The L*, a*, b* coordinates collected were tabulated and statistically analyzed using SPSS version 21 with (P < 0.05). Paired t test was used to compare the pre and post L, a and b values.

Results: The study found significant increase in the L* values and delta E values above 5.5 for all the volunteers indicating visible teeth whitening effect among all the volunteers. None of the patients experienced sensitivity at the end of 14 days.

Conclusion: PAP-based teeth whitening pen is an effective and safe option for achieving teeth whitening without causing sensitivity. Further research and larger-scale studies are warranted to validate these results and explore the long-term effects of the product.

Keywords: teeth whitening pen, PAP, Peroxide free bleaching, home bleaching.

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I. INTRODUCTION

The original color of pure hydroxyapatite is colorless or white, and this applies to the integrated proteins as well.^(1,2) Natural enamel appears white with some translucency, but as enamel wears down over time due to factors like erosion, it becomes thinner and more translucent. This allows the underlying dentin to become more visible, resulting in a darker tooth color.⁽³⁾ Additionally, teeth can become stained from substances like wine, tea, coffee, and smoking. To address this, there are home-use whitening products like toothpastes and professional treatments like bleaching.⁽⁴⁾ These aim to increase the visual whiteness of teeth and focus on teeth whitening due to cosmetic reasons and their potential impact on quality of life.⁽⁵⁾ Tooth whitening is a popular dental treatment performed in dental offices. There has also been a rise in the market for over-the-counter (OTC) whitening systems, driven by the demand for convenient home-based procedures. Dentists primarily use hydrogen peroxide (HP) or carbamide peroxide (CP) for in-office bleaching. CP has a slower degradation rate than HP and is applied using dental trays, allowing for longer contact with the teeth.⁽⁶⁾

Peroxide-based products applied in-office directly to the enamel surface release reactive free radicals that oxidize organic chromophores, resulting in a lighter tooth appearance. While tooth whitening with peroxides is generally safe and effective, it can cause temporary teeth sensitivity in a considerable number of patients. This sensitivity is likely due to microscopic surface damage to the enamel, leading to inflammation of the dental nerve.⁽⁷⁾

To overcome the potential side effects of peroxide containing products, OTC market released newer non peroxide ingredients like PAP, sodium chlorite, or sodium bicarbonate. PAP is an organic peroxide that oxidizes chromogens without generating free radicals.⁽⁸⁾

PAP is a gentle alternative to hydrogen peroxide for teeth whitening, as it does not cause sensitivity, gum irritation, or pain. It protects teeth from demineralization and is equally effective as peroxide-based whitening agents.⁽⁹⁾ The Perfora Teeth Whitening Pen, which contains PAP and other ingredients like sodium bicarbonate, hydroxyapatite, strawberry, and aloe vera extract, offers a safe and effective solution to remove stains and discoloration from teeth at home. With the increasing prevalence of teeth whitening as a routine dental procedure, the accurate measurement and effectiveness of tooth whitening have become crucial in esthetic dentistry.⁽¹⁰⁾ Traditionally, dentists rely on visual comparisons to a reference shade guide to determine the color of human teeth. However, instrumental assessments provide quantitative and objective data, which are valuable in determining dental whiteness—a vital aspect of these treatments. Various formulas can be utilized to analyze the objective data and determine dental whiteness accurately, emphasizing the significance of instrumental analysis in these procedures.⁽¹¹⁾

To analyze tooth shade, instrumental tools like spectrophotometers, colorimeters, and digital imaging offer precise and accurate results compared to subjective methods.⁽¹²⁾ This study aims to compare the effectiveness and sensitivity of a non-peroxide-based teeth whitening system. However, there is a limited literature evaluating the efficacy and sensitivity of a PAP-based PERFORA teeth whitening pen in the searched databases. The study also seeks to explore alternative teeth whitening methods, offering valuable insights into different approaches. Therefore, the primary objective of this study is to assess the bleaching efficacy and tooth sensitivity of a PAP-based teeth whitening pen.

II. MATERIALS AND METHOD

This observational clinical study was conducted after taking prior permission from the institutional ethical committee (SVIEC/ON/DENT/SRP/231801). The participants included in the study were dental students and an informed consent was obtained from all the participants.

Participant enrollment: Volunteers of both sexes aged between 18 to 30 years who were healthy and free of any parafunctional and adverse habits with complaints of yellowish teeth, with a shade darker than A2 or above on the Vita Classic Shade Guide scale (Vita Zahnfabrik, Bad Säckingen, Germany), and desired teeth whitening for aesthetic purposes. Written informed consent was obtained from all volunteers, and only those who were willing to sign the consent letter were enrolled for the study. The study excluded patients with known dentinal hypersensitivity, poor oral hygiene and gingival health, restorations in upper-front teeth, previous history of tooth bleaching procedure, severe internal tooth discoloration, exposed dentine, as well as pregnant and lactating women.

Sample size calculation: For sample size calculation, a study conducted by Müller-Heupt L.K. Wiesmann-Imilowski N., Kaya, S. et al. in 2023⁽¹³⁾ was considered. Based on this study, which examined the mean difference in delta E between six groups with a 2.0 unit difference, a 1% alpha error, and 99% power of the study, a clinically significant difference of 4 units was determined. The required sample size was calculated to be 13 participants, each participant had 6 teeth examined, resulting in a total of 78 teeth. To account for a potential 20% dropout rate or loss to follow-up, 2 additional participants were included, contributing an extra 12 teeth. This ultimately yielded a sample size of 90 teeth.

Treatment protocol: Pre-operative pulp sensibility tests were conducted using an Electric Pulp Tester (EPT), and oral prophylaxis was performed on all volunteers prior to the commencement of the study. In order to document the initial tooth shade, a preoperative digital image was captured using a DSLR Camera (Canon) equipped with a 100 mm focal length macro lens, maintaining a ratio of 1.5. A close-up Speedlight flash and retractors (lip and cheek) were utilized during the image capture process.

Clinical procedure:

Each volunteer participating in the study was provided with a teeth whitening pen (Perfora, India) and instructed to use it twice a day following their regular teeth brushing routine. The volunteers received clear instructions on how to properly utilize the pen for teeth whitening. The procedure for using the teeth whitening pen was as follows: Firstly, the volunteers were advised to thoroughly brush their teeth before using the pen. Subsequently, they were instructed to gently dry the labial surfaces of their anterior teeth using a clean, dry tissue paper. To dispense the whitening serum from the pen, the volunteers needed to click the end of the pen 3-4 times. The serum would be released from the tip of the pen which resembles a paintbrush. The volunteers were then instructed to generously apply the serum to all their anterior teeth, ensuring that the labial surfaces were adequately covered. After applying the serum, the volunteers were instructed to keep their mouths open for 30 seconds to allow the serum to dry. They were advised not to eat or drink anything for the subsequent 30 minutes. This procedure was to be repeated twice a day, once in the morning and once at night before bedtime, for a duration of

14 days. Following the completion of the 14-day period, the patients were requested to return to the department for evaluation of the teeth whitening effect and to report any sensitivity experienced during the usage of the teeth whitening pen.

The evaluation criteria involved taking post-operative photographs using a DSLR Camera. In these photographs, L*, a*, b* values were recorded from both preoperative and postoperative images. Adobe Photoshop was utilized to measure these values, and subsequently, delta E was calculated using the formula $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

Additionally, the volunteers were briefed on the usage of a visual analog scale. They were instructed to document any tooth sensitivity experienced during the 14-day period of using the teeth whitening pen and the patients were instructed to record their level of satisfaction after using the teeth whitening pen.

Statistical analysis:

The L*, a*, b* values collected were tabulated and statistically analyzed using SPSS version 21 (IBM Corp., Armonk, NY, USA) with (P < 0.05) and 95% confidence interval.

Paired t test was used to compare the preoperative and post operative L*, a*, b* values indicating the change in tooth shade at 14 days.

III. RESULTS

The study included 15 volunteers (4 males, 11 females) aged 18-30 years. Using Adobe Photoshop, the color difference was calculated based on pre and postoperative L*, a*, b* coordinates. The mean value of Post L (74.82±10.24) was higher than Pre L (66.42±9.48), indicating a significant increase in lightness after teeth whitening. The difference in mean values was 8.405, which was statistically significant with a p-value of less than 0.001. Similarly, when comparing the mean values of Pre a (red-green component) and Post a, it was observed that the mean value of Pre a was higher. This difference was statistically significant with a p-value of 0.003, indicating a change in the red-green component after teeth whitening.

In terms of the mean values of Pre b (yellow-blue component) and Post b, the mean value of Pre b was higher. This difference was also statistically significant with a p-value of less than 0.001, suggesting a change in the yellow-blue component after teeth whitening.

Table 1: Paired t test to compare the pre and post L, a and b

		N	Mean ± SD	Mean difference ± SD	t	P VALUE
Pair 1	Pre L	84	66.42±9.48	-8.41±2.42	-31.89	<0.001
	Post L	84	74.82±10.24			
Pair 2	Pre a	84	5.68±2.7	0.58±1.76	3.04	0.003
	Post a	84	5.1±2.32			
Pair 3	Pre b	84	22.23±5.44	2.08±2.98	6.40	<0.001
	Post b	84	20.14±5.12			

1 volunteer was lost to follow up and among the 14 volunteers who provided feedback, 4 patients expressed complete satisfaction with the results obtained after teeth whitening. Additionally, 5 patients reported being satisfied, while 5 patients expressed slight dissatisfaction with the results achieved.

Table 2: Table comparing patient satisfaction scores

		No of patients	Valid Percent
Score 1	Totally satisfied	4	28.6
Score 2	satisfied	5	35.7
Score 3	Slightly dissatisfied	5	35.7
	Total	14	100

IV. DISCUSSION

The appearance of teeth plays a significant role in facial beauty, and many individuals seek aesthetic dental treatments to address tooth discoloration. Discolored teeth are often perceived as detracting from an attractive image and can lead to social anxiety. Among the non-restorative aesthetic treatments available for managing tooth discoloration, tooth bleaching is the most commonly recommended approach.⁽¹⁰⁾

Professional in-chair bleaching protocols, which involve the use of gingival barriers and isolation of soft tissues, can help control the oral environment and minimize soft tissue irritation. However, they are unable to mitigate the potential adverse effects on enamel. In recent years, inexpensive home-bleaching products have

become widely available through online vendors or over-the-counter (OTC) channels. Many of these OTC products are used without professional guidance or supervision.⁽¹⁴⁾

Safety concerns arise due to the low pH of such products (which is necessary for their shelf life), suboptimal binding agents, and a lack of gingival protection. As a result, there has been growing interest in exploring alternative bleaching agents to HP and CP. Organic peroxides, such as phthalimidoperoxycaproic acid (PAP), have gained attention as potential active ingredients.⁽¹³⁾

PAP, as a teeth whitening agent, induces oxidation reactions that result in the decolorization of chromogens. This process involves the epoxidation of molecules containing conjugated double bonds. Notably, this reaction occurs without the generation of free radicals, which are known to be responsible for tooth sensitivity and gingival irritation commonly associated with conventional tooth bleaching using HP and CP.⁽⁸⁾

The findings of the study demonstrated a statistically significant difference in the pre- and post-operative L*, a*, and b* values, representing changes in tooth value, hue, and chroma, respectively. Specifically, there was a significant increase in tooth value, indicating a whitening effect. The chroma decreased, indicating a reduction in the intensity of the yellow shade, while the hue also decreased, suggesting a shift in shade along the red-green axis.

These findings are consistent with previous research conducted by Müller-Heupt LK, Wiesmann-Imilowski N, et al.,⁽¹³⁾ which examined the teeth whitening effects, cytotoxicity, and enamel surface changes caused by various over-the-counter (OTC) bleaching agents compared to hydrogen peroxide. While the whitening effect was not as strong as with hydrogen peroxide, a noticeable improvement in teeth whiteness was still observed, with an average ΔE of 6.95 ± 1.5 .

In a study by Junyuan Qin et al.⁽¹⁵⁾, the whitening effects of a PAP-based teeth whitening gel were compared to a hydrogen peroxide-based gel. The results indicated that both products significantly whitened the teeth, although the PAP-based pen exhibited slightly lower efficacy in terms of ΔE values compared to the hydrogen peroxide gel. Nonetheless, the PAP-based pen still resulted in a noticeable enhancement of tooth shade.

In a controlled trial conducted by Chen et al., the efficacy of a teeth whitening pen based on PAP was compared to a commercially available hydrogen peroxide gel. The results of the study showed that both products were effective in whitening teeth, and there was no significant difference between them in terms of effectiveness. Furthermore, the PAP-based pen demonstrated a lower incidence of tooth sensitivity compared to the hydrogen peroxide gel. This could be attributed to the inclusion of hydroxyapatite and the presence of an efficient citrate buffering system in the PAP-based pen, which helps maintain a near-neutral pH during treatment, thereby preserving the enamel surface and minimizing sensitivity issues.

These additional studies provide further evidence supporting the positive performance and safety of PAP-based teeth whitening gels. However, it is important to acknowledge that the current body of literature on clinical studies involving PAP-based products is still limited. Therefore, additional comprehensive research is needed to validate and expand upon the findings obtained in this study.

While various in vitro studies support the favorable performance of PAP-based teeth whitening gels, the existing literature on clinical studies of this nature is lacking, underscoring the need for further investigation to substantiate the results obtained in this study.

Limitations:

1. The sample size considered in the current study is relatively less. More studies could be conducted with larger sample size.
2. The follow-up time in this study was 14 days, thus studies with extended follow-up are required, providing a more precise knowledge concerning the longevity and clinical performance of the teeth whitening pen.
3. Only yellowish shade teeth were included without any dark discoloration. more studies could be conducted with flurosis or extrinsic discoloration.

V. CONCLUSION

The use of a teeth whitening pen based on (PAP) has been found to be both effective and safe for achieving teeth whitening without causing sensitivity. However, to ensure the reliability of these findings and gain a better understanding of the product's long-term effects, further research and larger-scale studies are needed.

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