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Clinical performance of chitosan modified glass ionomer in primary molars: a randomized control trial

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Abstract:
Background*: Antibacterial restorations increase the success rate of minimal invasive techniques where incomplete caries removal is done, in these cases pulp treatment is avoided preserving as much tooth structure as possible and increasing the longevity of teeth. This study was conducted to test the clinical performance of chitosan modified glass ionomer in carious primary teeth.*
Materials and Methods*: In this prospective randomized controlled study, the sample consisted of 26 primary molars of 4-8 years old patients, where they were randomly allocated into 2 groups, each group received a glass ionomer(GIC) restoration in at least one primary molar. Group A received a GIC with its liquid modified with chitosan Group B received unmodified Glass ionomer. After 6 months follow-up the patients were recalled, and the clinical performance was measured using the Modified United States Public Health Service (USPHS) Ryge Criteria.*
Results*: No statistically significant difference in score distributions of all outcomes between the two groups were evident. (p<0.05).*
Conclusion: *Addition of chitosan to Glass ionomer cement did not affect the clinical performance of GIC.*
Key Word*: Chitosan; Glass ionomer cement; Indirect pulp capping; incomplete caries removal*

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I. Introduction

World Health Organization reports states that dental caries remains to be a major health problem, specifically when it comes to disadvantaged social groups across the world[1] .Bacteria is one of the main culprits that leads to pulpal and periapical inflammation[2]. One of the recent trends in dentistry is Minimal invasive dentistry(MID)[3] with techniques like stepwise excavation and indirect pulp capping. Their success rates are increasing due to the new development of glass ionomer cements(GIC)[4].

One of the most conservative approaches to treat carious primary teeth is removing the soft dentine and sealing the wet leathery dentine with a biocompatible material[5], GIC can bond to carious dentine [6]which makes it a perfect candidate for indirect pulp capping. This technique is also followed when it is harder to control the patient's behavior where carious dentine is left behind since an excavator is used to remove dentine.

To increase the success rate of incomplete caries removal many bioactive materials were incorporated into the GIC[7]. One of these materials is chitosan which was proved to have an antibacterial effect when incorporated into GIC liquid ,especially against streptococcus mutans bacteria without affecting its mechanical properties or bonding to dentine[8–10].

Chitosan is a product of chitin which is the second most ubiquitous polysaccharide after cellulose, the exoskeleton of arthropods (specially shrimps crabs and lobsters) and in cell walls of fungi and yeast[11–14]. Chitin can undergo alkaline partial N-deacetylation to produce the modified natural carbohydrate polymer called chitosan.[12]

Chitin and chitosan are both organically plentiful, renewable polymers with attractive advantages like bio-compatibility, biodegradability, non-toxicity, and adsorption[15].

Since various in vivo studies proved the effectiveness of chitosan modified glass ionomer against caries and its acceptable mechanical and physical properties[8–10], and since chitosan is already being used in other various dental and medical studies , this study aimed to assess the clinical performance of chitosan modified GIC in class I cavities in primary molars

II. Material And Methods

The study was a randomized controlled clinical trial following the CONSORT standards, children were enrolled from the outpatient clinic of pediatric dentistry department, Ain shams University, Cairo, Egypt Recruitment of participants for the study started on the first of august 2019.

Study Design: single blind randomized control trial.

Study Location: The outpatient clinic of the Pediatric dentistry and public health department, Faculty of dentistry, Ain shams University, Cairo, Egypt.

Study Duration: August 2019 to august 2020.

Sample size: 26 primary molars in 13 patients.

Sample size calculation: Sample size was calculated using Epicalc program version 1.02 , assuming a power of 80 % and alpha=0.05 and considering a 90% success rate of chlorhexidine modified glass ionomer was evident after 2 years [6]. After an increase of 10% to the sample size was done to compensate for any potential loss to follow-up, a total of 26 primary molars were used in this study with 13 molars assigned to each group.

Subjects & selection method: Thirty-nine children with carious primary molars were examined for eligibility in the Pediatric Dentistry outpatient's clinic, Faculty of Dentistry, Ain Shams University. Out of these 39 children, 13 were eligible for the study. The teeth were randomly allocated into 2 groups.

Group A (n=13 primary molars) 10% (v/v) chitosan powder was added to the liquid of packable GIC

*Group B (*n=13 primary molars) unmodified packable GIC.

Inclusion criteria:

1. Age: 4-8 years.
2. Children having at least one primary molar with only occlusal caries having dentine lesions wide enough for the smallest excavator to enter (Ø=0.9 mm).
3. Dentine caries must be apparent visually and radiographically.

Exclusion criteria:

1. Teeth with pulp involvement, those suffering from pain, irreversible pulpits or pulp necrosis.
2. Children with systemic diseases.
3. Patients with history of active para-functional oral habits, xerostomia.
4. Patients who have difficulties in cooperating.

Procedure methodology

Modification of glass ionomer: Fuji XI packable glass ionomer was used (GC, Tokyo, Japan)

Chitosan: Low molecular weight and viscosity chitosan [Sigma- Aldrich (Merck-Germany)], was used .It was purified by dissolving in 0.1 mol/L acetic acid, then precipitated in 0.1 mol/L NaOH and the precipitate was be washed with ethanol/water (70/30 v/v) mixture followed by freeze drying.[16] Then a solution of chitosan was done by dissolving in 0.1 mol/L acetic acid to be used to modify the stock liquid provided with the glass ionomer.[17]

The teeth were randomly allocated to the two groups by a randomly generated sequence after T0 , the random chain was split into 2 groups by order and placed in a table, Care givers and patients involved were informed about the study procedure, an informed consent was obtained from the legal guardian and an assent was obtained from the child.

Cavity preparation

Topical anesthetic gel (Dharma, Lolite, 20 % benzocaine) was placed on the gingiva then rubber dam was placed for isolation of the designated teeth. Cavities were cleaned by stepwise caries removal[18]. A sterile short stone was used to increase the cavity opening if needed . A round bur (size #2) was used to clean all the axial walls of caries. All soft demineralized dentine was excavated but only the deepest layer of carious dentine was kept.

Usually the patients did not experience any pain that would need us to give any infiltration anesthesia , which helped keep the patients co-operative.

After the cavity preparation the clinician reveals the patient's group by opening an opaque envelope with a randomized sequence table inside.

The cavity was cleaned with a sterile gauze and then a dentine conditioner (GC dentine conditioner – Japan) was used to condition the axial walls of the cavity. and then the restorative material was packed into the cavity using an egg burnisher, then carver was used to remove the excess. occlusion was checked and adjusted. Then "GC Equia coat LC" (GC Japan) according to manufacturer instructions.

Follow-up

The patients were be recalled at 6 months for follow-up and clinical performance evaluation by the USPHS (table 1)[19,20]. Visual and clinical inspection with 3.5x magnification loupes (Ergo-vision, china) was be done with the help of a sharp explorer. If doubt existed, photographs was used to assist judgment.

One investigator was responsible for placing the restorations and a different investigator is responsible for the *Modified United States Public Health Service* (USHPHS) Ryge evaluation criteria test 6 months later[19–22].

Figure 1: Carious tooth

Figure 2 : after caries removal

Figure 3: after Glass ionomer placement

Figure 4: Follow-up after 6 months

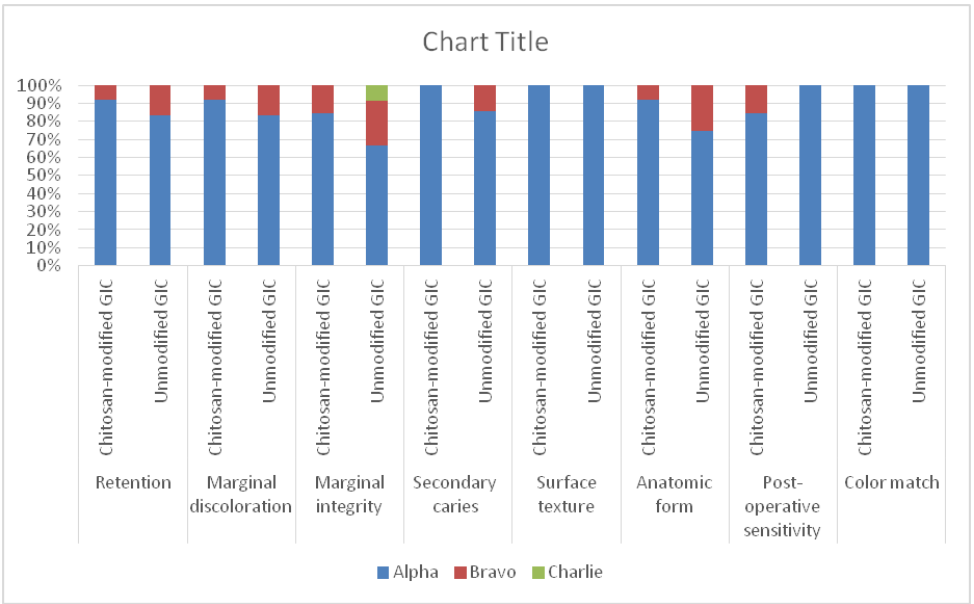
Statistical analysis

Statistical analysis was performed by IBM SPSS Statistics Version 2.0 for Windows. The data was presented as mean, standard deviation (SD) and percentage. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess data normality. The significance level was set at $P \leq 0.05$.

Chi-square test was conducted to compare the frequency of modified USPHS scores of each outcome between restorative materials.

III. Result

Chi-square test [Table (2) and Figure (5)] showed that there was no statistically significant difference in score distributions of all outcomes, between different GIC restorative materials (P=0.326 for retention, P=0.728 for marginal discoloration, P=0.539 for marginal integrity, P=0.343 for secondary caries, P=1.000 for surface texture, P=0.367 for anatomic form and P=0.371 for post-operative sensitivity).



IV. Discussion

The incentive for dental restorative materials that have antibacterial properties combined with superior physical and mechanical properties to manage deep caries in primary teeth has led to innovation of materials that contain antibacterial agents. Many trials of GIC containing antibiotics proved to decrease the mechanical properties of modified GIC[23], conversely studies done with chitosan modified glass ionomer measured the antibacterial, physical and mechanical properties of GIC containing chitosan found that when its concentration in the GIC liquid is 5-10%(v/v) it to be superior to GIC in its antimicrobial effect while not affecting other characteristics negatively [8–10,17] ,On the contrary studies found 10%(v/v) chitosan GIC to have an increased bond strength, flexural strength over conventional GIC[24,25]. Chitosan GIC also showed better overall fluoride release than unmodified GIC[17,25], different studies successfully proved that it could be helpful in releasing bioactive molecules and growth factors when loaded with them[16,26,27] .

It was not possible to blind the operator that places the GIC since the consistency of the liquid of chitosan is gel-like unlike the normal liquid of packable GIC.

Chitosan was used in this trial since it is a readily available naturally existing polymer that showed lots of promise with no side effects after being used in the medical field for a while[28,29]. This study shoed a 100% survival rate of both groups of restorations, the follow-up period will be extended every 3 months to see how much the restoration will survive and if it caused any side effects.

There were no other studies measuring the clinical performance of glass ionomer in primary or permanent teeth but the results of this study aligns with the results of the in vitro studies that measures its properties[10,17,25]. Since this study proves that the use of chitosan GIC was similar normal GIC with no failure of restorations and no adverse effects, more studies with a bigger sample size needs to be done . trying to improve it even better in the future with more additive material could prove helpful[8,30].

Clinical performance of 10% modified glass ionomer was equal to its non-modified glass ionomer counterpart in primary teeth, while its antibacterial effect gives it an advantage. this makes it a candidate for use in cases where the caries removal is incomplete either intentionally or otherwise to increase the success rate of the final restorations.

Based on the currents study's and similar studies' results GIC's modification with chitosan could have a potentially clinical significance in pediatric and preventive dentistry since it has proven its mechanical reinforcement, physical and antibacterial effects. It's ability to release growth factors and bioactive molecules is also a boon that could help innovate more uses for it down the road. More clinical trials need to be conducted with CH modified GIC and its different additions for it to have a role in dentistry in the coming years.

Ethical approval

Ethical approval was granted from the ethical committee of faculty of dentistry, Ainshams university before conduction the study. all the patients were told all the steps and signed an informed consent before clinical intervention.

Conflict of interest

The authors declare that they have no conflict of interest.

V. Conclusion

The addition of chitosan did not affect the clinical performance of GIC cement when used as a Class I filling for primary teeth.

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