Comparative Evaluation of the Effect of a Saliva Substitute on the Color Stability of Three Different Direct Tooth-Colored Restorative Materials: An in vitro Spectrophotometric Study

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Abstract
Context: An aesthetic restorative material that would be suitable to be used in patients who are prescribed saliva substitute (SS) for symptomatic relief from xerostomia. Aims: This study aimed to evaluate and compare the effect of SS on the color stability of three different direct tooth-colored restorative materials. Settings and Design: This is an in vitro spectrophotometric study where standard uniform disc-shaped specimens were immersed in a SS for 30 days. Materials and Methods: The materials investigated were resin-modified-glass ionomer cement (RM-GIC), light-cured (LC) resin composite restorative material (Filtek™ Z350 XT), and LC fluoride-releasing restorative material (Ketac™ N100). Sixteen disc-shaped samples of each test material were prepared using a polytetrafluoroethylene mold, making up a total of 48 samples and were assigned to three groups: Group I (RM-GIC), Group II (Filtek™ Z350 XT), and Group III (Ketac™ N100). They were further divided into two subgroups A and B with eight samples each based on the immersion solutions namely distilled water (DW) and SS, respectively. The samples were immersed for 30 days. Baseline and postimmersion color analysis was done with a spectrophotometer. The CIE L*a*b* values were measured and CIE ΔE values obtained were tabulated. Statistical Analysis Used: The data obtained were statistically analyzed using ANOVA and independent t-test, and the pair-wise significance between groups was obtained using least significant difference test. Results: All the samples immersed in SS showed greater discoloration (ΔE >3.3) than the samples immersed in DW and was found to be statistically significant (P < 0.05). Ketac™ N100 displayed relatively lesser discoloration when compared to RM-GIC and Filtek™ Z350 XT when immersed in a SS. Conclusions: Among the materials tested, Ketac™ N100 was found to be more color stable.

Keywords: Color stability, nanofilled glass ionomer, resin composite, resin-modified glass ionomer, saliva substitute

INTRODUCTION
Human saliva plays an important role in protecting and moistening the oral hard and soft tissues. Xerostomia or dry mouth is the primary symptom associated with salivary gland hypofunction or dysfunction. Several conditions can lead to hyposalivation such as Sjogren’s syndrome, salivary gland hypofunction in elderly patients, chemoradiotherapy for head-and-neck carcinomas and psychiatric disorders. A large number of medications cause dry mouth as an adverse effect. Decreased salivation promotes severe oral side effects such as difficulty in speaking and eating, swallowing, reduced antibacterial function, lack of remineralization, reduced buffer capacity and rampant caries of teeth.

The restoration of carious teeth in patients with xerostomia, especially for those who have undergone cervicofacial radiotherapy, can be challenging and adhesive restorative materials are often recommended, especially glass ionomer cements (GICs) and its modifications due to their anticariogenic properties. Resin composites can also be placed in selected cases with minimal tooth structure removal. Nanocomposites have displayed improved properties comparable or superior to that of microfill and microhybrid composite resins. Nano-ionomers (Ketac™ N100) are new hybrid tooth-colored restorative materials that combine resin-based composite and GICs. Ketac™ N100 contains nanofillers and clusters of

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Patients suffering from xerostomia are often prescribed saliva substitutes which are applied by them frequently in order to lubricate the tissues. Due to the constant contact, they may affect the physical, mechanical, and biological integrity of restorative materials. There are no documented studies evaluating the effect of SS on restorative materials. Hence, a preliminary investigation was undertaken to evaluate the color stability of esthetic restorative materials.

The aim of this in vitro study was to compare the color stability of light-cured (LC)-resin-modified GIC (LC-RMGIC), LC resin composite restorative material (Filtek™ Z350 XT), and a LC fluoride-releasing nano-filler-reinforced glass ionomer restorative material (Ketac™ N-100) at baseline and after immersing in distilled water (DW) and SS using CIE L*a*b* color system with a spectrophotometer. Null hypothesis tested was that there would be no difference in the effect of SS and DW on the color stability of three different direct tooth-colored restorative materials.

### Materials and Methods

#### Sample preparation

The tooth-colored restorative materials tested in this study were LC-RMGIC (GC TYPE II LC), Ketac™ N100, and Filtek™ Z350 XT. The composition of materials is presented in Table 1. Forty-eight disc-shaped samples, 16 of each material approximating the same shade (A2), were prepared using polytetrafluoroethylene (Teflon) molds of 10-mm inner diameter and 2 mm depth, the samples were finished with mylar strip. Light-emitting diode (LED)-curing light (Blue phase N, Ivoclar Vivadent, Schaan, Liechtenstein) was used to cure the samples for 40 s with the tip kept at a distance of 1 mm. The intensity of the light-curing unit was checked by a digital light meter (Bluedent BG Light LTD, Plovdiv, Bulgaria) before curing each sample. The samples were then retrieved from the molds and were stored at 37°C in an incubator within lightproof containers for 24 h.

#### Immersion in test solutions

The samples were assigned to three groups: Groups I, II, and III of 16 samples each of LC-RMGIC, Filtek™ Z350 XT, and Ketac™ N-100, respectively [Figure 1]. Each group was further randomly divided into two subgroups A and B of eight samples each. The samples of subgroups IA, IIA, and IIIA were immersed in DW; subgroups IB, IIB, and IIIB were immersed in SS for 30 days. The solutions were changed every day.

#### Color analysis

Baseline color analysis was done before immersing the samples in the test solutions with a spectrophotometer (Datacolor, Lawrenceville, New Jersey, USA) utilizing small-area view with ultraviolet value at 0 and mode set to reflectance. Single-type measurement was made with small aperture of 9 mm. The

### Table 1: Composition of materials used in the study

| Material                                      | Manufacturer                              | Composition                                                                                                                                 |
|-----------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| A light-cured RM-GIC                         | GC TYPE II (GC corporation Tokyo Japan)   | Powder: Fluoroaluminosilicate glass and a microencapsulated potassium persulfate and ascorbic acid catalyst system, camphorquinone                  |
|                                               | Lot no. 1503061                           |                                                                                                                                             |
|                                               |                                           | Liquid: Polycarboxylic acid modified with pendant methacrylate groups, HEMA, tartaric acid                                                |
| A light-cured nanoionomer restorative material – Ketac™ N100 | 3M™ ESPE™ Dental products, St.Paul, MN, USA | Aqueous paste - acidic polyalkenoic acid, reactive resins, and nano fillers                                                                |
|                                               | Lot no. N 753331                          |                                                                                                                                             |
| A light-cured resin composite restorative material - Filtek™ Z350 XT | 3M™ ESPE™ Dental products, St.Paul, MN, USA | Matrix: Dimethacrylates, such as Bis-GMA, Bis-EMA, UDMA, or TEGDMA, Inorganic filler - 78.5% by weight, zirconia filler, zirconia/ silica filler, SIO2, silicates or ceramics, dispersed within the matrix |
|                                               | Lot no. N755098                           | Coupling agents - organosilanes, camphorquinone and tertiary amine, pigments, inhibitors, or stabilizers                                      |
| Saliva substitute - wet mouth                 | ICPA Health products, Mumbai, India       | Sodium carboxymethyl cellulose, xylitol, potassium chloride, calcium chloride, potassium phosphate, potassium thiocyanate, glycerine, sodium saccharin, parabens, and a flavoring agent |

FAS: Fluoroaluminosilicate, RM-GIC: Resin-modified glass ionomer cement, HEMA: Hydroxyethylmethacrylate, Bis-GMA: Bisphenol-A-glycidyldimethacrylate, Bis-EMA: Ethoxylated bisphenol-A-glycol dimethacrylate, UDMA: Urethane dimethacrylate, TEGDMA: Triethylene glycol dimethacrylate
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Discussion

Tooth-colored restorative materials tend to get discolored when exposed to intraoral conditions. Frequent replacement of discolored restorations is uneconomical and leads to additional loss of tooth structure. Internal and external factors may be responsible for the color change of resin-based restorations. Internal factors include alterations of the resin matrix structure, matrix–filler interface, surface roughness, amount and size of filler particles, water sorption and the degree of conversion. External factors include adsorption and/or absorption of staining materials on exposure to intraoral environment. Salivary hyposecretion may considerably affect the physical and mechanical properties of the restorative materials since saliva provides a fluid environment for

Figure 2: Histogram comparing the mean ΔE values when the material were immersed in saliva substitute and distilled water

| Subgroup | n | Mean | SD | SEM |
|----------|---|------|----|-----|
| Group I  | SS| 8    | 8.0275 | 3.54477 | 1.25327 |
| Delta E  | DW| 8    | 2.3525 | 0.59586 | 0.21067 |
| Group II | SS| 8    | 11.9850 | 5.79739 | 2.04969 |
| Delta E  | DW| 8    | 1.9725 | 0.79460 | 0.28093 |
| Group III| SS| 8    | 3.9188 | 0.90632 | 0.32043 |
| Delta E  | DW| 8    | 1.9350 | 0.52394 | 0.18524 |

SD: Standard deviation, SEM: Standard error of mean

Table 2: Descriptive statistics for Group I (resin-modified glass ionomer cement), Group II (Filtek™ Z350 XT), and Group III (Ketac™ N100)

| Subgroup | n | Mean | SD | SEM |
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| Delta E  | DW| 8    | 1.9350 | 0.52394 | 0.18524 |

Table 3: Independent t-test for Group I (resin-modified glass ionomer cement), Group II (Filtek™ Z350 XT), and Group III (Ketac™ N100) when immersed in saliva substitute and distilled water

Table 4: ANOVA test result for subgroup A (distilled water)

| Sum of squares | Df | Mean square | F | Significant |
|----------------|----|-------------|---|-------------|
| Between groups | 0.854 | 2 | 0.427 | 1.015 | 0.379 |
| Within groups  | 8.827 | 21 | 0.420 |     |     |
| Total          | 9.680 | 23 |     |     |     |

Table 5: ANOVA test result for subgroup B (saliva substitute)

| Sum of squares | Df | Mean square | F | Significant |
|----------------|----|-------------|---|-------------|
| Between groups | 260.288 | 2 | 130.144 | 8.308 | 0.002* |
| Within groups  | 328.976 | 21 | 15.666 |     |     |
| Total          | 589.264 | 23 |     |     |     |

*P value statistically significant

Results

The mean and standard deviation of ΔE values of different groups are presented in Table 2. All the samples immersed in SS showed greater discoloration (ΔE >3.3) than the samples immersed in DW, which was perceptible [Figure 2]. Ketac™ N100 showed higher resistance to discoloration when compared to the LC-RMGIC followed by Filtek™ Z350 XT when immersed in SS. Filtek™ Z350 XT nanohybrid composite material showed least resistance to discoloration. The mean ΔE values were measured as mentioned previously. The CIE ΔE* values obtained were calculated using the formula [8,9]

\[
\text{ΔE} = \sqrt{\left(\text{ΔL}^2 + \text{Δa}^2 + \text{Δb}^2\right)}
\]

The CIE ΔE* values were measured as [9,10] and used to determine the statistical significance of color difference between the three groups. The ANOVA test was done using least significant difference (LSD) test. In the present study, P < 0.05 was considered statistically significant.

Table 5: ANOVA test result for subgroup B (saliva substitute)

Discussion

Tooth-colored restorative materials tend to get discolored when exposed to intraoral conditions. Frequent replacement of discolored restorations is uneconomical and leads to additional loss of tooth structure. Internal and external factors may be responsible for the color change of resin-based restorations. Internal factors include alterations of the resin matrix structure, matrix–filler interface, surface roughness, amount and size of filler particles, water sorption and the degree of conversion. External factors include adsorption and/or absorption of staining materials on exposure to intraoral environment. Salivary hyposecretion may considerably affect the physical and mechanical properties of the restorative materials since saliva provides a fluid environment for

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*P value statistically significant

Results

The mean and standard deviation of ΔE values of different groups are presented in Table 2. All the samples immersed in SS showed greater discoloration (ΔE >3.3) than the samples immersed in DW, which was perceptible [Figure 2]. Ketac™ N100 showed higher resistance to discoloration when compared to the LC-RMGIC followed by Filtek™ Z350 XT when immersed in SS. Filtek™ Z350 XT nanohybrid composite material showed least resistance to discoloration. The independent t-test for all the three groups showed statistically significant difference (P < 0.05) when immersed in SS in comparison to DW [Table 3]. Among the samples immersed in DW, the one-way ANOVA indicated no significance of difference between the three subgroups IA, IIA, and IIA [Table 4]. The mean ΔE values when compared by one-way ANOVA [Table 5] indicated significance of difference in samples when immersed in SS (subgroup B). The pair-wise significance obtained using LSD test showed statistically significant difference between groups IIB and IIIB [Table 6].
cleansing of the oral tissues, thereby preventing surface absorption of stains.

A clinical study on xerostomic patients with radiation caries has shown that resin composite and RMGIC have significantly better scores for marginal adaptation and structural integrity over the long term in patients who were amenable to fluoride application.[13] In these cases, resin composites could be placed, making best use of their adhesive potential, sealing ability, longer clinical retention and better wear resistance. However, they are susceptible to polymerization shrinkage which often results in marginal gaps and subsequent recurrent caries. Furthermore, they do not possess any antiangiogenic property. Frequently, fluoride-releasing restorative materials such as glass ionomer and its modifications are recommended to restore cavitated lesions. These materials bond to dentin, possess thermal and mechanical properties similar to tooth structure, and are also less sensitive to water and desiccation.[10,11]

The restorative materials evaluated in the study are RMGIC, Ketac™ N 100 and Filtek™ Z350 XT. All the samples were prepared using the Teflon mold and adapted against a mylar strip as it gives the smoothest finish, thus eliminating the need for different polishing steps, consequently minimizing operator-related variability. Intensity of the LED-curing light was checked with a light intensity meter to ensure that uniform and adequate light intensity was maintained throughout the study. The samples were immersed in either DW or SS in the current study. To minimize oral discomfort, patients are routinely prescribed SS or oral mucosal lubricants when they do not respond to pharmacological, gustatory, or masticatory stimulation.[12] SSs can be based on different substances such as animal mucin, carboxymethyl-cellulose (CMC), xanthan gum and aloe vera.[13] They can be categorized into solutions based on CMC, mucin, and linseed. Most commercially available SSs are based on CMC. It is a polymer derived from natural cellulose and used in SS formulation as a thickening agent. CMC produces crystal clear gel products and thickens the aqueous phase as well as renders good water retention and film formation.[14]

These formulations are applied on the oral tissues for various time durations depending on the extent of discomfort. Since these restorative materials will be in constant contact with SS, it may have deleterious effect on the restorative materials. One of the properties evaluated here is the color stability of various adhesive restorative materials. SSs may cause discoloration of these restorative materials on prolonged usage. In this study, CMC-based SS was selected. This interval was chosen assuming that the patient applies 5 mm, as per manufacturer’s instructions to be used often to maintain the wetness,[15] SS may be in contact with oral tissues and restorations for approximately 12 h. Hence, immersion for 30 days consisting of 720 h would correspond to 60 days of intraoral application.

Table 6: Multiple comparison test for subgroup B

| (I)  | (J)  | Mean difference (I-J) | Std. error | Sig.  |
|------|------|-----------------------|------------|-------|
| Group I | Group II | -3.95750 | 1.97898 | 0.059 |
| Group II | Group III | 4.10875 | 1.97898 | 0.050 |
| Group II | Group III | 3.95750 | 1.97898 | 0.059 |
| Group III | Group I  | 8.06625* | 1.97898 | 0.001* |
| Group II | Group II | -4.10875 | 1.97898 | 0.050 |
| Group II | Group III | -8.06625* | 1.97898 | 0.001* |

*P value statistically significant

According to the results of this study, the ΔE values of all the materials indicated clinically perceptible levels of discoloration when immersed in SS for 30 days. Among the three materials tested, Ketac™ N 100 showed higher resistance to discoloration followed by RMGIC and Filtek™ Z350 XT [Table 2 and Figure 2]. The Ketac™ N100 is based on acrylic and itaconic acid copolymers necessary for the glass-ionomer reaction with fluorooaluminosilicate (FAS) glass and water. It contains a combination of resin monomers such as bisphenol A-glycidyl methacrylate (Bis-GMA), triethylene glycol dimethylacrylate (TEGDMA), polyethylene glycol-dimethacrylate, and hydroxyethyl methacrylate (HEMA), which polymerize via the free radical addition upon light curing which is the primary curing mechanism.[16] The principle modification of this GIC is a unique combination of nano-fillers and acid-reactive FAS glass.[16] Lesser ΔE in Ketac™ N100 observed in the current study could be because of a decrease in HEMA content and the smaller filler particle size, resulting in an even surface.[6] However, Vance et al. found nanocomposite to be more resistant to discoloration compared to RMGIC and Ketac™ nano.[19] In agreement to our study, Nassar et al. found acceptable color match for cavities restored with Ketac™ N100 as compared to resin composites and more retentive too.[20]

In the present study, RMGIC samples showed ΔE values >3.3, probably because of rapid water sorption in the presence of HEMA.[21] Poor color stability may be due to the erosion of ions and degradation of metal polyacrylate salts, resulting in the formation of pores.[22] The GIC might not have matured fully since the acid-base reaction in resin-modified cements proceeds more slowly and as some of the water in the cement is replaced by water-soluble monomers accounting for the changes in color parameters.[23]
In the current study, nano composite, Filtek™ Z350 XT, showed the maximum discoloration [Figure 2].\(^{24}\) Filtek™ Z350 XT contains TEGDMA and Bis-GMA which are more vulnerable to staining than the other monomers.\(^{23,25,26}\) Nanocomposites have lesser filler content and more resin phase. An increase in resin content may lead to water absorption at the resin filler interface, thus leading to hydrolytic degradation of filler.\(^{24}\) The agglomerated particles and nanoclusters present could be less color stable.\(^{27}\) Better color stability for nanocomposites has also been reported as they are hydrophilic materials compared to GICs which are more hydrophobic.\(^{28}\)

Regardless of the solutions used, restorative materials used in the present study showed color change. The property of water retention and film formation of CMC-based SS could have caused deterioration of the polymer matrix by the way of liquid absorption, resulting in discoloration of restorative materials.\(^{116}\) Hence, the null hypothesis was rejected. The current study was carried out in in vitro conditions and the experimental conditions may not have replicated the intraoral environment. Moreover, the number of times a person uses SS is highly subjective and variable as it depends on the degree of dryness of mouth experienced by the patient.

In xerostomic patients with high susceptibility to caries and who are advised to use SS for symptomatic relief, nano filler-reinforced glass ionomer-based restorations could probably be used to restore cavities. In addition to protection against secondary caries, they would probably be color stable for longer periods of time. Direct comparisons could not be made as there were no previous studies. There is considerable evidence indicating that the implementations of adequate preventive strategies will help reduce caries development in patients with xerostomia. There is a need for improved SS formulations or oral lubricants that have an increased duration of action and at the same instance not interfere with the properties of restorative materials, harmless to teeth, pH neutral, and possess antacaries and antimicrobial properties. The data available on the effect of SS on the properties of various restorative materials are scarce. Further in vitro studies and clinical trials using various SS formulations are necessary to investigate the effects of these solutions on the property and longevity of restorative materials.

**Conclusion**

Within the limitation of this in vitro study, it was observed that all the restorative materials when immersed in SS showed discoloration. Among the materials tested, Ketac™ N100 displayed the least discoloration followed by RGMIC and Filtek™ Z350 XT.

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**Conflicts of interest**

There are no conflicts of interest.

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