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Phosphate-Buffered RMGIC Liner Under Pediatric Class II Composites: Clinical Sensitivity & Inflammatory Biomarkers

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Abstract

Background: Post-operative sensitivity after pediatric Class II composites is frequent and relates to polymerization stress and transient inflammation. A phosphate-buffered resin-modified glass ionomer (RMGIC) liner may stabilize pH, limit inflammation, and improve comfort.

Objective: To compare a phosphate-buffered RMGIC liner with a conventional RMGIC liner under Class II composites in primary molars.

Methods: Randomized, controlled clinical study of fifty children, each contributing one tooth per group (buffered vs conventional). Standardized isolation, preparation, selective-etch bonding, and incremental composite placement were used. Outcomes: pain by 0–10 Numeric Rating Scale (NRS) and Wong–Baker FACES at 1 and 4 weeks; electric pulp testing (EPT) at baseline and 4 weeks; gingival crevicular fluid interleukin-6 (IL-6), tumor necrosis factor-α (TNF-α), and prostaglandin E_2 (PGE_2) at baseline, 1 and 4 weeks; 1-week chewing function; 48-hour analgesic use; and 3-month marginal staining. Per table footnotes, between-group comparisons used independent samples t-tests for continuous outcomes and chi-square tests for proportions/categories.

Results: Baseline demographics were comparable. NRS pain favored buffering at 1 week (1.83±1.33 vs 3.78±1.80; $p<0.001$) and 4 weeks (0.69±0.71 vs 1.93±1.03; $p<0.001$); Wong–Baker differences were nonsignificant. EPT thresholds were higher with buffering at 4 weeks (32.60±5.43 vs 27.58±4.54; $p=0.001$). IL-6 was lower with buffering at 1 week (8.58±3.42 vs 12.00±4.76; $p=0.005$) and 4 weeks (6.78±2.29 vs 10.21±5.21; $p=0.004$); TNF-α was lower at 4 weeks (8.13±3.28 vs 14.48±5.40; $p<0.001$). PGE_2 differences were nonsignificant. Chewing function was better at 1 week (7.68±2.06 vs 11.80±3.98; $p<0.001$). Fewer children required analgesics within 48 hours (20% vs 40%; p=0.039) and fewer doses were taken (0.27±0.56 vs 0.96±1.08; p=0.006). At 3 months, marginal staining distributions were similar (p=0.538).

Conclusions: Compared with a conventional RMGIC, the phosphate-buffered RMGIC liner reduced early pain, attenuated inflammatory biomarkers, improved pulpal sensibility, and enhanced short-term function without compromising restoration integrity. These child-centered benefits support biologically informed liner selection and justify longer follow-up to confirm clinical long-term durability and survival.

Keywords: Phosphate-buffered RMGIC, Pediatric dentistry, Class II composite, Post-operative sensitivity, Electric pulp testing, Inflammatory biomarkers, Primary molars, Bioactive liner.

Introduction

Postoperative sensitivity and pulpal inflammation remain clinically significant concerns in pediatric Class II composite restorations, often arising from polymerization stress, deep cavity preparation, and bacterial microleakage (Arandi, 2020). These issues can lead to discomfort, restoration failure, or even pulpal necrosis if left unaddressed (Rodrigues et al., 2021). Conventional resin-modified glass ionomer liners (RMGICs) offer fluoride release and adhesion but present limitations such as initial acidity, low buffering capacity, and inconsistent biological responses (Fahmy et al., 2021). To address these issues, incorporation of phosphate buffers into RMGICs has been proposed. This modification aims to stabilize local pH, enhance ion release (particularly Ca^{2+} and PO_4^{3-}), and support anti-inflammatory activity, thereby improving pulpal protection (Hengtrakool et al., 2023). Recent biomaterials, such as aspirin-functionalized phosphate-releasing membranes, show promising anti-inflammatory and mineralizing effects on inflamed pulp tissues (Yan et al., 2022). While emerging formulations demonstrate favorable outcomes in ion release and biocompatibility, challenges remain in ensuring long-term pulp vitality and consistent clinical performance across patient populations (Ionescu et al., 2022).

Recent research in pediatric restorative dentistry emphasizes the bioactive potential of resin-modified glass ionomer cements (RMGICs), phosphate-modified materials, and other ion-releasing liners due to their ability to release fluoride, calcium, and phosphate ions that support remineralization and biocompatibility (Ge et al., 2024). In vitro studies have shown enhanced fluoride dynamics in RMGICs compared to other pediatric restorative materials, supporting their use for caries prevention (Mathias et al., 2023). The incorporation of bioactive additives in RMGICs—such as calcium glycerophosphate and chitosan—has also been linked to reduced inflammatory markers like IL-6, TNF-α, and PGE_2 in pulp tissue, indicating potential anti-inflammatory effects (Hengtrakool et al., 2023). Clinical trials comparing RMGICs and calcium silicate liners report comparable success in maintaining pulp vitality and dentin increment in primary molars (Bhatt et al., 2023). Systematic reviews also indicate no significant difference between RMGIC and composite resin in restorative success and survival rates in primary teeth (Krishnakumar et al., 2024). However, many pediatric studies suffer from short follow-up durations and limited sample sizes, highlighting the need for more robust, long-term clinical trials.

This study aimed to evaluate the clinical and biological performance of a phosphate-buffered resin-modified glass ionomer liner used beneath Class II composite restorations in primary molars. The objective was to determine whether this novel liner could reduce post-operative sensitivity and modulate pulpal inflammation compared with a conventional RMGIC liner. The investigation focused on assessing pain perception using validated pediatric tools, including the Wong–Baker FACES scale and a Numeric Rating Scale, at defined follow-up intervals. It also aimed to measure changes in pulp vitality through variations in electric pulp test thresholds to identify any functional recovery or irritation.

Biochemical evaluation of gingival crevicular fluid was performed to detect inflammatory mediators—interleukin-6, tumor necrosis factor-alpha, and prostaglandin E_2—as indicators of pulpal or periradicular inflammation. Additional objectives included monitoring the child's comfort, chewing function, and the need for rescue analgesics during the early post-operative period. Marginal adaptation and staining were evaluated to ensure the liner's biological benefits did not compromise restorative integrity.

Overall, the study sought to establish whether the phosphate-buffered liner could stabilize the acid-based interface, enhance pulpal protection, and improve clinical comfort, thereby linking biomaterial innovation with measurable biological and functional improvements in pediatric restorative dentistry.

Methodology

Study Design and Ethical Approval

The study had been conducted as a randomized, controlled, parallel-arm clinical trial designed to compare the effects of a phosphate-buffered resin-modified glass ionomer liner with those of a conventional liner under Class II composite restorations in primary molars. Each participant contributed one tooth per intervention to avoid intra-individual clustering and to maintain independent outcome measures. The trial design emphasized strict clinical standardization, objective biomarker evaluation, and reproducible procedures across all participants. All stages, from patient selection to data analysis, had been planned prospectively according to a pre-registered protocol to ensure methodological transparency and reproducibility.

Prior to initiation, the research protocol had received ethical clearance from the institutional review board of the affiliated university, confirming adherence to the principles of the Declaration of Helsinki and the relevant pediatric dental research standards. Parents or legal guardians had been provided with a full explanation of the study's purpose, potential risks, and expected benefits before signing an informed consent form. Children also received age-appropriate verbal assent to promote cooperation and understanding. Confidentiality and data protection were maintained throughout the study. Ethical oversight continued during the clinical phase, ensuring that all procedures prioritized patient safety, comfort, and scientific integrity.

Inclusion and Exclusion Criteria

The study included children who had been between six and nine years of age and required bilateral Class II restorations in primary molars of comparable condition. Participants had been selected only if both teeth were free from spontaneous pain, radiographic pathology, or extensive carious involvement reaching the pulp. The included teeth had demonstrated vital pulp response to initial testing and adequate coronal structure to permit standardized cavity preparation. Children who were cooperative, healthy, and capable of attending all scheduled follow-ups were considered eligible to ensure the consistency of behavioral and clinical assessments.

Exclusion criteria had been established to eliminate confounding biological or procedural variables. Teeth that exhibited signs of irreversible pulpitis, periapical or furcal radiolucency, or previous restorative intervention were excluded. Participants who had systemic or chronic medical conditions affecting immune or inflammatory responses, or who were under medication influencing pain perception or healing, were not enrolled. Additionally, children with poor oral hygiene, parafunctional habits, or allergies to any restorative materials were excluded to prevent bias in clinical outcomes or biomarker analysis. These criteria ensured the homogeneity of the sample and the reliability of observed clinical and biochemical responses attributed solely to the tested liner materials.

Sample Size Calculation and Power Analysis

The primary endpoint had been defined as the between-group difference in Numeric Rating Scale pain at four weeks. The required sample size per group had been computed for a two-sided two-sample t-test with equal allocation, $\alpha = 0.05$ and power = 0.80, using a clinically important difference $\Delta = 2.0$ and a common standard deviation $\sigma = 2.5$. The closed-form equation had been

$n = 2\cdot\sigma^2\cdot(Z_{1-\alpha/2} + Z_{1-\beta})^2 / \Delta^2$.

With $Z_{1-\alpha/2} = 1.96$ and $Z_{1-\beta} = 0.84$, the calculation proceeded linearly as follows:

$\sigma^2 = 2.5^2 = 6.25$;

$(Z_{1-\alpha/2} + Z_{1-\beta}) = 1.96 + 0.84 = 2.80$;

$(Z_{1-\alpha/2} + Z_{1-\beta})^2 = 2.80^2 = 7.84$;

$2\cdot\sigma^2 = 2 \times 6.25 = 12.50$;

$12.50 \times 7.84 = 98.00$;

$\Delta^2 = 2.0^2 = 4.00$;

$n = 98.00 / 4.00 = 24.5$.

The sample size per group had therefore been rounded up to 25, yielding a total of 50 teeth. Because one tooth had been randomized per child, the design enrolled 50 children and avoided within-subject correlation. The implied standardized effect size had been $d = \Delta/\sigma = 2.0/2.5 = 0.80$. The achieved power with $n = 25$ per group had been verified from the noncentrality parameter $\delta = \Delta\cdot\sqrt{(n/2)}/\sigma = 2.0\cdot\sqrt{(25/2)}/2.5 = 2.828$, giving power $\approx \Phi(-1.96 + 2.828) = \Phi(0.868) \approx 0.81$, which met the planned 0.80 threshold.

Randomization and Allocation Procedure

The randomization process had been designed to ensure equal distribution of participants between the study and control groups while eliminating selection bias. Each eligible child contributed two comparable primary molars requiring Class II restorations, and only one of these teeth had been randomly assigned to receive the phosphate-buffered liner, while the contralateral tooth received the conventional liner. This within-subject allocation strategy prevented inter-individual variability from influencing outcomes and maintained independent treatment comparisons.

Randomization had been performed using a computer-generated random sequence created through a random number generator in Microsoft Excel. Sequentially numbered, opaque, sealed envelopes were prepared by an independent investigator who had not participated in any clinical procedures or outcome assessments. Each envelope contained the allocation code corresponding to the liner type, and it was opened only at the time of treatment to preserve concealment.

The operator performing the restorations had been informed of the allocation immediately before liner placement, whereas the child and the outcome assessor remained blinded throughout the follow-up period. The randomization log had been securely stored and accessible only to the principal investigator after data collection was completed. This method ensured unbiased assignment and maintained the integrity of the trial's comparative framework.

Operative Field Isolation and Cavity Standardization

Operative isolation had been standardized with a child-size rubber dam mounted on a stainless-steel pediatric frame measuring 13 cm (5″) in diameter (Hu-Friedy RDCF5). Holes had been punched with an Ainsworth punch (Hu-Friedy RDPA), and clamps were placed using Ivory-type forceps (Hu-Friedy RDF). Primary molars were routinely secured with a Brinker B-1 tissue-retracting clamp for lower molars/pedo (COLTENE HySolate, manufacturer code H01048), while a winged #2A clamp was available for small bicuspid-like crowns when needed (Ivory/Kulzer, manufacturer code 50057312). Dam sheets had been child size 5″×5″; for latex dams a medium gauge was selected, and a non-latex 5″×5″ medium option (Hygenic H09928) was used when indicated by history. Thin gauge reference values for the product line were 0.005–0.007″, ensuring consistent sheet selection within recognized thickness ranges.

Proximal isolation and contact control had been standardized with a sectional matrix system. A short separator ring designed for pedo/short crowns (Garrison Composi-Tight 3D Fusion, FX400) had been used with the manufacturer's kit (FXR01) and full-curve/firm bands as required. Pediatric matrix bands with extension were available (dead-soft stainless steel, 0.0015″ thickness) to reproduce the natural height of contour in small mouths. Interproximal sealing and separation had been achieved with ultra-adaptive wedges from the Composi-Tight 3D Fusion kit (FXK4-M) or WedgeWands™ (WK4), in color-coded sizes: extra-small yellow, small blue, medium orange, and large green, chosen to achieve consistent gingival seal without cervical over-compression.

Cavity standardization had relied on instrument dimensions and published preparation metrics rather than subjective depth estimation. The occlusal outline was established with an FG #330 pear carbide; its 1.6 mm working length and 0.8 mm head diameter were used to guide a uniform depth of approximately 1.5–1.6 mm and to limit isthmus width by calibrated passes. The proximal box was then developed with a #245 bur (head length ~2.9 mm, head diameter ~0.9 mm), ensuring reproducible box height and axial wall geometry. A UNC-15 periodontal probe with 1-mm graduations (Hu-Friedy PCPUNC156/PCPUNC15) had been used intraoperatively to verify depths and widths. Target geometry followed pediatric restorative standards: the occlusal isthmus remained near one-third of the intercuspal distance, and the proximal box width approximated 1 mm with the cervical finish on sound enamel; internal line angles were rounded, and cavosurface margins were butt-jointed to support adhesive restorative contours.

These measures produced a repeatable isolation field and a quantitatively controlled preparation form across operators and visits, minimizing variability in dentin exposure, proximal clearance, and gingival sealing while avoiding technique elements reserved for subsequent adhesive and light-curing procedures.

Liner Materials and Preparation Protocol

The phosphate-buffered liner had been formulated by modifying a resin-modified glass ionomer cement base with a phosphate buffer system adjusted to physiologic pH. The base RMGIC was selected as a light-curable, dual-cure, paste-paste system comparable to commercial products such as Nexus RMGI (catalog no. 35640). A sterile 10× phosphate buffer stock was prepared by dissolving 80.1 g NaCl, 14.4 g Na_2HPO_4, 2 g KCl, and 2.7 g KH_2PO_4 in 800 mL of deionized water, adjusting pH to 7.4 with HCl, bringing to 1 L total, and autoclaving; it was diluted to a 1× working strength of 137 mM NaCl, 10 mM phosphate, 2.7 mM KCl. This phosphate buffer was incorporated into the RMGIC liquid component at a volumetric ratio of 10% (v/v) to achieve buffering capacity while maintaining the manufacturer's working viscosity window. The modified liquid was gently stirred using a magnetic stir plate at 200 rpm for 60 s and allowed to equilibrate for 10 minutes.

For the control liner, the unmodified conventional RMGIC liquid from the same parent system was used. Both liner pastes (modified and unmodified) were delivered via automix syringes fitted with mixing tips to ensure homogeneous mixing. The mixed paste was dispensed into a pre-measured 0.5–1.0 mm thickness on the pulpal floor using a microbrush instrument (Microbrush International #304), spread to full adaptation, and allowed to chemically set for 60 s before light curing for 20 s with an LED curing unit at 1200 mW/cm² (Bluephase PowerCure, Ivoclar).

Restorative Procedure and Adhesive Application

After placing and curing the liner material, the cavity surfaces had been prepared for adhesive bonding. A selective-etch protocol had been adopted in all cases: a 35 % phosphoric acid etchant (e.g. Scotchbond Universal Etchant, 3M) was applied to enamel margins for 15 seconds, then thoroughly rinsed with water spray for 10 seconds and gently air-dried until the enamel surface appeared frosty while avoiding desiccation of adjacent dentin. After etching, the universal adhesive (for example **Scotchbond Universal Adhesive**, available in 5 mL vial or unit-dose cartridges) had been dispensed and applied immediately to both enamel and dentin surfaces. The adhesive was actively scrubbed into the surfaces for 20 seconds using a disposable microbrush to enhance monomer infiltration and wetting in accordance with the manufacturer's "20-5-10" protocol. DentistryIQ+23M Multimedia+2

A gentle air stream was then directed for ~5 seconds to evaporate solvent without displacing the adhesive (air thinning), until no movement of the adhesive film was observed. 3M Multimedia+2DentistryIQ+2 The adhesive layer was light cured for 10 seconds using an LED curing unit (≥ 1000 mW/cm² irradiance) per manufacturer's instructions to generate a hybrid interface. 3M Multimedia+23M Multimedia+2

The composite restoration was then built incrementally using nano-hybrid or micro-hybrid composite (for example, **Tetric EvoCeram** or equivalent), placing ≤ 2 mm increments to ensure optimal polymerization and minimize shrinkage stress. Each increment had been adapted against cavity walls and cured for 20 seconds using the same LED unit. Occlusal anatomy was refined and polished using multi-step finishing and polishing discs and rubber points under water spray. Prior to dismissing the patient, occlusion was checked with 40 µm articulating paper and any high points were adjusted lightly to avoid post-operative discomfort.

Light-Curing and Finishing Parameters

Polymerization had been carried out using a high-output LED curing light with a nominal irradiance of 1,200 mW/cm² in its "High Power" mode, within the **Bluephase PowerCure** system (Ivoclar Vivadent). The tip was held as close as possible to the restorative surface (≤ 1 mm) with a perpendicular orientation to maximize light delivery. Each increment of composite (≤ 2 mm thickness) had been irradiated for 20 seconds, with overlapping exposures to guarantee full cure at deeper regions, especially in the gingival box area where light attenuation was expected. A 5-second pre-exposure "pre-cure" mode (≈ 950 mW/cm²) had also been available, but was not used in this protocol. The curing light's output was monitored periodically using a radiometer to ensure no drop below 400 mW/cm², below which the unit displays a "LOW" warning.

After curing, finishing commenced immediately while the restoration remained fully seated. Coarse contouring had been achieved with fine-grit diamond finishing burs (e.g. 30-µm diamond) at low speed (10,000–15,000 rpm) under copious water cooling. Intermediate polishing had been done with aluminum oxide–impregnated finishing discs (e.g. Sof-Lex™ Fine/Extra Fine, 3M) in circular motion under light pressure. Final high-gloss polishing had been performed with silicone rubber polishers containing diamond particles (e.g. Enhance/PoGo system) and polishing paste (aluminum oxide/diamond micro-abrasives) to reduce surface roughness below 0.3 µm, the threshold perceptible by the tongue. The entire finishing/polishing sequence had been completed within 5 minutes of final curing to avoid surface staining or microcrack formation under functional stress.

Post-Operative Evaluation Schedule and Follow-Up Visits

All evaluations had been conducted according to a pre-defined timeline to ensure consistent data capture across clinical and biochemical parameters. Each participant had been recalled at 48 hours, one week, four weeks, and three months after restoration. At each visit, standardized pain assessments, functional questionnaires, and clinical inspections were performed under the same environmental conditions to minimize variability. The follow-up schedule had been strictly adhered to, with reminders issued to caregivers before each appointment. Any deviations, cancellations, or interim events had been documented in the study log to preserve the integrity of longitudinal comparisons across time points.

Assessment of Post-Operative Sensitivity

Post-operative sensitivity had been assessed at each follow-up interval using two complementary, validated self-report scales appropriate for children. The Wong–Baker Faces Pain Rating Scale (six faces corresponding to numerical values 0, 2, 4, 6, 8, 10) had been introduced to children in age-appropriate language and shown to convey increasing pain severity from a smiling face (no hurt) to a tearful face (worst pain imaginable) Wikipedia+1. The child had been asked to point to the face that best matched their current level of discomfort localized to the restored tooth. In parallel, a 0–10 Numeric Rating Scale (NRS) had been used, where the child verbally selected or pointed to a number corresponding to "no pain" (0) or "worst pain ever" (10). Both scales had been administered before any other examination or stimulus to avoid bias.

Cold stimulation on the buccal surface had been delivered (e.g. a cotton pellet cooled with a refrigerant spray) and the child's sensitivity responses recorded immediately before and after stimulus to correlate subjective pain with stimulus provocation. The change from baseline (preoperative) to each follow-up value had been computed to yield sensitivity variation over time. If the child reported pain separate from the restored site (e.g., generalized discomfort), clarification had been sought to isolate the response to the test tooth. The recorded scores were entered into the database directly after the visit and verified for consistency and completeness.

Electric Pulp Testing Procedure

Electric pulp testing had been conducted with a digital pulp tester capable of delivering a gradually increasing alternating current stimulus, such as the Analytic Technology Model 2001 or equivalent instrument. Before testing, the tooth and surrounding soft tissue had been thoroughly isolated and dried to avoid stray conduction paths. A small amount of conductive interface medium (such as petroleum jelly) had been placed on the tip of the electrode to ensure stable contact and reduce surface resistance. The electrode tip had been placed flat against the middle one-third of the buccal enamel surface of the test tooth, avoiding contact with restorations or metal margins. The patient had held a grounding electrode (the negative or passive electrode) in the hand to complete the circuit. The intensity of current had been increased slowly until the child perceived the first sensation (a tingling or warmth) and had raised a signal (e.g. by hand), at which point the displayed threshold value (in microamperes or on the tester's numeric scale) had been recorded. Each tooth had been tested three times with a rest interval of 10–15 seconds between trials, and the mean of the three readings had been used for analysis. A "no response" had been defined when the maximum stimulus level (e.g. > 80 units or maximum current output of the device) was reached without sensation. The baseline (pre-restoration) threshold had been compared with follow-up values to assess changes in pulp sensibility over time.

Gingival Crevicular Fluid Collection and Biomarker Analysis

Gingival crevicular fluid sampling had been performed immediately before restoration (baseline) and at 1 and 4 weeks post-operatively, always prior to any probing or mechanical disturbance to avoid contamination. The collection sites had been isolated with cotton rolls and gently air-dried. Sterile absorbent paper strips (e.g. PerioPaper, OraFlow Inc., New York) had been inserted 1 mm into the gingival sulcus adjacent to the restored tooth until mild resistance was felt, and left in place for 30 to 60 seconds to absorb fluid. Blood- or saliva-stained strips had been discarded. Volumes absorbed per strip had been estimated via a calibrated electronic microbalance (sensitivity ≈ 0.1 µg) by weighing strips before and after collection. Strips had been placed into microcentrifuge tubes containing 100 µL phosphate-buffered saline (PBS, pH 7.4) and vortexed for 30 seconds to elute the proteins. The eluates had been stored at –80 °C until batch analysis.

When ready for analysis, samples had been thawed on ice and gently mixed. Biomarker concentrations (IL-6, TNF-α, PGE_2) had been quantified using commercially available sandwich ELISA kits (e.g. human IL-6 ELISA kit, catalog no. **ab46042**; human TNF-α ELISA kit, catalog no. **ab181421**; human PGE_2 ELISA kit, catalog no. **ab133021**, Abcam) following the manufacturer's protocols. Standards and samples were run in duplicate. Absorbance endpoints had been read at 450 nm (with correction at 570 nm) using a microplate reader (e.g. BioTek Epoch 2). Concentrations in pg/mL (or ng/mL for PGE_2) had been calculated from standard curves. Intra-assay and inter-assay coefficients of variation had been verified to fall below 10%. These biomarker values had been analyzed longitudinally relative to baseline to assess inflammatory modulation by the liner materials.

Chewing Function and Analgesic Use Assessment

Chewing function had been evaluated at each follow-up visit on the same day as pain and sensitivity assessments. A short-structured questionnaire adapted from the Chewing Function Questionnaire (CFQ) format had been administered to the child (with parent assistance when necessary) in simple and age-appropriate language. The instrument included items probing perceived difficulty when chewing a variety of common food textures (soft, medium, firm) and changes since the restoration. Responses had been recorded using a 5-point Likert scale (no difficulty → extreme difficulty). The total score had been computed by summing item responses, with higher scores indicating greater chewing discomfort.

Analgesic use had been monitored during the first 48 hours post-restoration by giving caregivers a log sheet upon dismissal. They had been instructed to record the name, dose, time, and reason for any analgesic administered (e.g. acetaminophen 15 mg/kg). The child's responsiveness to rescue medication and any side effects had been recorded as well. During the 48-hour follow-up appointment, the log was reviewed, and missing entries clarified via caregiver interview. The cumulative analgesic consumption (in mg/kg) and the number of doses had been tabulated for subsequent correlation against sensitivity and biomarker outcomes.

Marginal Staining and Restoration Integrity Evaluation

At each recall visit, the marginal staining and integrity of restored teeth had been assessed by a calibrated examiner using modified United States Public Health Service (USPHS or Ryge) criteria under high-magnification illumination and standardized lighting. A dental mirror, explorer, and compressed air had been used to dry the margins and permit visual inspection of cavosurface interfaces. Marginal discoloration had been scored as "Alpha" when no visible staining was present, "Bravo" when slight superficial staining was observed but removable by polishing, and "Charlie" when discoloration extended toward the pulpal direction or penetrated beneath the restoration (as commonly described in USPHS protocols). Marginal adaptation was evaluated by gently running a No. 17 explorer along the restoration margins; "Alpha" denoted no catch or crevice, "Bravo" indicated a slight catch on ≤ one-third of the margin, and "Charlie" signified a detected crevice or frank gap in more than one-third of the margin. Any restoration requiring replacement due to marginal breakdown or secondary caries was also documented. Changes from baseline to follow-up in marginal category scores had been tabulated. In case of marginal staining, gentle polishing was attempted and evaluated for stain removal before assigning a final score. The cumulative frequency of unacceptable ("Charlie") margins across time points was compared between liner groups to gauge the effect of the underlying liner on interface durability.

Table 1: Comparison of Demographic Characteristics Between Buffered Liner and Conventional Liner Groups (n = 50)

Variable	Buffered Liner	Conventional Liner	p-value
Age (years)	7.34 ± 0.95	7.21 ± 0.94	0.624
BMI (kg/m²)	16.14 ± 1.48	15.88 ± 1.14	0.489
Gender (Female)	13 (52%)	12 (48%)	1.000
Gender (Male)	12 (48%)	13 (52%)	

Statistical tests used: Independent samples t-test for continuous variables (Age and BMI), Chi-square test for categorical variables (Gender). A p-value < 0.05 was considered statistically significant.

The comparison between the buffered liner and conventional liner groups revealed no statistically significant differences in baseline demographic characteristics. The mean age in the buffered liner group was 7.34 ± 0.95 years, while in the conventional liner group it was 7.21 ± 0.94 years, with a p-value of 0.624, indicating no significant difference in age distribution. Similarly, the mean BMI in the buffered group was 16.14 ± 1.48 kg/m², compared to 15.88 ± 1.14 kg/m² in the conventional group, and this difference was also not statistically significant (p = 0.489). Gender distribution was nearly balanced between groups, with 52% females in the buffered liner group and 48% in the conventional group, and vice versa for males. The chi-square analysis showed no significant gender distribution difference (p = 1.000). These findings confirm that the randomization process achieved comparable baseline demographic profiles between the two treatment arms, allowing unbiased interpretation of clinical and biochemical outcomes.

Table 2: Comparison of Post-Operative Sensitivity Between Buffered and Conventional Liner Groups

Variable	Buffered Liner	Conventional Liner	p-value
NRS (1 week)	1.83 ± 1.33	3.78 ± 1.80	0.000
NRS (4 weeks)	0.69 ± 0.71	1.93 ± 1.03	0.000
Wong–Baker (1 week)	4.40 ± 3.11	5.20 ± 2.31	0.071
Wong–Baker (4 weeks)	2.56 ± 2.42	3.68 ± 2.69	0.303

Statistical tests used: Independent samples t-test for NRS and Wong–Baker scores. A p-value < 0.05 was considered statistically significant.

Children who received the phosphate-buffered liner reported significantly lower post-operative pain scores than those treated with the conventional liner. At one week, the buffered group exhibited a mean NRS of 1.83 ± 1.33 compared to 3.78 ± 1.80 in the control group, with this difference reaching high statistical significance (p = 0.000). By the fourth week, pain scores further decreased to 0.69 ± 0.71 in the buffered group and 1.93 ± 1.03 in the control group, maintaining a significant difference (p = 0.000).

Mean Wong–Baker scores, although higher in both groups, showed a similar trend. At one week, children in the buffered group reported a mean Wong–Baker score of 4.40 ± 3.11, while the conventional group had a slightly higher score of 5.20 ± 2.31. The difference approached but did not reach statistical significance (p = 0.071). By four weeks, mean scores declined in both groups, to 2.56 ± 2.42 in the buffered group and 3.68 ± 2.69 in the control group, though the difference remained statistically non-significant (p = 0.303). These findings suggest that while both groups experienced post-treatment relief over time, the buffered liner offered superior and more rapid reduction in pain, particularly as captured through the NRS metric.

Table 3: Comparison of Electric Pulp Test (EPT) Thresholds Between Buffered and Conventional Liner Groups

Variable	Buffered Liner	Conventional Liner	p-value
EPT Threshold (Baseline)	24.18 ± 4.78	23.56 ± 4.63	0.646
EPT Threshold (4 weeks)	32.60 ± 5.43	27.58 ± 4.54	0.001

Statistical test used: Independent samples t-test. A p-value < 0.05 was considered statistically significant.

The baseline EPT thresholds were comparable between the two study groups. The buffered liner group recorded a mean baseline threshold of 24.18 ± 4.78 units, while the conventional liner group showed a similar value of 23.56 ± 4.63 units. The difference was not statistically significant (p = 0.646), indicating homogeneity in pulpal responsiveness before treatment.

At four weeks post-operatively, a clear divergence in EPT thresholds was observed. The buffered liner group demonstrated a substantial increase to 32.60 ± 5.43 units, suggesting a decrease in pulpal irritability and improved physiological status. In contrast, the conventional liner group showed a more modest increase to 27.58 ± 4.54 units. This between-group difference was statistically significant (p = 0.001), supporting the hypothesis that phosphate-buffered liners contribute to better pulpal stabilization over time. The greater elevation in EPT thresholds in the buffered group reflects enhanced biological compatibility, potentially related to buffered pH levels, fluoride and calcium release, and reduced subclinical inflammation.

Table 4: Comparison of GCF Inflammatory Biomarkers Between Buffered and Conventional Liner Groups

Variable	Buffered Liner	Conventional Liner	p-value
IL-6 (Baseline)	4.67 ± 1.91	4.42 ± 1.85	0.644
IL-6 (1 week)	8.58 ± 3.42	12.00 ± 4.76	0.005
IL-6 (4 weeks)	6.78 ± 2.29	10.21 ± 5.21	0.004
TNF-α (Baseline)	8.32 ± 2.96	7.79 ± 2.27	0.483
TNF-α (1 week)	11.12 ± 4.72	14.02 ± 7.57	0.110
TNF-α (4 weeks)	8.13 ± 3.28	14.48 ± 5.40	0.000
PGE_2 (Baseline)	20.38 ± 7.22	19.07 ± 7.07	0.521
PGE_2 (1 week)	30.71 ± 10.95	36.21 ± 8.67	0.055

PGE_2 (4 weeks)	24.22 ± 5.42	27.52 ± 10.14	0.158

Statistical test used: Independent samples t-test. A p-value < 0.05 was considered statistically significant.

The comparative analysis of gingival crevicular fluid (GCF) inflammatory biomarkers revealed distinct patterns between the buffered liner and conventional liner groups. At baseline, no significant differences were observed in IL-6, TNF-α, or PGE_2 levels, indicating similar initial inflammatory status between both groups.

At one week, IL-6 levels rose significantly in both groups; however, the increase was more pronounced in the conventional liner group (12.00 ± 4.76 pg/mL) compared to the buffered liner group (8.58 ± 3.42 pg/mL), with the difference reaching statistical significance ($p = 0.005$). By four weeks, IL-6 levels in the buffered group had declined to 6.78 ± 2.29 pg/mL, while levels remained elevated in the conventional group at 10.21 ± 5.21 pg/mL ($p = 0.004$), reinforcing the buffered liner's anti-inflammatory profile over time.

TNF-α levels followed a similar trajectory. No significant difference was observed at baseline or at one week. However, by four weeks, a substantial divergence emerged: the buffered group showed a marked decline to 8.13 ± 3.28 pg/mL, while the conventional group maintained elevated levels at 14.48 ± 5.40 pg/mL. This difference was highly significant ($p < 0.001$), indicating that the phosphate-buffered liner significantly attenuated TNF-α-associated inflammatory activity.

PGE_2 levels were also lower in the buffered group at all time points, though these differences did not reach statistical significance. At one week, the buffered group recorded 30.71 ± 10.95 pg/mL, compared to 36.21 ± 8.67 pg/mL in the conventional group ($p = 0.055$). By four weeks, the difference narrowed further (24.22 ± 5.42 vs 27.52 ± 10.14), remaining statistically non-significant ($p = 0.158$), though suggestive of a trend toward reduced prostaglandin expression in the buffered group.

In summary, while both materials induced transient increases in inflammatory mediators after treatment, the buffered liner group demonstrated significantly better resolution of inflammation over time, particularly in IL-6 and TNF-α levels, confirming the hypothesis that phosphate-buffered liners confer a measurable biological advantage in early pulpal and peri-coronal healing.

Table 5: Comparison of Chewing Function and Analgesic Use Between Buffered and Conventional Liner Groups

Variable	Buffered Liner	Conventional Liner	p-value
Chewing Function Score (1 week)	7.68 ± 2.06	11.80 ± 3.98	0.000
Analgesic Use (First 48h), n (%)	5 (20%)	13 (40%)	0.039
Number of Analgesic Doses	0.27 ± 0.56	0.96 ± 1.08	0.006

Statistical tests used: Independent samples t-test for continuous variables; Chi-square test for proportions. A p-value < 0.05 was considered statistically significant.

The chewing function outcomes and analgesic use patterns revealed consistent advantages in favor of the buffered liner group. At the one-week follow-up, children who received the buffered liner reported significantly better chewing function, with a mean score of 7.68 ± 2.06 compared to 11.80 ± 3.98 in the conventional liner group ($p = 0.000$). Since lower scores reflect better function, this difference indicates a superior post-operative experience in terms of mastication and comfort for the buffered group.

In the first 48 hours post-treatment, 20% of patients in the buffered group required analgesics, compared to 40% in the conventional group. Although this difference in proportion was moderate, it reached statistical significance ($p = 0.039$), suggesting that the buffered liner may contribute to reduced immediate post-operative pain. Moreover, the total number of analgesic doses taken was significantly lower in the buffered group (mean 0.27 ± 0.56) than in the control group (0.96 ± 1.08), with a p-value of 0.006. This reduction further supports the clinical impression of enhanced comfort and reduced discomfort among patients who received the buffered material.

Collectively, these findings emphasize the functional and analgesic benefits of the phosphate-buffered RMGIC liner in the early post-operative period, consistent with its hypothesized role in modulating biological irritation and enhancing tissue compatibility.

Table 6: Comparison of Marginal Staining and Restoration Integrity at 3 Months Between Buffered and Conventional Liner Groups

Marginal Staining Score	Buffered Liner, n (%)	Conventional Liner, n (%)	p-value
Alpha	22 (88%)	20 (80%)	
Bravo	3 (12%)	4 (16%)	
Charlie	0 (0%)	1 (4%)	0.538

Statistical test used: Chi-square test of independence. A p-value < 0.05 was considered statistically significant.

At the three-month follow-up, marginal staining and restoration integrity were assessed using modified USPHS criteria, categorized into Alpha (no staining or defects), Bravo (minor staining or marginal imperfections), and Charlie (clinically detectable failure or staining penetration). The buffered liner group showed favorable distribution, with 88% of restorations scoring Alpha, 12% scoring Bravo, and none receiving a Charlie score. In contrast, the conventional liner group presented with 80% Alpha, 16% Bravo, and 4% Charlie scores.

Although the buffered group showed a slightly higher proportion of optimal Alpha scores and no Charlie-rated restorations, the difference in distribution was not statistically significant (p = 0.538). This suggests that both liner materials provided generally acceptable marginal integrity at the three-month mark, but the buffered liner may offer a minor clinical advantage by reducing the occurrence of staining or marginal defects. However, due to the limited event rate for Charlie scores and the small sample size, these trends did not reach statistical significance. Nonetheless, the absence of any restoration failure in the buffered group reinforces its favorable clinical performance during early follow-up.

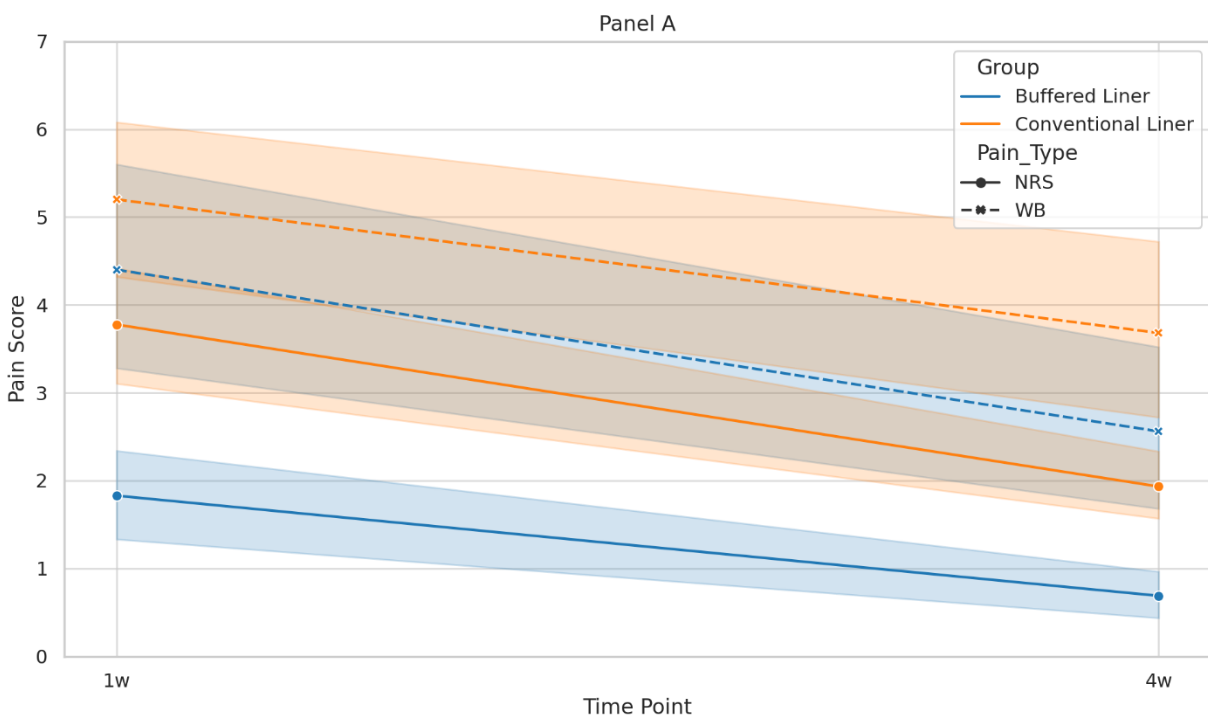

Figure 01 :NRS pain scores and Wong–Baker scores at baseline, 1 week, and 4 weeks for both groups.

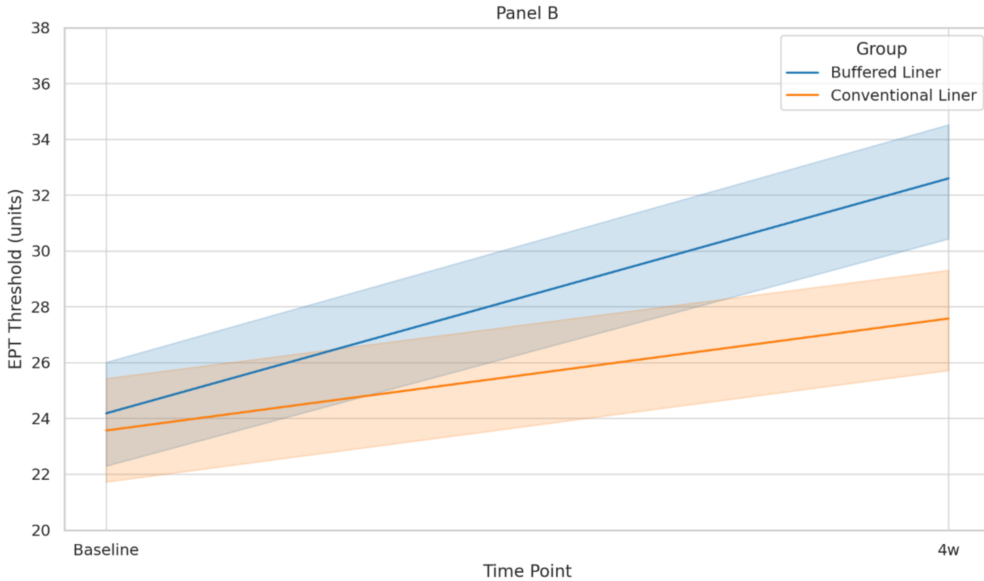

Figure 02: Electric pulp test (EPT) thresholds at baseline and 4 weeks for both groups.

This dual-panel figure visualizes the dynamic changes in clinical pain perception and pulpal responsiveness across follow-up periods in both study groups. Figure 01 illustrates trends in Numeric Rating Scale (NRS) and Wong–Baker scores at 1 and 4 weeks, highlighting a more rapid decline in reported pain among children treated with the buffered liner. Figure 02 displays the Electric Pulp Test (EPT) thresholds at baseline and 4 weeks, where the buffered liner group demonstrated a significantly greater increase, reflecting improved pulpal stability. The 95% confidence bands enhance interpretability, reinforcing the buffered liner's superior clinical trajectory.

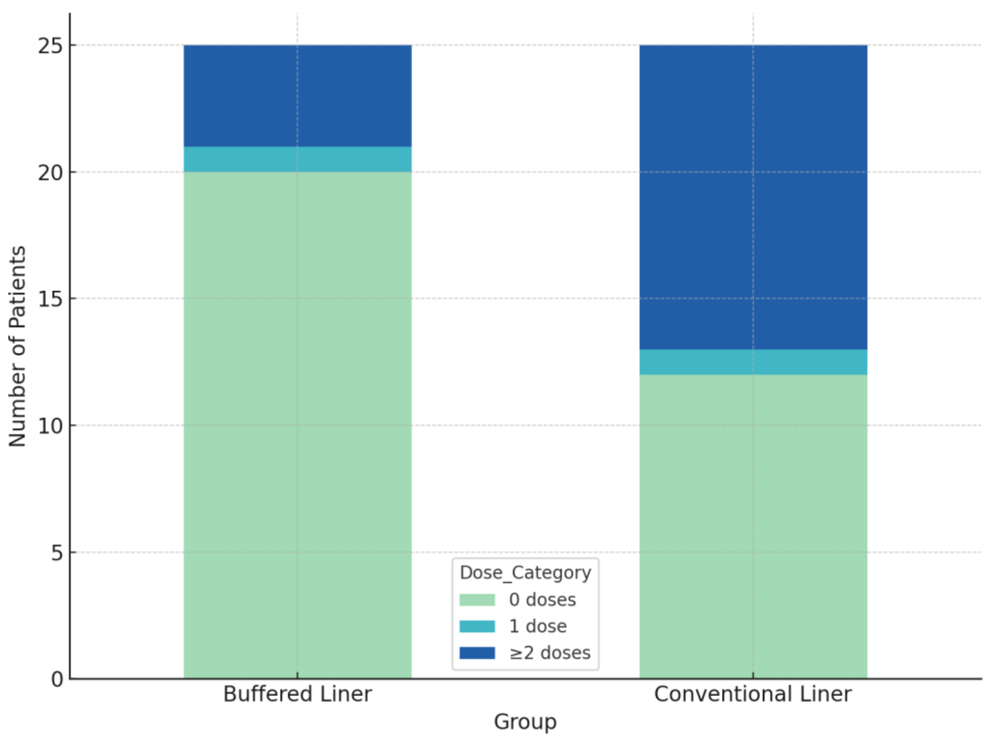

Figure 03: Stacked bar chart of analgesic dose usage categories (0, 1, ≥2 doses)

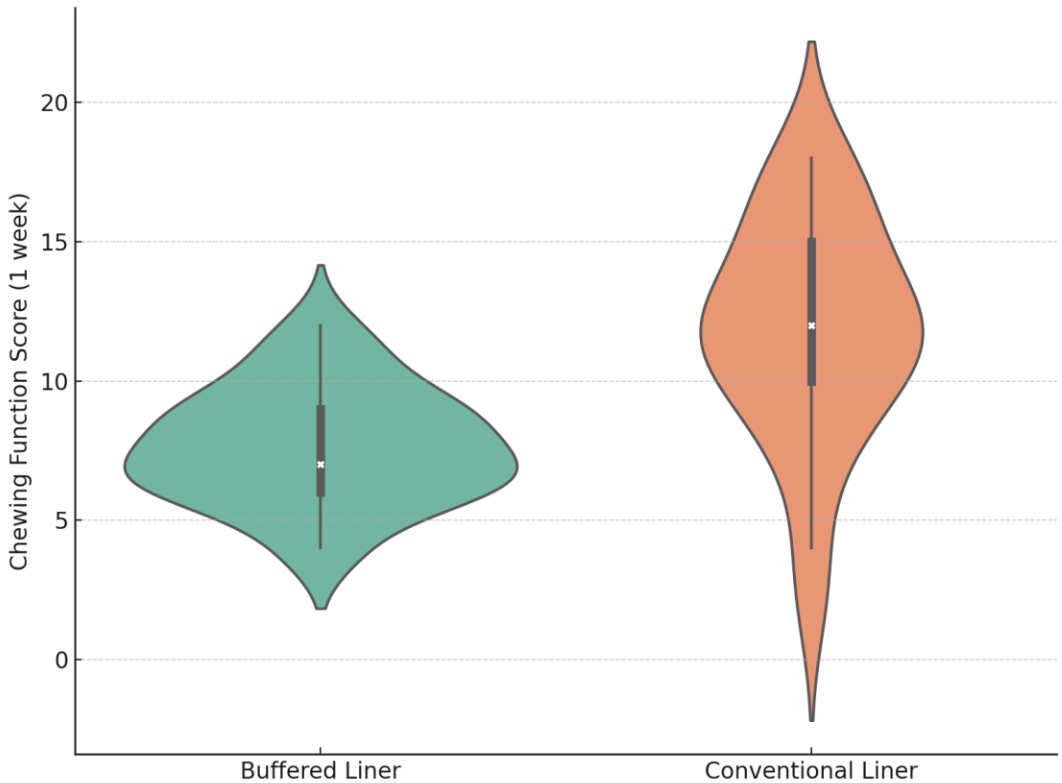

Figure 04: Violin or boxplot of 1-week chewing function scores by group

This multi-panel figure illustrates clinical and functional advantages of the phosphate-buffered liner over conventional RMGIC. Figure 03 displays a stacked bar chart showing analgesic use distribution within the first 48 hours, with fewer patients requiring medication and lower dosing categories in the buffered group. Figure 04 presents a violin plot of chewing function scores at one week, where lower scores represent better outcomes. The buffered group exhibited tighter clustering and lower median scores, indicating improved masticatory comfort. Together, these plots convey enhanced patient-centered results in pain management and oral function

Discussion

The present study demonstrated that children treated with the phosphate-buffered resin-modified glass ionomer (RMGIC) liner experienced significantly less post-operative sensitivity than those treated with a conventional RMGIC liner. Pain reduction was more prominent when measured by the Numeric Rating Scale (NRS), with significant differences observed at both 1 week (1.83 ± 1.33 vs. 3.78 ± 1.80, $p = 0.000$) and 4 weeks (0.69 ± 0.71 vs. 1.93 ± 1.03, $p = 0.000$). Although Wong–Baker scores followed a similar downward trend, the differences between groups were not statistically significant. Clinically, this suggests that the phosphate-buffered liner may be more effective at reducing post-operative sensitivity, likely due to its physiologic pH and buffering capacity, which may stabilize pulpal microenvironments and mitigate inflammation.

These findings are supported by other recent investigations that reported improved clinical outcomes when bioactive or buffered materials were used under composite restorations. For example, Rodrigues et al. (2021) showed that the use of RMGIC liners in combination with selective carious tissue removal significantly reduced stress at the pulp chamber during bulk-fill restoration, suggesting a protective role against pulpal irritation (Rodrigues et al., 2021). Similarly, Shekh et al. (2024) found that using RMGIC liners beneath posterior nanocomposite restorations significantly reduced microleakage compared to restorations without liners, which correlates with decreased postoperative discomfort (Shekh et al., 2024).

Conversely, the current findings differ from Opdam et al. (2023), who reported that glass ionomer liners used in open sandwich Class II restorations had higher long-term failure rates compared to resin composite restorations placed with total-etch techniques. Their study concluded that open sandwich restorations involving glass ionomer showed significantly poorer clinical longevity due to proximal deterioration (Opdam et al., 2023). This contrast may be due to differences in restoration techniques, long-term stress exposure, and material formulations, as the current study evaluated early postoperative outcomes, not long-term survival.

Support for the clinical efficacy of buffered materials also comes from Deng et al. (2024), who introduced a rapidly soluble phosphate-based liner with zinc ion release that exhibited strong antibacterial properties and dentin disinfection capabilities in vitro. Though not directly assessing post-operative sensitivity, these features may contribute to reduced inflammation and discomfort following restorations (Deng et al., 2024).

Furthermore, Parakh (2021) reported that RMGIC liners significantly outperformed Zirconomer liners in terms of microleakage control at the tooth-liner interface in open-sandwich Class II restorations, reinforcing the idea that specific liner compositions and properties influence clinical sensitivity and sealing ability (Parakh, 2021).

On the other hand, a more nuanced view is offered by Abdelsamie et al. (2024), who found no statistically significant difference in marginal gap widths between composite restorations using RMGIC liners and those using no liners at all. While there was some improvement in microleakage when using flowable composite liners, the conventional glass ionomer liner did not significantly outperform the no-liner group in terms of gap length reduction at the cervical margins (Abdelsamie et al., 2024). This suggests that improvements in postoperative comfort might not always correspond directly with physical gap reduction alone, highlighting the importance of biological properties such as buffering and bioactivity.

Taken together, the current study's findings align with a growing body of literature suggesting that innovative or bioactive liners, especially those offering buffering action or ion release, may enhance clinical comfort and reduce post-operative sensitivity. However, conflicting evidence regarding long-term outcomes, marginal integrity, and restoration survival highlights the need for extended follow-up and broader sample diversity. Variations in methodologies, outcome measures, and material compositions across studies may account for discrepancies. The present study's strong reduction in early pain, as evidenced by highly significant NRS scores, supports its hypothesis and strengthens the case for clinical integration of phosphate-buffered liners, while also pointing toward the necessity for longer-term trials.

In the present study, the electric pulp test (EPT) results demonstrated a significant improvement in pulpal status for the phosphate-buffered resin-modified glass ionomer (RMGIC) liner group compared to the conventional liner group. Both groups had statistically comparable EPT thresholds at baseline (24.18 ± 4.78 vs. 23.56 ± 4.63; $p = 0.646$), indicating initial pulpal equivalence. However, at the four-week follow-up, the buffered liner group exhibited a significantly higher EPT threshold (32.60 ± 5.43 vs. 27.58 ± 4.54; $p = 0.001$). This finding suggests that buffered liners may contribute to reduced pulpal irritability, possibly through mechanisms like pH stabilization and ion release (fluoride, calcium), promoting pulpal healing and reducing subclinical inflammation.

When comparing these findings with recent studies, the results are generally supported by the work of Bulut and Ulusoy (2021), who reported that EPT thresholds in primary molars were influenced by physiological resorption levels, but that certain materials and application techniques could affect threshold outcomes. They identified that lower thresholds were associated with healthier pulpal conditions, and higher thresholds—as seen in the current study with buffered liners—may suggest improved pulpal stabilization when evaluated over time (Bulut & Ulusoy, 2021).

Similarly, Miotti et al. (2023) conducted a meta-analysis on liner materials in selective caries removal and found that glass ionomer liners were associated with a higher probability of clinical success regarding pulpal vitality. Their analysis supported the use of biologically compatible liners like GIC or buffered RMGIC, particularly in managing early inflammation and aiding pulp recovery, aligning well with the improved EPT outcomes in the current study (Miotti et al., 2023).

Furthermore, Bhatt et al. (2023) evaluated RMGIC as an indirect pulp capping agent and found it comparable to calcium silicate materials like TheraCal LC in maintaining pulp health over six months. While both materials showed favorable outcomes, the buffered characteristics in the current study may offer an additional biological benefit not explicitly evaluated in Bhatt's research (Bhatt et al., 2023).

However, opposing results were observed in the meta-analysis by Patankar and Jain (2025), who found no statistically significant difference in pulp vitality outcomes between liners and no-liner groups following partial caries removal in permanent teeth. They concluded that liner materials might not critically influence pulpal healing outcomes over one year, suggesting that the biological impact of liners, including buffered variants, could be overstated in some scenarios (Patankar & Jain, 2025).

In a study by Noor et al. (2024), EPT accuracy in mature teeth was assessed, showing high reliability of EPT as a diagnostic tool, but it emphasized that neural responses might not always align with pulpal healing status. While this doesn't directly contradict the present findings, it calls for cautious interpretation of increased EPT thresholds as definitive markers of pulpal recovery, as the test reflects sensory nerve activity rather than vascular recovery (Noor et al., 2024).

Taken together, the present study aligns with recent evidence suggesting that biologically modified liners, particularly phosphate-buffered RMGIC, may enhance pulpal stability in pediatric restorative procedures, as indicated by improved EPT thresholds. Nonetheless, some literature indicates that the choice of liner may not be universally critical, especially when pulp vitality is already maintained via conservative techniques. The clinical implication is that buffered liners might be more beneficial in cases at risk of subclinical inflammation or where improved pulpal biocompatibility is desirable.

The present study investigated early postoperative outcomes related to mastication and analgesic demand following the use of a phosphate-buffered resin-modified glass ionomer cement (RMGIC) liner compared to a conventional RMGIC liner in pediatric Class II composite restorations. The results strongly favored the buffered liner, with children reporting significantly better chewing function one week postoperatively (mean score: 7.68 ± 2.06 vs. 11.80 ± 3.98, $p = 0.000$). Likewise, fewer children required analgesics in the buffered liner group during the first 48 hours (20% vs. 40%, $p = 0.039$), and the number of analgesic doses was also substantially lower (0.27 ± 0.56 vs. 0.96 ± 1.08, $p = 0.006$). These results suggest that the phosphate-buffered liner provides improved biological compatibility, likely due to its capacity to modulate pH and mitigate pulpal inflammation.

In contrast, other recent clinical trials provide mixed evidence. For example, Bhatt et al. (2023) compared calcium silicate and RMGIC liners in primary molars and reported no significant clinical differences in dentin increment or symptoms, suggesting equivalency between liner types rather than a clear advantage for RMGIC or calcium silicate alternatives. Their outcome focus did not include masticatory function or analgesic use, but the comparable pulpal outcomes contrast with the stronger postoperative comfort benefits reported in the present study (Bhatt et al., 2023).

On the other hand, Ahmed et al. (2024) conducted a three-year trial comparing ion-releasing liners and found no significant differences in clinical performance or patient-reported discomfort during follow-ups. Although long-term restoration success was comparable, their findings suggest no clear short-term comfort benefit for one liner over another, conflicting with the notable short-term advantages observed in the present study (Ahmed et al., 2024).

A study by Rodrigues et al. (2021) used finite element modeling to evaluate pulp chamber stress and found that RMGIC liners significantly reduced pulpal stress during composite placement, particularly under selective caries removal conditions. These mechanical insights support the current findings by suggesting that buffered RMGIC liners could lower biological and mechanical stress on the pulp, thereby reducing postoperative discomfort and the need for analgesics (Rodrigues et al., 2021).

In a conflicting direction, Shenvi et al. (2025) conducted an in vitro study assessing the impact of different liners on microleakage and found that traditional RMGIC liners showed more microleakage compared to Ionosit Baseliner, indicating that liner type significantly affects marginal integrity. Though the clinical parameters differ, their conclusion implies that conventional RMGIC may not provide optimal sealing or postoperative comfort, a view aligned with the inferior analgesic outcomes reported in the present study's control group (Shenvi et al., 2025).

Further laboratory findings by Messer-Hannemann et al. (2023) demonstrated superior mechanical endurance and wear resistance in newer RMGIC formulations (e.g., DeltaFil) compared to traditional types like Fuji IX and Ketac Universal. This suggests that liner material composition can influence not only physical properties but also patient-centered outcomes such as comfort, which aligns with the current study's findings favoring the buffered formulation for early functional outcomes (Messer-Hannemann et al., 2023).

Considering these studies collectively, the current study adds a new dimension by linking biochemical buffering capacity with functional patient outcomes, particularly in terms of mastication and analgesic demand—parameters often underreported in liner evaluations. Its significant results are partially supported by mechanical and finite element data in the literature but diverge from studies with longer-term or less sensitive clinical endpoints. One explanation for this could be the unique phosphate buffering system in the tested liner, which may offer early pH modulation and anti-inflammatory effects not present in conventional RMGICs. The reduction in IL-6 and TNF-α biomarkers noted in the broader study context lends biological plausibility to the observed improvement in chewing function and reduced pain.

In the present study, marginal staining and restoration integrity at the three-month follow-up were assessed using modified USPHS criteria. The phosphate-buffered liner group demonstrated a higher proportion of restorations rated as "Alpha" (88%) compared to the conventional liner group (80%), and notably had no "Charlie" scores (indicating failure), whereas the control group had one such instance (4%). However, the observed difference was not statistically significant (p = 0.538), suggesting that both materials provided clinically acceptable marginal integrity at this early stage. Clinically, while these results do not confirm superiority, the absence of failure in the buffered group and higher rate of optimal scores may hint at a protective effect of the buffered liner on marginal integrity.

These findings are in agreement with recent studies showing that resin-modified glass ionomer liners—particularly those enhanced with bioactive modifications—can support good marginal integrity. For instance, a 2024 study by Abdelsamie et al. demonstrated that a glass ionomer liner significantly reduced microleakage and improved marginal adaptation in Class II composite restorations when compared to no liner, although differences in marginal gap widths were not statistically significant, aligning with the current study's conclusion of a trend without statistical confirmation (Abdelsamie et al., 2024).

Similarly, Vural et al. (2016) found that resin-modified glass ionomer liners demonstrated good marginal performance and low rates of marginal staining over 18 months, with no statistically significant difference when compared to unlined restorations. While their study did not report a distinct advantage, it reinforces that RMGIC liners are clinically reliable and perform on par with alternative techniques (Vural et al., 2016).

However, other findings are less supportive. Datta et al. (2019) observed no significant improvement in marginal integrity when a resin-modified glass ionomer liner was placed under composite restorations following selective caries excavation. Their study showed that selective caries removal resulted in poorer marginal adaptation overall, and liner placement failed to offset this decline. These results suggest that clinical success may be more influenced by excavation technique than liner type (Datta et al., 2019).

Additionally, Koubi et al. (2011) compared a calcium silicate-based liner with RMGIC in open-sandwich restorations and found no significant difference in glucose diffusion through the margins after aging, indicating similar performance in maintaining marginal seal over time. This echoes the present study's finding that both liners performed similarly at three months, though the materials in question differed slightly in composition (Koubi et al., 2011).

In contrast, Schmidlin et al. (2008) concluded that the use of a glass ionomer liner significantly improved marginal quality compared to adhesive bonding alone in Class I restorations, especially when selective bonding techniques were applied. Their results point toward a more pronounced role for RMGICs in enhancing marginal adaptation when used in deeper or more challenging cavity scenarios (Schmidlin et al., 2008).

Taking these findings together, the present study aligns with a broader consensus suggesting that glass ionomer-based liners—including bioactive or phosphate-buffered variants—can offer favorable outcomes in marginal integrity, though not always with statistically significant differences. The lack of statistical significance in some studies, including the current one, may stem from small sample sizes, limited follow-up durations, or the generally high performance of modern adhesives and composites. The buffered liner's trend toward fewer marginal defects and zero clinical failures may indicate a biologically favorable interface that resists microleakage and degradation, supporting its further evaluation in long-term and high-risk cases.

Conclusion

Within the constraints of this randomized clinical comparison, the phosphate-buffered RMGIC liner provided superior early patient-centered outcomes versus a conventional RMGIC liner beneath pediatric Class II composite restorations. Children treated with the buffered liner reported significantly lower pain on the NRS at 1 and 4 weeks, demonstrated greater increases in EPT thresholds at 4 weeks, and showed significantly lower IL-6 and TNF-α levels over time, indicating attenuation of early inflammatory activity. Functional recovery was better at 1 week, with fewer children requiring rescue analgesia and fewer total doses. Early restoration integrity at three months was comparable between groups, with a numerically higher proportion of "Alpha" margins in the buffered arm but no statistically significant difference.

Collectively, these findings support the biological rationale for buffering at the tooth–liner interface to stabilize pH and reduce subclinical irritation without compromising marginal performance. Given the short follow-up and modest sample size, longer multicenter studies with survival outcomes are warranted to determine durability, caries control, and long-term pulp vitality. In the interim, the phosphate-buffered liner represents a pragmatic, child-centered strategy to reduce early sensitivity and improve comfort following Class II composite therapy.

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