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To Evaluate the Efficacy of Recently Introduced Caries Preventive Varnishes in Visually Impaired Institutionalized Children: A Randomized Clinical Trial

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KEYWORDS

Fluoride Varnish; Embrace Varnish (CXP); Bioactive Glass Fluoride Varnish; DMFT; Visual Impaired Children

ABSTRACT:

Background: Children with Special Health Care Needs (SHCN) face increased risk of poor oral hygiene, dental caries, and periodontal disease. Fluoride varnish, Bioactive Glass, and Embrace can help prevent tooth decay and promote remineralization. These varnishes release fluoride, calcium, and phosphate ions to strengthen tooth enamel, promote remineralization, and prevent acid attacks. Embrace Varnish, in particular, offers enhanced fluoride release and remineralization capabilities.

Aim: To comparatively evaluate the efficacy of recently introduced caries preventive varnishes in visually impaired institutional children aged 6-12 years.

Methods: This study aimed to evaluate the effectiveness of different fluoride varnishes in preventing tooth decay in visually impaired children. Ninety visually impaired children aged 6-12 years were randomly divided into three groups of 30 children each(n=30). The Group A received conventional fluoride varnish, Group B fluoride varnish with Bioactive Glass (BAG), and Group C fluoride varnish with CXP (Embrace). The varnishes were applied at 0, 3, and 6 months, and the decayed component of the DMFT/def index was evaluated at each follow-up visit.

Results: The DMFT scores showed a significant reduction over time, with a statistically significant difference among the groups at 3 months ($p = 0.023$). Post hoc analysis revealed that Group C (CXP varnish) had better results compared to Group A (conventional fluoride varnish) and Group B (BAG varnish), following the trend A > B > C. However, at 6 months, the difference among the groups was not statistically significant ($p = 0.248$).

Conclusion: The CXP (Embrace) varnish demonstrated better efficacy in reducing DMFT scores compared to conventional fluoride varnish and BAG varnish. Although it showed significant improvement at 3 months ($p = 0.023$), the difference diminished by 6 months ($p = 0.248$).

Introduction

The AAPD defines special health care needs as "any physical, developmental, mental, sensory, behavioral, cognitive, or emotional impairment or limiting condition that requires medical management, health care intervention, and/or use of specialized services or programs.[1] Vision, our most dominant sense, is essential to nearly every aspect of our lives. We often overlook its significance, but without sight, we face challenging in learning, mobility, reading, and fully engaging in

Journal of Chemical Health Risks
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school and work.[2] WHO identifies the issue of visual impairments as a top priority on a global scale. Approximately 1.4 million children worldwide suffer from vision problems. Alarmingly, India bears the largest burden, with a staggering 15 million visually impaired children, making it the country with the highest number of visually impaired children worldwide.[3] Dental caries is acknowledged as a chronic infectious disease, rather than merely a condition that continuously progresses over time. This understanding emphasizes the importance of early intervention and preventive measures, allowing for more effective management and potentially reversing the disease process before extensive damage occurs.[4] It has been proposed that to restore the natural balance, it is essential to either boost remineralization or slow down demineralization processes.[5] Fluoride varnish has been used since the 1960s to prevent tooth decay in children. It works by replacing hydroxyl ions with fluoride ions in tooth enamel, making it more resistant to acid attacks. Topical fluoride applications, including varnishes, gels, and foams, can be professionally applied or self-administered. Fluoride has been shown to, increase tooth enamel's strength and resistance to acid attacks, promote remineralization of demineralized enamel and dentin, have anti-bacterial effects, preventing the growth of acid-producing bacteria, Reduce the incidence of caries by up to 33% when applied 3 times a year.[5] Profluorid Varnish is a clear desensitizing varnish formulated with 5% sodium fluoride (NaF). It is optimized for rapid fluoride release, making it especially suitable for treating demineralized enamel and exposed dentin.. It is frequently utilized to reduce tooth sensitivity and seal dentinal tubules, providing effective protection for vulnerable teeth.[6] Bioactive glass (BAG) is a type of bioceramic material made up of numerous inorganic compounds, including silicon, sodium, calcium, phosphorus, and other elements. Its active component is amorphous calcium-sodium phosphosilicate, which contains minerals that are naturally found in bodily fluids. When BAG comes into contact with water or saliva, it releases calcium, phosphorus, sodium, and silicon ions. This process facilitates the formation of hydroxyapatite crystals (HAP) that are deposited on the tooth surface; enhancing the remineralization of demineralized enamel.[7] Embrace™ Varnish represents a next-generation fluoride varnish, merging xylitol-coated calcium and phosphate (XCP) within a resin matrix. This innovative formulation significantly prolongs the fluoride release duration of the varnish. When xylitol is dissolved by saliva, it facilitates the release of calcium and phosphate ions, which then interact with fluoride ions to form fluoroapatite on the enamel surface. Additionally, the combination of xylitol with sodium fluoride enhances the remineralization process of demineralized subsurface enamel by promoting the penetration and deposition of calcium ions.[8] Thus, the goal of this study was to compare the efficacy of recently introduced caries preventive varnishes in visually impaired institutionalized children.

Materials & Method

This study was conducted in the Department of Pediatric and Preventive Dentistry, Uttar Pradesh Ghaziabad, Shree Bankey Bihari Dental College and Research Centre. The present study was Randomized Controlled Trial. A sample size of 90 visually impaired institutionalized children between the age group of 6 – 12 years was taken for the study. 90 visual impaired children of age 6-12 years were included. Permission was taken from the institute before commencing the study. Informed consent was sent to the institute prior the day of examination. Random assignment of the patients was done into the following groups:

- Group A Conventional Fluoride Varnish
- Group B Bioactive Glass Varnish
- Group C CXP Varnish

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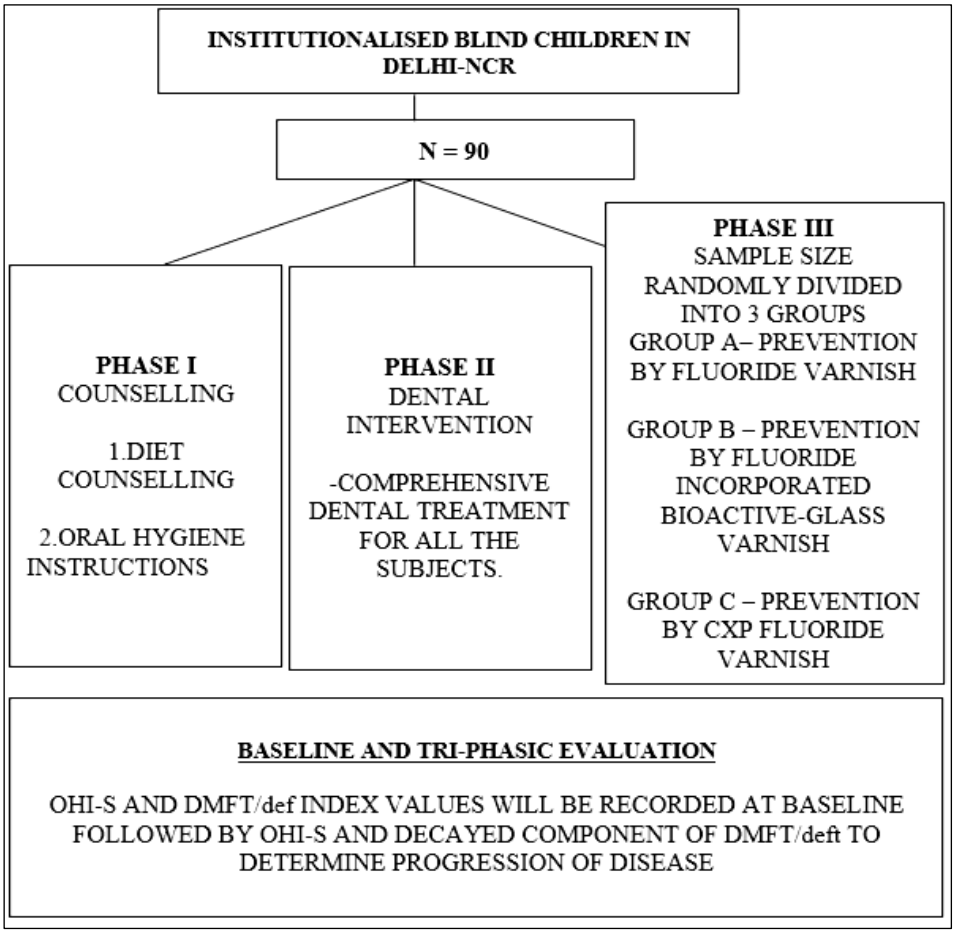

These varnishes with different compositions were used for applications to the 3 monthly intervals for a total period of 6 months. And the decayed component of DMFT/def index was evaluated at each visit of the follow-up in order to carry out a comparative assessment.

Inclusion Criteria

1. Subjects should be visually impaired

2. Subjects should not be suffering from any systemic disease

3. Subjects should be between the ages of 6 to 12 years

4. Subjects should be institutionalized

5. Informed consent from the concerned authorities mandatory

Exclusion Criteria

1. Subjects who are not visually impaired

2. Subjects suffering from systemic diseases

3. Subjects below 6 and above 12 years of age

4. Subjects not residing in institutions

5. Informed consent not received from the concerned authorities

Phase I: Counseling

Counselling was provided to both the subjects and their caretakers, who would reinforce it daily with the children, considering each child's specific disability. Diet counselling was done regarding importance of balanced diet and focus on carbohydrates with frequency as opposed to quantity of sugar intake emphasized on. In addition, fibrous food is recommended in order avoiding dental caries. Soft-tipped multi-tufted nylon brushes featuring rounded bristles and fluoridated toothpaste was given to the subjects. It incorporates various sensory inputs to enhance learning. For teaching effective tooth brushing, the recommended method is the horizontal scrub technique. This method is particularly beneficial as it is

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JCHR (2025) 15(5), 3351-3360 | ISSN:2251-6727

straightforward and easy for children to learn and master.

Phase II: Intervention with Dental Treatment

Intraoral examination coupled helps the dental professional to come to a final diagnosis regarding the disease process in order to plan the treatment effectively and efficiently. In planning treatment for a child with visual impairment, it makes sense to conduct comprehensive dental treatment procedures which are long lasting and will not require the patient for repeated follow-ups as it would inconvenience them greatly. Oral prophylaxis and fluoride releasing materials like glass ionomer cements were used in these children. Behavior management techniques customized to the need of the patient was incorporated during the treatment procedure like changing the desensitization technique commonly used in other children like Tell-Show-Do to Tell-Feel-Do in this particular group. Techniques emphasizing on the other senses not only to deliver the treatment effectively but also to instill a positive dental attitude was used to compensate for the lack of vision in this group of special children.

Phase III: Maintenance Phase with 3 Different Types of Varnishes

Here only the decayed component of the DMFT/deft was taken to compared the progression of the caries process after the dental intervention phase as it is well known that the DMFT/deft index. The 90 subjects were randomly divided into 3 groups.

Group A: n = 30, Conventional Fluoride varnish was applied to blind children at 1, 3 and 6, months follow up.

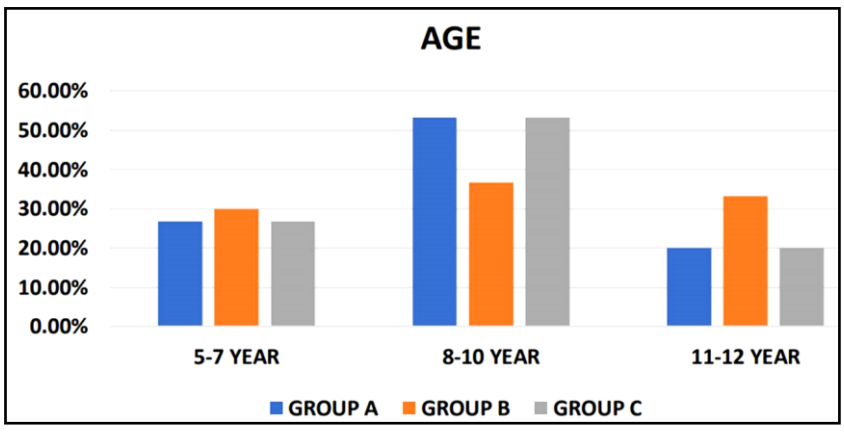
Group B: n = 30, Fluoride varnish with BAG was applied to blind children at 1, 3 and 6, months follow up.

Group C: n = 30, Fluoride varnish with CXP was applied to the subjects at 1, 3 and 6 months respectively.

These varnishes with different compositions were used for applications to the 3 monthly intervals for a total period of 6 months. And the decayed component of DMFT/def index evaluated at each visit of the follow-up in order to carry out a comparative assessment.

Results

1. Age Wise Distribution



Graph-1-The distribution of participants across age groups was similar among the three study groups. In Group A, 8 (26.7%) participants were aged 5-7 years, 16 (53.3%) were aged 8-10 years, and 6 (20.0%) were aged 11-12 years. Group B had 9 (30.0%) participants in the 5-7 years category, 11 (36.7%) in the 8-10 years category, and 10 (33.3%) in the 11-12 years category. Group C showed the same age distribution as Group A, with 8 (26.7%) in the 5-7 years range, 16 (53.3%) in the 8-10 years range, and 6 (20.0%) in the 11-12 years range. The overall distribution across all groups was 27.8%, 47.8%, and 24.4%, respectively. The result showed no significant difference in age distribution among the groups (p = 2.69).

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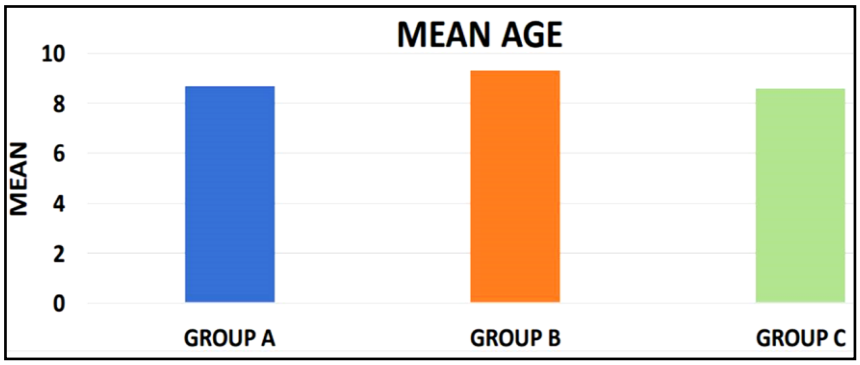
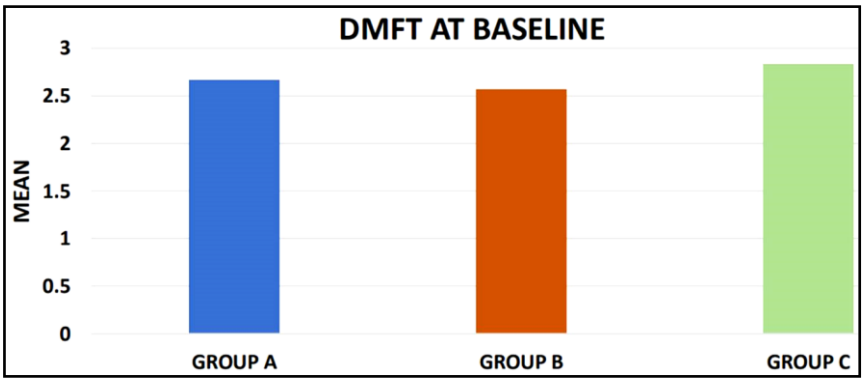
2. Intergroup Comparison of Mean Age



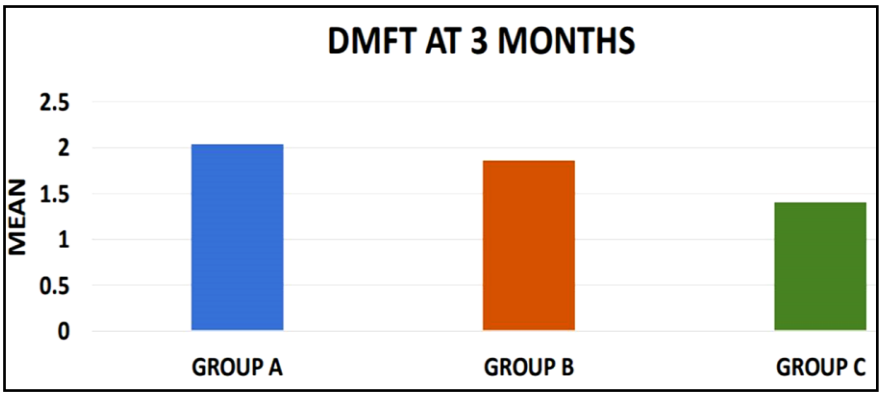
Graph 2-The mean age for Group A was 8.67 ± 2.040 years, for Group B it was 9.30 ± 1.985 years, and for Group C it was 8.57 ± 1.924 years. The overall mean age across all groups was 8.84 ± 1.988 years. The one-way ANOVA test (F = 0.206) showed no statistically significant difference in mean age among the groups (p = 0.304).

3. Intergroup Comparison of DMFT at Baseline



Graph 3, at baseline, the mean DMFT score was 2.67 ± 0.959 for Group A, 2.57 ± 0.728 for Group B, and 2.83 ± 1.020 for Group C. The overall mean DMFT score was 2.69 ± 0.907. The ANOVA test (F = 0.656) showed no significant difference in DMFT scores at baseline among the groups (p = 0.521).

4. Intergroup Comparison of DMFT at 3 Months



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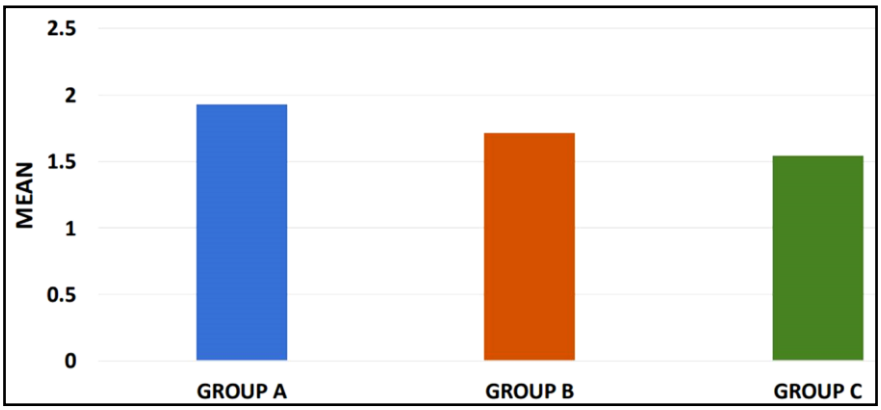
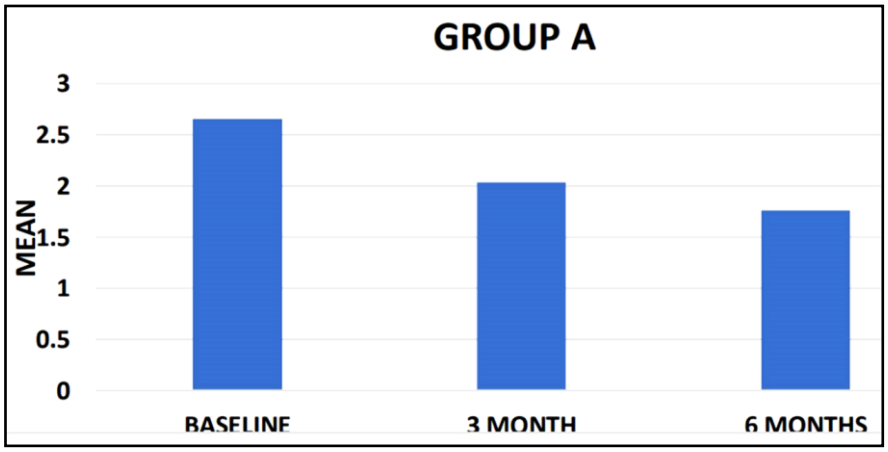
Graph 4 at 3 months, the mean DMFT score for Group A was 2.03 ± 1.085, for Group B it was 1.86 ± 0.848, and for Group C it was 1.40 ± 0.724. The overall mean DMFT score was 2.03 ± 1.085. The ANOVA test (F = 3.93) showed a statistically significant difference among the groups (p = 0.023). Post hoc analysis indicated that the DMFT scores followed the trend A > B > C, suggesting better improvement in Group C.

5. Intergroup Comparison of DMFT at 6 Months



Graph 5, at 6 months, the mean DMFT score for Group A was 1.93 ± 0.923, for Group B it was 1.71 ± 0.937, and for Group C it was 1.54 ± 0.793. The overall mean DMFT score was 1.73 ± 0.892. The ANOVA test (F = 1.4) showed no statistically significant difference among the groups (p = 0.248). However, the trend A > B > C was observed in post hoc analysis.

6. Intragroup Comparison for Group A



Graph 6, The mean DMFT score in Group A reduced from 2.655 ± 0.181 at baseline to 2.034 ± 0.201 at 3 months and further to 1.759 ± 0.146 at 6 months. The repeated measures ANOVA test showed a statistically significant reduction in DMFT scores over time (p = 0.001), with post hoc analysis indicating the trend Baseline > 3 Months > 6 Months.

Journal of Chemical Health Risks
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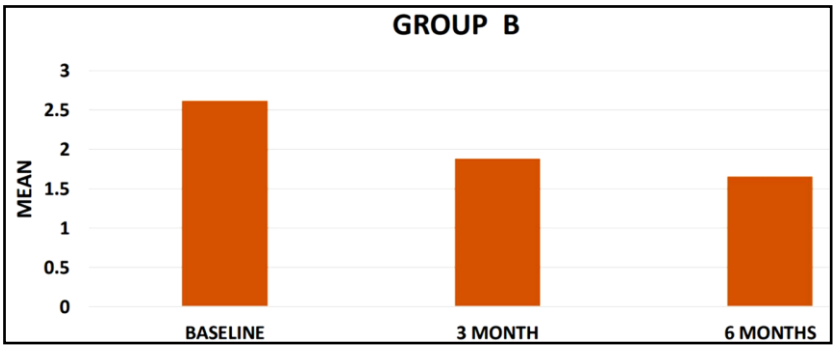
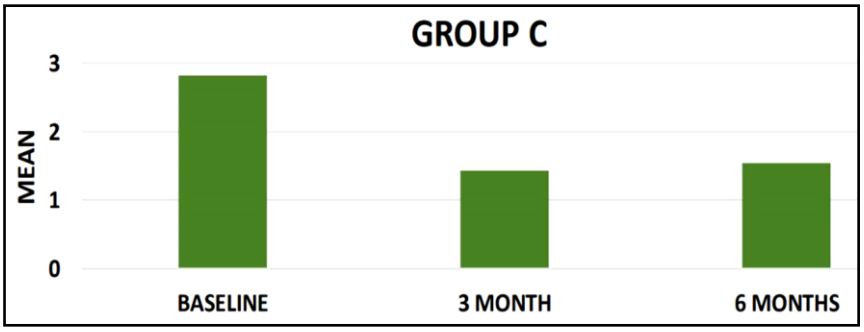
7. Intragroup Comparison for Group B



Graph 8, In Group B, the mean DMFT score decreased from 2.615 ± 0.148 at baseline to 1.885 ± 0.169 at 3 months and further to 1.654 ± 0.183 at 6 months. The reduction was statistically significant (p = 0.001), with post hoc analysis showing the trend Baseline > 3 Months > 6 Months.

8. Intragroup Comparison for Group C



Graph 8, Group C showed significant improvement, with the mean DMFT score reducing from 2.821 ± 0.193 at baseline to 1.429 ± 0.140 at 3 months, followed by a slight increase to 1.536 ± 0.150 at 6 months. The reduction was statistically significant (p = 0.001), with post hoc analysis showing the trend Baseline > 3 Months > 6 Months.

Discussion

Approximately 10% of the global population, equating to 650 million individuals, live with a disability. Addressing the unique healthcare needs of these demographic presents ongoing challenges in the 21st century. Among these concerns, childhood visual impairment has emerged as a significant public health issue worldwide. Visual impairment represents a substantial segment of the population of disabled children. Globally, it is estimated that over 1.4 million children experience visual impairment, with India having the highest prevalence, around 15 million affected children.[9] Fluoride varnishes shown great effectiveness in decreasing dental caries, in addition to their ease of application and high patient acceptability.[10] Bioactive Glass (BAG) releases calcium, phosphorus, and silicon ions, forming hydroxyapatite crystals to remineralize demineralized enamel.[11] Embrace Varnish Combines xylitol-coated calcium and phosphate (XCP) with fluoride, releasing calcium and phosphate ions to form fluoroapatite on enamel, with 10 times more fluoride release over 4 hours compared to leading varnishes.[8,11,12] Thus, this study aims at comparing evaluate the efficacy of recently introduced caries preventive varnishes in visually impaired institutional children aged 6-12 years: A randomized

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JCHR (2025) 15(5), 3351-3360 | ISSN:2251-6727

clinical trial. In our study 53.3% were 8–10-year age group in Group A (conventional fluoride) and group B (Fluoride varnish with BAG) and whereas 36.7% were into 8-10 year in group C (Fluoride varnish with CXP). We can say that majority i.e., 47.8% were into age group of 8-10 years with mean age of 9.30 yr which is high in group B (Fluoride varnish with BAG) and in 8.57 yr. were in the group C (Fluoride varnish with CXP) and A (conventional fluoride) comprised of 8.67yr at non-significant level. Gender wise, in group A (conventional fluoride) 53.3% were female whereas 83.3% male in group B (Fluoride varnish with BAG) and 86.7% were also male in group C (Fluoride varnish with CXP) at significant level. Study by Ibrahim et al (2022)[13] showed the prevalence varies between 11% and 33%, with affected individuals typically aged between 20 and 50 years, and a higher prevalence observed among female patients. In present study mean age for Group A was 8.67, Group B it was 9.30, and in Group C it was 8.57. The overall mean age across all groups was 8.84, which showed no statistically significant difference in mean age among the groups ($p = 0.304$). similarly, mean DMFT in present study i.e., 2.83 in Group C (Fluoride varnish with CXP) was high followed by 2.67 in group A (conventional fluoride) and in group B (Fluoride varnish with BAG) it was 2.57 but at non-significant level. At baseline, No difference was observed for Mean DMFT among all of the study groups whereas at 3 months least DMFT mean was found in group C (Fluoride varnish with CXP) i.e 1.40 followed by group B (Fluoride varnish with BAG) where mean DMFT was 1.86 and highest mean DMFT was seen in group A (conventional fluoride) i.e. 2.03 at significant level. After 6 months, the group that received fluoride varnish with CXP (group C) had the lowest mean DMFT score of 1.54. This was followed by group B, which received fluoride varnish with (BAG), where the mean DMFT was 1.71. The highest mean DMFT was observed in group A, which received conventional fluoride, with a score of 1.93 however, this difference was not statistically significant. A study by Wu et al (2020) It was reported that the DMFT score for 12-year-old children consistently declined from 2.77 to 1.64 following the biannual application of fluoride varnish over the course of one year. Bravo et al[12] assessed the effectiveness of fluoride varnish in preventing dental caries on first permanent molars, revealing a 43.9% reduction in the incidence of caries following fluoride application. Also, Cochrane review found that the application of fluoride varnish significantly decreased the DMFS score in the permanent dentition, showing a reduction of 43% (95% CI: 0.3–0.57, $P > 0.0001$) when compared to a control group.[14] The study by Agarwal et al. (2022) further validated fluoride varnish as an reliable defence tool for early childhood caries over a 3year period, with a significant reduction in caries incidence in high-fluoride regions.[15] Marinho et al. in (2013) in his study using topically applied 5% Na fluoride varnishes as was applied, dental caries decreased, as evidenced by the pooled DMFS estimate of 43% and the overall d (e/m)fs estimate of 37% as compared to placebo or no theapy.[16] In our study mean DMFT was compared at different time intervals among all of the studied groups and it was seen that in group A, (conventional fluoride) mean DMFT was reduced from baseline (2.655) to 6 months (1.759) at significant level. Similar to the studies carried out by Patil SK et al, in 2017, Gao et al. in 2016 where they have found similar results showing significant cariesreversal afterintensive fluoride application. The study by Agarwal et al. (2022)[13] further validated fluoride varnish as a successful barrier tool for early childhood caries over a 3-year period, with a significant reduction in caries incidence in high-fluoride regions. Author, Mishra et al. in 2016 also reviewed examining the effectiveness of fluoride varnish in preventing early childhood caries revealed that the application of 1% fluoride varnish resulted in a caries preventive fraction ranging from 6.4% to 30%. In contrast, the use of a 5% concentration of fluoride varnish demonstrated a broader preventive effect, with a caries preventive fraction between 5% and 63%.[17] O Baik A et al. in 2024, which examined similar parameters, reported that Embrace Varnish demonstrated significantly greater efficacy than fluoride varnish in preventing caries on the occlusal surfaces of newly erupted first permanent molars at the 6, 12, and 18-month.[18] In group B (Fluoride varnish with BAG), mean DMFT was reduced from baseline (2.615) to 6 months (1.654) at significant level. Similar to studies performed by Prabhakar et al. (2009) examined the remineralization potential of bioactive glass and found it significantly effective in enhancing remineralization.[7] Also, Narayana et al. (2014) assessed various remineralizing agents, concluding that bioactive glass showed an increase in calcium levels, reinforcing its role as an effective

Journal of Chemical Health Risks
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JCHR (2025) 15(5), 3351-3360 | ISSN:2251-6727

remineralizing agent.[19] On the contrary, Rajendran et al. (2019) further confirmed that CPP-ACP had a higher remineralization potential than bioactive glass, highlighting the significance of calcium and phosphate supplementation alongside fluoride.[20] In Group C (Fluoride varnish with CXP), mean DMFT was reduced from baseline (2.821) to 3 months (1.429) and at 6 months i.e. (1.536) at significant level. These results are in consistent with the study done by Janneson et al. in 2002, which demonstrated that xylitol consumption leads to positive outcomes, including a reduced incidence of caries following varnish application in the studied pediatric population.[21] Milburn et al, 2015, in his study a comparison of fluoride release from enamel treated with Embrace varnish versus three other fluoride systems revealed that Embrace varnish exhibited the highest fluoride release within the first four hours, demonstrating a release rate that was ten times greater than that of the other fluoride varnishes tested. More recent study by O Baik A et al. in 2024, which examined similar, reported that Embrace Varnish was much more effective than fluoride varnish in preventing caries on newly erupted first permanent molars.[18] On the contrary, Ibrahim et al (2022) this observation clarifies the reduced sensitivity values observed after 2 days and 4 months intervals. In contrast, for longer follow-up periods, the effect appeared to decreased gradually.[13]

Conclusion

Embrace varnish showed better efficacy as compared to other two groups. The DMFT scores demonstrated a significant decrease over the 6-month study period, indicating an overall improvement in oral health. Xylitol is dissolved by the saliva leading to the release of calcium and phosphate ions to react with the fluoride ions and form fluorapatite on the enamel surface. Xylitol with sodium fluoride can enhance remineralization of the demineralized subsurface enamel by assisting calcium ions penetration and deposition. The Embrace Varnish exhibits a significantly higher fluoride release profile, releasing ten times more fluoride than comparable varnishes over a 4-hour period. Notably, the difference in DMFT scores among the three groups was statistically significant at the 3-month mark ($p = 0.023$). This suggests that the type of varnish used had a significant impact on oral health outcomes. Post hoc analysis revealed that Group C, which received the CXP (Embrace) varnish, showed the most significant improvement in DMFT scores compared to Group A (conventional fluoride varnish) and Group B (BAG varnish). The finding showed where A > B > C, indicating that Group C had the lowest DMFT scores, followed by Group B, and then Group A. However, by the 6-month mark, the difference in DMFT scores among the three groups was no longer statistically significant ($p = 0.248$).

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