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Comparative Clinical Evaluation of Indirect Ceramic and Composite Restorations Bonded with Fourth- and Eighth-Generation Adhesives Using Dual-Cure Resin Cement

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Abstract: ***The aim of the present study was to evaluate the clinical performance of indirect aesthetic restorations luted using dual-cure resin cement paired with adhesive systems from two different generations – fourth and eighth. A durable adhesive bond plays a decisive role in the longevity of such restorations by ensuring marginal integrity, retention and resistance to functional stresses. Fourth-generation systems, which have seen extensive clinical use over several decades, demonstrate high predictability due to the separate application of etchant, primer and adhesive, resulting in the formation of a stable hybrid layer. However, the more complex multi-step protocol may increase the risk of operator error. By contrast, eighth-generation adhesives are defined as universal systems, applicable in etch-and-rinse, self-etch, or selective enamel etch techniques. They typically contain functional monomers such as 10-MDP, which enable chemical bonding to hydroxyapatite, as well as nanofillers to enhance mechanical stability. Additional advantages include integrated desensitisers, reduced water sorption and improved resistance to hydrolytic degradation, which collectively may contribute to superior long-term clinical effectiveness. During clinical follow-up, indirect restorations (ceramic and composite) were assessed according to criteria including marginal adaptation, retention, postoperative sensitivity, colour stability, and overall aesthetics. The results indicate that both adhesive protocols – fourth- and eighth generation – provide a high degree of clinical success, although universal adhesives appear to offer greater versatility and more optimised performance across a range of clinical situations. This study highlights the importance of adhesive system selection for the clinical outcome of indirect aesthetic restorations and provides comparative clinical data that may guide practitioners in optimising restorative protocols.***

Keywords: adhesive systems, clinical performance, dual-cure resin cement immediate dentine sealing (IDS), indirect restorations, universal adhesives

1. Introduction

The development of adhesive systems and composite materials over the past few decades has profoundly transformed restorative dentistry. Increasing aesthetic expectations, combined with the pursuit of minimally invasive approaches, have established indirect restorations, ceramic and composite, as preferred options for the rehabilitation of tooth structure defects. Their clinical success depends not only on the physico-mechanical properties of the materials but also on the reliability of the adhesive interface and the cementation protocol [1,2].

Dual-cure composite cements have become the gold standard for luting indirect restorations, as they combine the advantages of light- and chemically activated polymerisation. They ensure a sufficient degree of conversion even in areas with limited light access, while allowing control over working time and placement. This results in optimal retention, reduced microleakage, and enhanced long-term bond stability [3].

A crucial factor determining success is the choice of adhesive system. Fourth-generation adhesives long considered the "gold standard" in adhesive dentistry, employ separate etching, priming, and bonding steps, enabling the formation of a durable hybrid layer and a reliable bond to both enamel and dentine. Their well-documented effectiveness provides excellent predictability; however, the complexity of the multi-step protocol increases the risk of operator error [4,5].

Eighth-generation, or "universal," adhesives represent the latest development in the field. Designed for versatility, they can be used with etch-and-rinse, self-etch, or selective enamel etch protocols. They contain functional monomers (e.g., 10-MDP) that form chemical bonds with hydroxyapatite, as well as nanofillers that enhance mechanical strength. In addition, formulation modifications aim to reduce postoperative sensitivity and enhance hydrolytic stability, thereby improving long-term performance [6,7].

Comparing the established fourth-generation and modern universal adhesives is clinically significant. While the former show proven reliability, universal systems offer simplified application, broader indications, and improved resistance to ageing, raising the question of whether they can achieve comparable or superior outcomes [7,8]. Evaluating indirect aesthetic restorations luted with dual-cure composite cements and different adhesive systems is therefore essential for optimising restorative protocols and ensuring long-term clinical success and patient satisfaction.

2. Method and Materials

Patient Selection

The study included patients aged 20–65 years in good general health, presenting with vital teeth and occluso-proximal defects (MO, DO, MOD) suitable for indirect restorations, allowing rubber dam isolation and without active caries or endodontic indications. Exclusion criteria included uncontrolled systemic diseases, bruxism, allergies to materials, pregnancy, or inadequate isolation conditions.

Study Design

The study included 35 patients, for whom a total of 44 indirect aesthetic restorations were fabricated (*n=44*). The restored teeth were allocated into two main groups:

- Group I (*n=22*): ceramic inlays/onlays/overlays – e.max Press (*Ivoclar, Liechtenstein*).
- Group II (*n=22*): hybrid ceramic inlays/onlays/overlays – breCAM.HIPC (*Bredent, Germany*).

Each group was further divided into two subgroups according to the adhesive system used:

- Subgroup A (*n=11*): fourth-generation adhesive *Syntac* (*Ivoclar, Liechtenstein*) combined with dual-cure resin cement Variolink Esthetic DC (*Ivoclar, Liechtenstein*).
- Subgroup B (*n=11*): eighth-generation universal adhesive Adhese *Universal Pen* (*Ivoclar, Liechtenstein*) combined with Variolink Esthetic DC (*Ivoclar, Liechtenstein*).

Clinical Procedure

1) <u>Cavity preparation:</u>
   To preserve as much sound tooth structure as possible, cavity preparation followed the principles of biomimetic dentistry. Margins were placed supragingivally whenever feasible to ensure optimal isolation. In cases with subgingival margins, the gingival margin elevation technique was considered.
2) <u>Immediate dentine sealing (IDS):</u>
   Immediately after preparation and under rubber dam isolation, adhesive sealing of dentine was performed to create a hybrid layer under ideal conditions. This step protects dentinal tubules during provisionalisation and reduces the risk of postoperative sensitivity [9].
3) <u>Impression and laboratory fabrication:</u>
   Following IDS, a silicone impression was taken. The restorations were fabricated in a dental laboratory from lithium disilicate ceramic (e.max Press, Ivoclar, Liechtenstein) or hybrid ceramic (breCAM.HIPC, Bredent, Germany).
4) <u>Surface treatment of restorations:</u>
   Ceramic restorations were etched with 5% hydrofluoric acid, rinsed, dried, and salinized. Composite restorations underwent airborne-particle abrasion with aluminium oxide, followed by silanization.
5) <u>Isolation and cavity conditioning:</u>
   All teeth were isolated with a rubber dam. Selective etching of the enamel was performed using 37% phosphoric acid for 20 seconds. Depending on the subgroup, either a fourth- or eighth-generation adhesive was applied according to the manufacturer's instructions.
6) <u>Cementation:</u>
   Restorations were luted using dual-cure composite cement (*Variolink II, Ivoclar, Liechtenstein*). Polymerisation was initiated with a light-curing unit (*Bluephase G4, Ivoclar, Liechtenstein*) in "Pre-Cure mode" (950 mW/cm² for 2 s per side). Excess cement was removed before final polymerisation (20 s per surface, ≥1200 mW/cm², 385–515 nm). Final curing was performed under glycerine gel to eliminate the oxygen-inhibited layer.
7) <u>Finishing and clinical monitoring:</u>
   Margins were finished and checked for residual cement before rubber dam removal. Occlusal contacts were verified and adjusted as needed. Marginal transitions were polished with diamond polishers and abrasive discs. Patients received oral hygiene instructions and were recalled for follow-up at 6 and 12 months, and after 2 and 4 years.

Each restoration (*n=44*) was evaluated at the same intervals for marginal integrity (microleakage/caries), postoperative sensitivity, discolouration, and fracture/chipping.

3. Results

Clinical Survival Analysis

Follow-up of a total of 44 (*n=44*) indirect aesthetic restorations over a four-year period revealed variations in clinical performance among the different groups and subgroups:

Group I (ceramic – lithium disilicate, e.max Press)

- Subgroup A (fourth-generation adhesive Syntac + Variolink Esthetic DC): all restorations maintained full clinical success with no evidence of discolouration, marginal defects, postoperative sensitivity, or fractures. Survival remained 100% at the end of the 48-month observation period.
- Subgroup B (eighth-generation Adhese Universal + Variolink Esthetic DC): at 24 months, two cases of chipping were observed (4.55%), and at 48 months, two cases of marginal discolouration (4.55%). Nevertheless, all restorations remained functional, and no reintervention was required.

Group II (hybrid ceramic, breCAM.HIPC)

- Subgroup A (fourth-generation Syntac + Variolink Esthetic DC): at 24 months, two cases of chipping (4.55%) and one case of postoperative sensitivity with discolouration (2.27%) were recorded. At 48 months, two additional cases of marginal discolouration (6.82%) and one with persistent sensitivity (2.27%) were observed.
- Subgroup B (eighth-generation Adhese Universal + Variolink Esthetic DC): at 12 months, three cases of postoperative sensitivity were detected (6.82%). At 24 months, two further cases of sensitivity (total 11.36%), three cases of marginal discolouration (6.82%), and two cases of marginal fracture (4.55%) were reported. At 48 months, two additional cases of discolouration (total 11.36%), one case of sensitivity (total 13.64%), and two further marginal fractures (total 9.09%) were registered.

Analysis by clinical parameters:

- Marginal gap: in the subgroup with eighth-generation adhesive and breCAM.HIPC – two cases (2/11; 18.18%) at both 24 and 48 months.
- Postoperative sensitivity: in the same subgroup – three cases (27.3%) at 12 months, two (18.18%) at 24 months, and one (9.09%) at 48 months. In the subgroup with fourth-generation Syntac, one case (9.09%) was observed at both 24 and 48 months.
- Fractures / chipping: in the subgroup with eighth-generation adhesive and e.max Press – two cases (18.18%) at 24 months; in the subgroup with Syntac and

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breCAM.HIPC – two cases (18.18%) at 24 months; and in the subgroup with eighth-generation adhesive and breCAM.HIPC – one case (9.09%) at 48 months.

- Marginal discolouration: in the subgroup with eighth-generation adhesive and e.max Press – two cases (18.18%) at 48 months; in the subgroup with Syntac and breCAM.HIPC – two cases (18.18%) at 48 months; and in the subgroup with eighth-generation adhesive and breCAM.HIPC – three cases (27.3%) at 24 months and two cases (18.18%) at 48 months.

Evaluation of clinical survival:

Assessing the clinical survival of indirect restorations is a key aspect in analysing their long-term effectiveness. Unlike simple reporting of defect frequencies at fixed time intervals, survival analysis allows the evaluation of the dynamics of clinical event occurrence - such as marginal defects, fractures, postoperative sensitivity, or discolouration—and the estimation of the probability that a restoration remains clinically successful over a given period. This provides a more informative and objective view of the long-term behaviour of different materials and adhesive systems.

Statistical analysis:

The Kaplan–Meier method was employed to calculate the cumulative probability of restoration “survival” without clinical failure. This statistical approach accounts for different time points and includes censored cases (e.g. when follow-up was discontinued before the occurrence of a defect or complication). The resulting curve typically displays a stepwise pattern, where each event corresponds to a sharp decline, and horizontal segments represent intervals without new clinical failures.

To evaluate the temporal dynamics of clinical parameters, in addition to between-group comparisons, statistical methods for paired data were applied. These analyses allowed assessment of whether the condition of the same tooth changed across the follow-up intervals, thereby capturing within-group variation and longitudinal trends.

The McNemar test was employed for the analysis of dichotomous variables (e.g. presence/absence). For instance, postoperative sensitivity was examined to determine whether changes occurred between the 12- and 24-month evaluations in the same restorations. This test considers only those cases where the outcome changed (e.g. from “no sensitivity” to “sensitivity” or vice versa), and the resulting statistic indicates whether the observed shifts are statistically significant or attributable to random variation.

The Wilcoxon signed-rank test was used for parameters measured on ordinal scales (e.g. marginal discolouration or sensitivity intensity, graded from 0 to 3). This non-parametric test compares the medians of two related datasets (for example, scores at 24 versus 48 months), taking into account both the direction and magnitude of individual differences. In this way, it identifies whether there is a systematic trend—such as a gradual deterioration in a clinical parameter over time—that might not be evident from frequency analyses alone.

The combination of both tests provides a more comprehensive understanding of the temporal dynamics in the clinical performance of indirect restorations. The McNemar test is particularly suitable for infrequent events and small sample sizes, whereas the Wilcoxon test enables the analysis of progressive changes in ordinal outcomes. Together, they complement the between-group comparisons and allow detection of subtle yet clinically meaningful variations over time in adhesively cemented restorations.

According to the Wilcoxon signed-rank test, the difference was statistically significant ($z = -2.02$, $p = 0.043$), indicating that over the four-year observation period, restorations bonded with the eighth-generation adhesive showed a tendency towards increased marginal discolouration (Fig.1).

4. Discussion

The results of the present clinical follow-up demonstrated that, over the four-year observation period, no statistically significant differences were found between the subgroups using fourth- and eighth-generation adhesive systems in any of the evaluated parameters - marginal gap, postoperative sensitivity, fractures/chipping, or marginal discolouration. Nonetheless, certain clinical events were observed at specific time points, including a higher frequency of sensitivity and discolouration in the eighth-generation subgroup, as well as the occurrence of marginal defects. Although not statistically significant, these findings indicate trends that merit further consideration [10,11]. One plausible explanation for the absence of statistically significant differences lies in the small sample size within each subgroup (*n=11*) and the low incidence of clinical events, largely attributable to the strict selection of indications for restoration.

Under such conditions, the statistical power of Fisher’s exact test is limited, making it unlikely to detect significant differences even when clinical disparities exist. This observation aligns with previous publications highlighting the inherent challenges of analysing small clinical cohorts in adhesive dentistry [12].

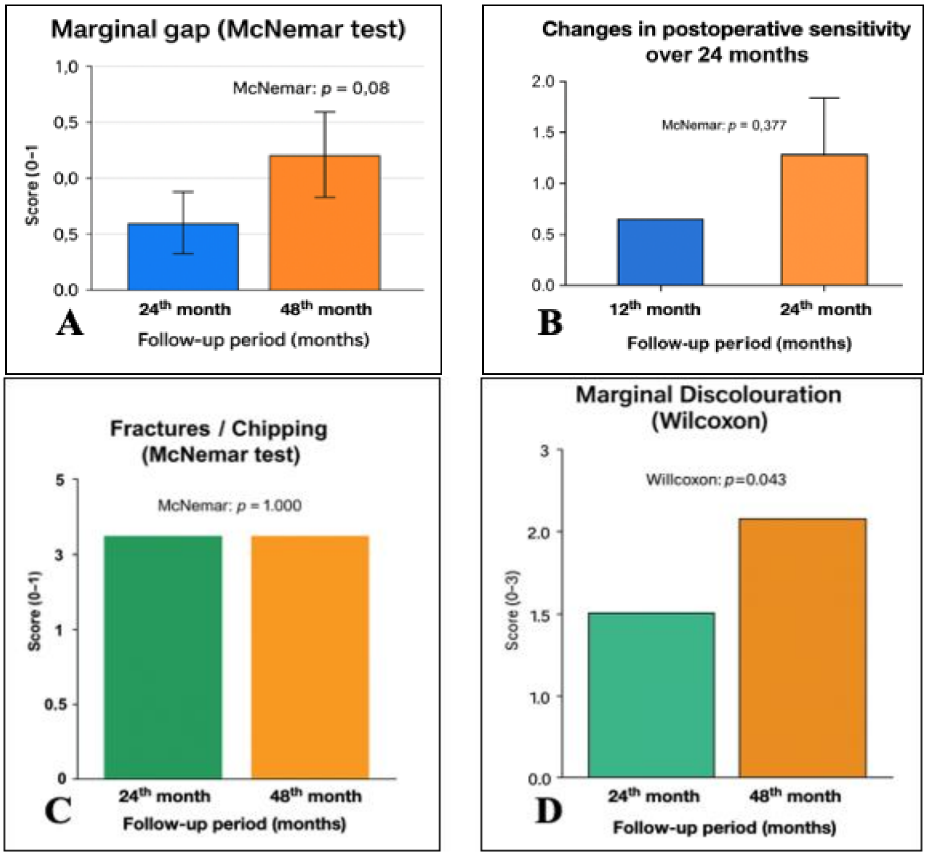

Figure 1: The figure presents graphical representations of McNemar and Wilcoxon analyses: **A/** Marginal gap (*McNemar test*); **B/** Postoperative sensitivity (*McNemar test*); **C/** Fractures/Chipping (*McNemar test*); **D/** Marginal discolouration (*Wilcoxon*).

The observed tendency for more frequent discolouration and sensitivity in the eighth-generation adhesive subgroup may be attributed to the specific interactions between universal adhesives and dentinal substrates. As noted by Van Meerbeek *et al.*, the bond to dentine remains more delicate and less durable over time, potentially predisposing these systems to microleakage and postoperative symptoms. Conversely, fourth-generation adhesives, despite their more complex application protocols, have demonstrated superior long-term reliability due to the formation of a more stable hybrid layer [13].

These findings underscore the need for larger-scale, longer-term clinical trials to more accurately assess the potential advantages and shortcomings of different adhesive generations. Combining clinical evaluation with laboratory assessments—such as microleakage testing, degree of polymerisation, and bond strength stability—could provide deeper insights into the clinical performance of these systems [14,15].

Statistical Approach

The data analysis combined descriptive and analytical statistical methods appropriate to the nature of the variables and study design. Clinical parameters—marginal adaptation, postoperative sensitivity, discolouration, and fractures/chipping—were expressed as absolute and relative frequencies. For ordinal data (e.g. sensitivity score or discolouration intensity), medians and interquartile ranges (*IQR*) were calculated, providing a more representative measure than mean values. Comparisons between groups were conducted using different methods depending on the data type. For dichotomous variables (presence/absence of defects), the χ^2 test was applied, while Fisher's exact test was used for small sample sizes. Ordinal data (0–3 scale ratings) were analysed using non-parametric tests—Mann–Whitney U for two-group comparisons and Kruskal–Wallis for four-group comparisons, followed by Dunn's post-hoc test with Holm correction when significant differences were detected. The statistical approach used in this study aligns with methodologies reported in current clinical trials in restorative dentistry, where nonparametric tests such as the Mann–Whitney U test, the Kruskal–Wallis test, and post hoc Dunn analyses with Holm correction are employed to handle ordinal or nonnormally distributed data. Similar statistical frameworks have been used in recent long-term clinical studies evaluating restorative materials and adhesive systems [16,17]. These examples support the robustness and suitability of the applied analytical strategy for assessing clinical outcomes in studies with small and diverse samples.

Temporal dynamics were assessed using Kaplan–Meier survival analysis, defining as an "event" any clinically relevant defect requiring reintervention (e.g. functionally significant discolouration, pronounced postoperative sensitivity, or fracture/chipping). Survival curves were compared using the log-rank test. Additionally, Cox regression analysis was performed to determine the influence of "restorative material type" and "adhesive system" on the risk of clinical failure, expressed as Hazard Ratios (HR) with 95% confidence intervals. These methodologies are well established in adhesive dentistry research and have been successfully applied in long-term clinical evaluations. Previous studies have employed Kaplan–Meier survival analysis and Cox regression models to assess prognostic factors and the risk of clinical failure in various adhesive scenarios, including posterior composite restorations [18] and adhesively bonded post restorations [19]. Collectively, these investigations confirm the suitability of survival-based statistical approaches for analysing clinical performance and identifying variables influencing restoration longevity. Accordingly, a similar analytical framework was adopted in the present study to ensure methodological consistency and comparability with previous research.

For repeated measures on the same teeth across time points, McNemar's test (for binary variables) and the Wilcoxon signed-rank test (for ordinal data) were applied to detect within-subject changes. In cases where a patient had multiple restorations, Generalised Estimating Equations (GEE) were employed to account for data clustering.

Key Observations

In the subgroup using the eighth-generation adhesive with breCAM.HIPC, marginal gaps were observed in two cases at 24 and 48 months (18.18%), while none occurred in the fourth-generation subgroup. Despite this apparent difference, Fisher's exact test showed no statistical significance ($p = 0.476$). Regarding postoperative sensitivity, three cases (27.3%) were reported at 12 months, two (18.18%) at 24 months, and one (9.09%) at 48 months in the eighth-generation/breCAM.HIPC subgroup, compared with one case at 24 months and one at 48 months (both 9.09%) in the fourth-generation/Syntac subgroup ($p = 1.000$). These results support previous studies indicating that postoperative sensitivity following adhesive restorations is typically transient and rarely leads to clinical failure [20,21,22]. Fractures/chipping occurred in two cases (18.18%) in both the eighth-generation/e.max and fourth-generation/breCAM.HIPC subgroups at 24 months, and in one additional case (9.09%) in the latter at 48 months, again without significant differences ($p = 1.000$). Similarly, marginal discolouration increased over time, reaching statistical significance ($p = 0.043$) according to the Wilcoxon test, in line with reports linking hybrid layer degradation and microleakage to long-term staining [23,24].

Overall, over a four-year observation period, no significant differences were detected in the clinical performance of restorations bonded with fourth- and eighth-generation adhesives. However, the eighth-generation system showed a tendency towards increased postoperative sensitivity and marginal discolouration, likely due to a less stable dentine hybrid layer. The lack of statistical significance is probably related to the small sample size and low event rate [25,26,27].

Limitations

This study's main limitations include the relatively small sample size (44 restorations across four subgroups, *n=11* each), which restricts the ability to detect small but clinically important differences, and its single-centre design, which limits wider applicability. Although the four-year follow-up adequately reflects short- to medium-term outcomes, longer-term research is needed to assess the durability of these restorations.

Perspectives in Adhesive Dentistry

Adhesive dentistry continues to evolve as a dynamic and multifaceted discipline aiming to overcome traditional limitations such as hybrid layer degradation, moisture contamination, bacterial infiltration, and technique sensitivity. Current trends focus on the development of universal (*multimode*) adhesives, which can be applied in etch-and-rinse, self-etch, or selective enamel etching protocols, providing versatility with minimal compromise in adhesion to either enamel or dentine [7].

One promising approach involves integrating crosslinking agents or modified monomers, either incorporated into the adhesive formulation or used as a pre-treatment, to improve long-term bond durability by stabilising the collagen matrix and reducing enzymatic and hydrolytic degradation [8]. Furthermore, the addition of nanofillers and bioactive components—such as fluoride-releasing or antibacterial particles and antioxidants—may endow adhesives with therapeutic potential, enabling not only passive bonding but also active participation in remineralisation and inhibition of interface breakdown [28].

Another key focus is improving resistance to hydrolytic degradation and to long-term mechanical stress. Despite major advances, hydrolysis at the adhesive interface remains a critical challenge, particularly in the presence of marginal microgaps or moisture ingress through microcapillaries. Strategies under investigation include HEMA-free formulations to reduce hydrophilicity and the use of more hydrolytically stable monomers [29,30].

Furthermore, advanced application techniques—such as mechanical agitation, ultrasonic or microvibrational delivery, and verification of adhesive layer thickness—are being examined to reduce operator-related variability in clinical settings. Although some of these methods are still at the research stage, the trend is clear: future adhesives are likely to be easier to apply, more durable, biologically active, and adaptable to various clinical protocols.

5. Conclusions

The four-year clinical follow-up of indirect restorations demonstrated a consistently high success rate and stable clinical performance, irrespective of the restorative material or adhesive system employed. Nonetheless, notable variations between subgroups revealed both the potential and the limitations of contemporary adhesive approaches. Ceramic restorations (e.max Press) exhibited superior long-term stability, maintaining 100% success in the subgroup bonded with the fourth-generation adhesive and presenting only minimal defects when combined with the eighth-generation system. In contrast, hybrid ceramics (breCAM.HIPC) showed a higher incidence of clinical alterations—marginal discolouration, chipping, and postoperative sensitivity—particularly when used with the universal adhesive. These findings suggest that the interaction between restorative material and adhesive system plays a decisive role in long-term clinical performance.

Achieving predictable and durable adhesion to dentine remains a key challenge. Unlike enamel, whose mineralised structure enables reliable bonding following conventional etching, dentine's complex organic matrix, high water content, and tubular morphology increase its vulnerability to technique sensitivity, polymerisation stress, and hydrolytic degradation. The postoperative sensitivity observed with universal adhesives corroborates this susceptibility. Emerging strategies, such as immediate dentine sealing (IDS), the use of modified monomers, nanofillers, and bioactive components, aim to reinforce the adhesive interface and mitigate long-term degradation. Although universal adhesives offer flexibility, the present findings indicate that their long-term clinical reliability still warrants further validation.

In the limitations of this study, it could be concluded that indirect aesthetic restorations bonded with contemporary adhesive systems demonstrate good short- to medium-term predictability. However, the establishment of durable dentine adhesion remains a fundamental challenge, emphasising the need for continued development of materials and techniques to ensure optimal long-term outcomes.

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