Keywords
Pediatric syrups, Colour stability, Composite restorations, Glass ionomer restorations, Spectrophotometer.

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Effect of Pediatric medication syrups on colour stability of tooth-coloured restorations in children

Abstract

Aim and background: Esthetics play a significant role in pediatric dentistry. Tooth colored restorative materials are used to restore the damaged or discolored tooth structure. Oral intake of beverages and pediatric syrups have the potential to stain the tooth-coloured restorative materials. This study aims to evaluate the effect of colouring agents present in pediatric syrups on the colour stability of Nano hybrid composite (Tetric N Ceram®) and Glass ionomer restorations (Fuji II®)

Methods: 32-disc shaped samples of GIC, Composite resin were prepared using customized moulds. The samples were randomly allotted to 4 subgroups of peditric syrups. Subgroup I (Ascoril D®), Subgroup II (Ambrodil S®.), Subgroup III (Recofast®.), Subgroup IV (Children's Benadryl®.). After acquiring baseline colour readings, the samples were immersed in respective syrups for 2mins, thrice daily for 7 days. Spectrophotometric readings were taken after 7 days. Statistical analysis was performed using One Way ANOVA and paired t- test with a significance level of $p<0.05$.

Results: Results revealed that ΔE values were higher for GIC than composites when exposed to 4 test syrups for 7 days. When exposed to Ambrodil S®, GIC exhibited highest discoloration (2.350±1.003) and composite resin showed the lowest (0.725±0.742). Exposure to Ascoril D® showed lowest colour change in GIC (0.988±0.849). Exposure to Children's Benadryl®. composite showed highest discoloration (1.488).

Conclusion: The nano hybrid composite resin exhibited more resistance to discoloration compared to conventional GIC when they were exposed to various pediatric syrup formulations.

Clinical significance: Pediatric syrups with these colouring agents can be safely prescribed to children for up to 7 days without causing clinically detected colour change in the restorative material.

Introduction

Juvenile idiopathic arthritis remains the most prevalent chronic rheumatic disease of childhood and is an essentially

The demand for esthetic restorations in pediatric patients is equivalent to adults. Unsightly appearance of teeth in children immensely affects their psychological and personality development.1 Composite resin and glass ionomer cement (GIC) are the esthetic restorative materials of choice for pediatric patients.2 Frequent exposure of restorations to beverages like Tea, Cola, coffee, etc., can discolour the restorations.3–5 It is also evident that liquid medications like syrups prescribed for children cause change in the colour of restorations. 6 Children are often prescribed liquid medications as they are easier to administer. Most commonly prescribed class of medications for children includes analgesics, antibiotics, antihistamines, antiepileptics, multi vitamins, and antitussives which are in the form of syrups.7 Syrups contain buffering agents, acids, sugars, and permitted coloring and flavouring agents which increase the palatability and acceptability in children.6,8 High sugar content in syrups causes low plaque pH resulting in the initiation of caries and have an erosive effect on the primary teeth in children who are prescribed with pediatric medications for long term use.7 Besides this, it leads to decreased tooth strength or can degrade the surface of the restorative material.8 Some studies that investigated the influence of pediatric syrups on the color stability of esthetic restorative materials, concluded that restorative materials discolor when exposed to pediatric syrups.2,6,7,9 Previous studies that evaluated the influence of pediatric syrups on discoloration of restorative materials contained the following colouring agents: Quinoline Yellow, Carmoisine, Sunset Yellow, Colourless, Ponceau 4R, Quinoline Yellow, Erythrosine, Tartrazine.7,9–11 This study was aimed to evaluate the colour stability of composite resin and GIC restorative material when exposed to pediatric syrups that contain colouring agents (Caramel USO-NF, D&C red no#33, FD&C Red #40, Brilliant blue FCF, Tartrazine, Carmosine, Ponceau 4R) which were not tested by the earlier studies. The objective of this study is to evaluate and compare the influence of colouring agents (Caramel USO-NF, D&C red no#33, FD&C Red #40, Brilliant blue FCF, Tartrazine, Carmosine, Ponceau 4R) on the colour stability of composite resin and GIC restorative materials. A null hypothesis stating that there would be no colour change in the restorative materials (Fuji II® and Tetric N Ceram®) when exposed to four different pediatric syrups was proposed.

Materials and Methods:

Ethical clearance was obtained from the institutional ethics committee (IEC Number 718/2020). A total sample size of 64 was derived based on the previous study conducted by Yogesh J Kale et al. with 90% power and 95% confidence level using the formula n= 2 (Zα + Zβ)2 * S2 d2. 9

Specimen preparation: 32-disc shaped samples were prepared for each of these materials (Composite resin, GIC) using customized moulds made of vinyl siloxane impression material with a halo in the middle that has a diameter of 10mm and height of 2mm to attain samples of uniform size of 8 mm in diameter and 2mm in thickness (Fig.1). Samples in group 1 were prepared by placing composite resin (Tetric N Ceram-A2 shade, Ivoclar Vivadent, Liechtenstein) in the mould. The excess material was removed by placing a glass slab on mylar strip with slight pressure before curing with LED light curing unit (i Led, Guilin Woodpecker Medical Instrument Co., Ltd.) for 20 seconds.12 Samples in group 2 were prepared by placing GIC (GC Fuji II, Tokyo, Japan) in the mould. GIC samples were prepared by mixing 1 scoop of powder with 1 drop of liquid. The powder on the mixing pad was divided into two portions using a plastic spatula. The first increment was mixed well with all the liquid for about 10 seconds, then the second increment was added and thoroughly mixed for 15 to 20 seconds. Excess material was removed by placing a glass slab over a mylar strip with slight pressure to produce a uniformly smooth samples.9 The prepared samples were stored in distilled water for 24 hours for rehydration and complete polymerization.6

Grouping of the samples: A total of 64 samples were divided into two groups (n=32) Group 1: Nano Hybrid Composite Resin (Tetric N-Ceram®, Ivoclar Vivadent, Liechtenstein), Group 2: Type II Glass Ionomer Cement (GC Fuji II®, Tokyo, Japan). Both the groups were further divided into 4 subgroups (n=8), based on the pediatric syrups to be tested which are as follows (Table 1): Subgroup 1: Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride + Chlorpheniramine Malate (Ascoril D®), Subgroup 2: Ambroxol Hydrochloride + Salbutalmol Sulphate (Ambrodil-S®), Subgroup 3: Triprolidine Hydrochloride + Phenylephrine (Recofast®), Subgroup 4: Diphenhydramine chloride (Children's Benadryl®).

Colour change measurement and Immersion cycles: The baseline colour of all the samples were measured using a spectrophotometer (X-rite i1 pro, Germany) with illumination adjusted to average daylight (D65) and an observer angle of 2 degree against a white background.9 All the samples were rinsed with distilled water and dried with a filter paper before and after immersion. Samples were immersed in 10 ml of 4 different undiluted pediatric syrups as assigned and agitated for 2 minutes, then placed in artificial saliva 13 in between the exposure cycle. This exposure pattern was repeated every 8th hourly for 7 days to simulate the exposure in the oral cavity. All the samples were brushed once daily using soft toothbrush (Colgate, Colgate Palmolive India Ltd) with 2mg of fluoridated toothpaste (Pediflor, Group Pharmaceutical Ltd, India) on the samples for 15 seconds and rinsed for 5 seconds and dried 6,7. Artificial saliva, pediatric syrups were maintained at a standard temperature of 37 ℃ using a water bath.12 At the end of test period the samples were rinsed for 5 seconds and dried using filter paper. The assessment of colour change was recorded using a spectrophotometer. The difference in colour of restoration from baseline to end of the test period was quantified by using the formula ΔE (L * a * b*) = [(ΔL*)2+ (Δa*)2+ (Δb*)2] ½. Where DL* is the difference between the L* values, Da* is the difference between the a* values, and Db* is the difference between the b* values.9 Wherein L* represents brightness or lightness (value), a * and b * represent the numeric correlates both for hue and chroma.

This quantification of change in color from baseline to end of test period is expressed as ΔE*.9

Results

The data obtained with regard to resistance to staining i; e ΔE were subjected to statistical analysis using SPSS version 20 statistical package for windows. A p value of < 0.05 was considered statistically significant. Based on the results of our study, ΔE value is less than 3 which states that the restorative materials tested in the four pediatric syrups have color change that can be perceived only by an expert. Intragroup comparison was done using One Way ANOVA, Intergroup comparison was done using paired t test. Means and standard deviation of ΔE were assessed. In intra group comparison, the highest ΔE value in composite resin (Tetric N Ceram) group was observed in subgroup 4 (1.75±0.886) followed by subgroup 3 (1.13±0.835) and lowest was observed in subgroup 2 (0.63±0.916). In GIC (Fuji II), the highest ΔE value was observed in subgroup 2 (2.25±0.886) followed by subgroup 4 (1.62±1.188) and lowest was observed in subgroup 1 (1.13±0.991). This suggests that Nano hybrid composite when exposed to children's Benadryl had higher change in color from baseline and least change in colour was observed when exposed to Ambrodil S®.. Similarly, GIC samples exhibited higher colour change when exposed to Ambrodil S and least change in colour was observed when exposed to Ascoril D®(Table 2). An intergroup comparison between composite and GIC showed that a statistically significant difference ($p<0.023$) in color change from baseline to end of the test period was observed when samples were exposed to Ambrodil S®., suggesting that GIC exhibited the highest discoloration as compared to composite resin. There was no statistical difference ($p>0.05$) between subgroups 1(Ascoril D®.), 3 (Recofast®.), 4 (Children's Benadryl®) when composite resin and GIC were exposed to test syrups (Table 3).

Discussion

Esthetic appeal of anterior restorations is frequently compromised due to changes in the characteristics of the color of restorations over time. A number of factors like the consumption of beverages can influence the color stability of a given restoration.4,5,14 Color stability describes the ability of restoration to retain the color characteristics over time. Pediatric syrups is a common source of exposure to restorations in children. Hence, frequent exposure could discolor the existing restorations.15 Therefore, we aimed to conduct this study to evaluate the influence of pediatric syrups on the color stability of composite and glass ionomer restorations. A null hypothesis stating that there will be no change in color in the restorative material when exposed to pediatric syrups was proposed for this study. The effect of color stability of restorations exposed to following syrups Amoxyclav DS, Augmentin, Macrol, Metrogyl, Cephaks, Phexin, Calpol, Ibuprofen, Ibugesic plus, Keppra, Ferrosanol B, Ventoloin, Atrax, Sudafed, Dolven, Paracetamol, Prospan, Floradix, Feton have been tested earlier. The coloring agents present in these previously tested syrups were Quinoline Yellow, Carmoisine, Sunset Yellow, Colorless, Ponceau 4R, Quinoline Yellow, Erthrosine, Tartrazine.7,9–11 This led to the choice of pediatric syrups containing coloring agents Caramel USP-NF, Brilliant blue FCF & Tartrazine, Carmoisine & ponceau 4R, D&C redno 33, FD&C redno 40 which were not tested before were included in our study. Previous studies testing the color stability of composites exposed to certain beverages used A3 vita shade of composite.14 However, A2 shade of composite was tested in our study since pediatric liquid medications are prescribed to children in the age group of 5-7 years and A2 is commonly used shade in anterior restoration of primary teeth. GIC being the other commonly used restorative material in children was included in this study. The samples of restorative materials were exposed to the selected pediatric syrups as described in the methodology. Faghihi T et al.,2 assessed the color change in the restorative material by visual inspection, whereas Kale JY et al, Almutairi M et al, Tuzuner T et al, measured the color change in the restorative material using spectrophotometer.6,7,9 In this study spectrophotometer was used since it has high repeatability, sensitivity, and objectivity.3 The difference in the color of restorative material measured by spectrophotometer was expressed as ΔE. The ΔE is a value used to distinguish color change perceived by human eye. Human eye cannot detect any color change if ΔE value is less than 1. If the ΔE value is between 1 to 3.3 then, the color change can be detected only by an expert. If the ΔE value>3.3 then, the color change can be easily detected by naked eye.10 The results observed in our study was ΔE value < 3.3 which suggests that the color change could be detected only by the expert. Based on the results of our study, when the composite resin samples were exposed to the test syrups, highest color change was observed when exposed to Children's Benadryl and least change in color was observed when exposed to Ambrodil S®. When the GIC samples were exposed to the test syrups, highest color change was observed when exposed to Ambrodil S® and least change in color was observed when exposed to Ascoril D®. Amongst the syrups tested, Ambrodil S® shows significant change in color in both composite and GIC samples, with higher change in color in GIC samples than composite samples. Hence, the null hypothesis was rejected. Almutairi M et al 2022, Jamal DY 2022 and Faghihi T etal 2021 found that GIC has higher color change when compared with composite resin to the syrups they tested in their study. 2,6,16 Almutairi M et al 2022 6 concluded that GIC (Fuji II LC®) was the least color-stable material when exposed to the liquid medications they tested compared to compomer (Dyract Xp®) and composite resin (Tetric N Ceram®). Jamal DY et al 2022 16 reported that nano composite resin (Filtek TM Z350 XT) and RMGIC (Photac TM Fil Quick) has less color change when compared to Compomer (Compoglass F). Faghihi et al 2021 2 concluded that GIC (Equia Fil) had a greater color change when compared to composite resin (Filtek Z350 and Filtek Z250 XT). Tüzüner T et al, Yıldırım S et al, Kale YJ et al suggested that GIC has less color change when compared to composite resin when exposed to syrups tested in their study. 7,9,10 Tüzüner T et al 7 Equia (GIC) was compared with Nano hybrid composite (Nova Compo-B plus) and compomer(Dyract XP). While Yildirum S 10 compared Equia forte with compomer (Dyract XP) and Glass carbomer (GCP Glass

Fill). Abushanan A et al 2022 12 compared Giomer (Beautifill II) and Zirconia reinforced GIC to nano hybrid composites (Tetric N Ceram). The above-mentioned studies did not compare conventional GIC to nano hybrid composite except for the study conducted by Kale JY et al 9. In the study conducted by Kale JY et al 9 nanohydrid composite (Tetric N Ceram) and conventional GIC were exposed to pediatric syrups not similar to the one tested in our study. Hence, the results of these studies cannot be directly compared to the results of our study. Both GIC and composite resin restorations can undergo discoloration based on the coloring agent they are exposed to, or the duration and frequency of exposure. According to Kalampalikis et al and Chhabra C et al, greater color change in GIC was due to polyacid content associated with degradation of metal polyacrylate salts,17,18 porosity of glass particles, dehydration after setting resulting in microcracks which allow staining & discoloration of the restorative material.2 The discoloration in composite resin could be due to chemical changes in the initiator activator system, water absorption of the monomer, or interfacial gaps between the filler particle and resin matrix. The type of matrix, particle size, filler content and size, polymerization depth, mode of polymerization, and the hydrophilic property of the material also influence the color of composite resin.9 According to Rueggeberg and Craig 1988, salinization of filler particles also has a significant effect in staining.19
The limitations of this in vitro study were that it cannot simulate the in vivo conditions completely. Various factors like salivary flow rate, viscosity, and buffering capacity can influence the staining potential of these syrups. Hence the results of this study cannot be directly extrapolated to the clinical situations. Only A2 shade of composite resin was tested in this study. Further studies with other shades of composite should be conducted. In this study, only a 7-day exposure cycle was used. As per the results of our study, the following syrups Ascoril D, Recofast, and Children's Benadryl tested in this study can be prescribed without concerns of clinically significant discoloration in the restorative material when prescribed for 7 days duration. But at times, these syrups are prescribed repeatedly for a longer duration. Hence, further studies should be conducted evaluating the effect of long-term exposure to these syrups

Conclusion

Amongst the syrups tested in our study Ambrodil S® (Brilliant blue FCF and Tartrazine) showed significant change in color in both restorative materials. Ambrodil S®. showed clinically and statistically significant color change in GIC as compared to composite. Composite resin exhibited more color change when exposed to Children's Benadryl and least colour change when exposed to Ambrodil S®. GIC exhibited more colour change when exposed to Ambrodil S ® and least colour change when exposed to Ascoril D®.

List of Abbreviations

GIC - Glass Ionomer Cement
CIELAB system - Commission Internationale de l'Eclairage (CIE) L*a*b color space

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Figures & Tables

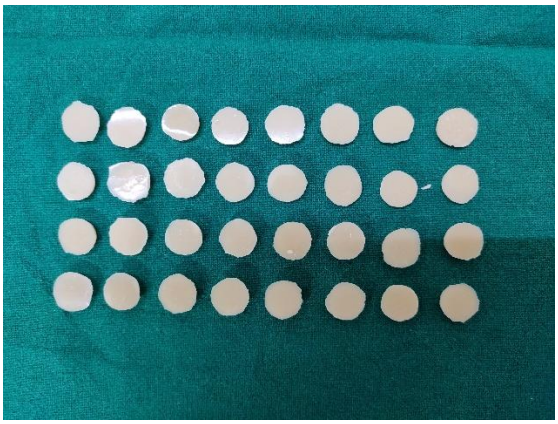

Figure.1: Disc shaped samples

Tables:

Table.1: Pediatric syrups used in the study

Syrups (Trade name)	Manufacturer	Active ingredient	Coloring agents/ Dyes	Application	Indication and duration of prescription
Ascoril D	Glenmark pharmaceuticals, Mumbai, India	Dextromethorphan Hydrobromide (10mg/5ml) + Phenylephrine Hydrochloride (5mg/5ml) + Chlorpheriramine Malate (2mg/5ml)	Caramel USP-NF	8th hourly	Cough for 5-7 days
Ambrodil-S	Aristo pharmaceutical pvt. Ltd., India	Ambroxol Hydrochloride (15mg/5l) + Salbutalmol Sulphate (1mg/5ml)	Brilliant blue FCF & Tartrazine	8th hourly	Cough & allergic reactions for 5-7 days
Recofast	Sherya life sciences pvt. Ltd., India	Triprolidine Hydrochloride (0.625mg/5ml) + Phenylephrine (5mg/5ml)	Carmoisine & ponceau 4R	8th hourly	Common cold & allergies for 5-7 days
Children's benadryl	Johnson & Johnson consumer, Japan	Diphenhydramine HCL (12.5 mg/ 5ml)	D&C redno 33, FD&C redno 40	4-6th hourly	Allergies for 5-7 days

Table. 2: Intra group comparison of mean ΔE of all subgroups between two restorative materials using one-way ANOVA

Materials	Groups								ANOVA Total		p value
	Sub Group 1 Ascoril ®		Sub Group 2 Ambrodil – S®		Sub Group 3 Recofast ®		Sub Group 4 Benadryl ®				
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Composite Group 1	.88	.641	.63	.916	1.13	.835	1.75	.886	1.09	.893	0.063 (NS)
GIC Group 2	1.13	.991	2.25	.886	1.25	1.389	1.63	1.188	1.56	1.162	0.212 (NS)

Table.3: The pairwise inter group comparison of mean difference of ΔE value of Composite resin & GIC restorative material.

Subgroups	Composite (Group 1)		GIC (Group 2)	
	Mean	P value	Mean	p value
Subgroup 1 (Ascoril D®)	.963	.068	.988	.947
Subgroup 2 (Ambrodil S®)	.725	3.684	2.350	.0023
Subgroup 3 (Recofast®)	1.288	.264	1.425	.796
Subgroup 4 (Benadryl®)	1.488	.025	1.500	.98