

Original Research

Clinical performance of bioflex crowns in primary molars: a 12-month prospective evaluation

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ABSTRACT:

Background: Bioflex crowns have emerged as esthetic, tooth-colored alternatives to stainless steel crowns for restoring primary molars; however, clinical evidence regarding their performance remains limited. This study evaluated the 12-month clinical behavior of Bioflex crowns with respect to gingival health, plaque accumulation, marginal adaptation, and crown retention. **Methods:** A prospective clinical evaluation was conducted on pulpectomized primary second molars restored with Bioflex crowns. Tooth preparation, crown selection, and cementation followed standardized protocols. Clinical assessments were performed at baseline, 1, 3, 6, and 12 months using the Løe and Silness Gingival Index, Silness and Løe Plaque Index, modified USPHS criteria for marginal integrity, a 3-point retention score, and the Smith & Knight Wear Index. **Results:** Gingival and plaque index values increased progressively throughout the study period, indicating mild to moderate inflammation. Marginal adaptation remained ideal during early follow-ups but showed a decline at 6 and 12 months. Crown retention was excellent initially, with mild loss at 6 months and more pronounced loss at 12 months. No wear was observed on opposing natural teeth, and alveolar bone levels remained stable. **Conclusion:** Bioflex crowns demonstrated acceptable short-term clinical performance with favorable esthetics, good early retention, and compatibility with opposing teeth. Increasing plaque accumulation, gingival inflammation, and declining marginal integrity over time highlight the need for regular follow-up and good oral hygiene. Bioflex crowns represent a viable esthetic option for restoring primary molars, though further long-term studies are recommended.

Keywords: Bioflex crowns, pediatric dentistry, primary molars, esthetic crowns, full-coverage restoration, pulpectomy, gingival health, marginal integrity.

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INTRODUCTION

Early Childhood Caries (ECC) is one of the most common chronic conditions affecting children globally and may progress rapidly when untreated, leading to pain, infection, and functional impairment [1]. Restoration of carious primary molars is essential for maintaining mastication, arch integrity, occlusal development, and speech [2]. Because multisurface carious lesions and pulpectomized teeth have high failure rates when restored with intracoronal restorations, full-coverage crowns remain the treatment of choice [3].

Stainless steel crowns (SSCs) have long been considered the gold standard due to their durability and predictable success; however, their esthetic

limitations often lead to parental dissatisfaction [4]. The demand for esthetic pediatric restorations has facilitated the development of alternatives such as pre-veneered SSCs, zirconia crowns, and fiber-reinforced composite crowns [5,6]. While esthetic, these crowns often require extensive tooth reduction, are technique-sensitive, costly, and sometimes lack adjustability.

Bioflex crowns are a newer generation of hybrid polymer-based esthetic crowns designed to overcome these shortcomings. Their flexibility, biocompatibility, tooth-colored appearance, and minimal preparation requirements make them attractive options in pediatric restorative care [7]. Finite element analysis and early clinical trials have reported favorable stress

distribution and acceptable short-term performance [8–10], but longitudinal clinical data remain limited. Thus, the present study aimed to evaluate the 12-month clinical performance of Bioflex crowns on pulpectomized primary second molars, focusing on gingival health, plaque accumulation, marginal integrity, crown retention, and occlusal wear.

AIM

To evaluate the clinical performance of Bioflex crowns placed on pulpectomized primary molars over a 12-month period.

OBJECTIVES

1. To evaluate gingival index, plaque index, marginal integrity, crown retention, and wear of opposing teeth at baseline, 1, 3, 6, and 12 months.
2. To assess overall functional behavior and periodontal response during the 12-month observation period.

RESEARCH HYPOTHESIS

Bioflex crowns will demonstrate satisfactory clinical and radiographic performance over a 12-month period.

NULL HYPOTHESIS

Bioflex crowns will not demonstrate satisfactory clinical or radiographic performance over a 12-month period.

MATERIALS AND METHODS

This prospective clinical study was conducted in the Department of Pediatric and Preventive Dentistry following approval from the Institutional Ethics Committee (Ref: GDC/Perio/ethical committee/1685, dated 05/01/2024). Only Bioflex crown data from a larger split-mouth study were analyzed.

Sample Selection: Children aged 6–8 years requiring full-coverage restorations for bilaterally pulpectomized primary second molars were screened. Cooperative children (Frankl positive or definitely positive) were included. Teeth exhibiting proper obturation, normal bone levels (CEJ–crest \leq 2 mm), and absence of pathology were selected. Exclusion criteria included uncooperative behavior, systemic conditions, allergies to dental materials, deeply resorbed roots, and abnormal opposing dentition.

Clinical Procedure: Mesiodistal crown width was measured using a digital vernier caliper. Tooth

preparation involved 1–1.5 mm occlusal reduction, proximal slicing, and rounding of all line angles. Bioflex crowns were tried in, trimmed 0.5–1 mm below the gingival mark, contoured, and finished. Resin-modified glass ionomer cement was used for cementation. Excess cement was removed, and baseline radiographs were taken.

Follow-Up:

Evaluations were performed at baseline, 1, 3, 6, and 12 months.

Clinical parameters included:

- **Gingival Index** (Löe&Silness)
- **Plaque Index** (Silness&Löe)
- **Marginal Integrity** (modified USPHS criteria)
- **Crown Retention** (0 = intact, 1 = chipped, 2 = lost)
- **Opposing Tooth Wear** (Smith & Knight Index)

Statistical Analysis

Data were analyzed using SPSS v26. Normality was assessed using Kolmogorov–Smirnov test. Repeated measures ANOVA evaluated changes over time; Chi-square test analyzed categorical data. Significance was set at $p < 0.05$.

RESULTS

Bioflex crowns demonstrated satisfactory performance in the early period, with progressive changes noted over time.

Gingival Index: (Graph 1)

Increased from 0 (baseline) to 1.40 (12 months), indicating mild to moderate inflammation.

Plaque Index: (Graph 2)

Increased from 0 to 1.87 over 12 months, showing plaque accumulation around crown margins.

Marginal Adaptation: (Graph 3)

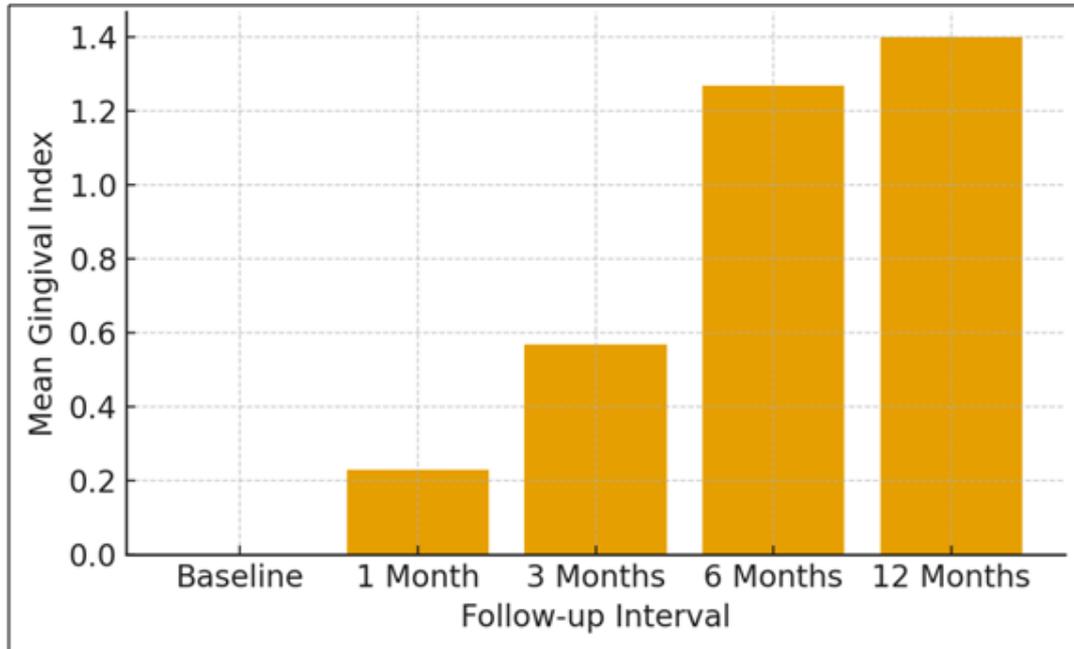
Ideal at baseline–3 months (100% Alpha). Declined at 6 months (73.33% Alpha) and 12 months (63.33% Alpha).

Retention: (Graph 4)

Perfect retention at 1–3 months. Slight loss at 6 months (mean 0.10) and noticeable loss at 12 months (mean 0.77).

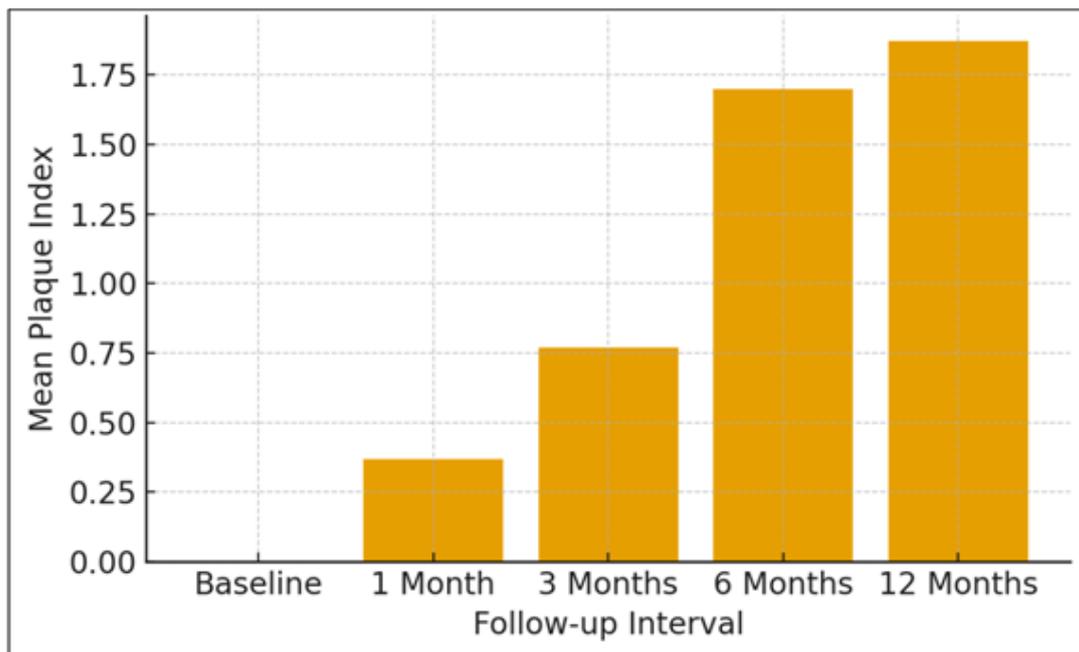
Opposing Tooth Wear: (Graph 5)

Wear score remained 0 at all intervals.

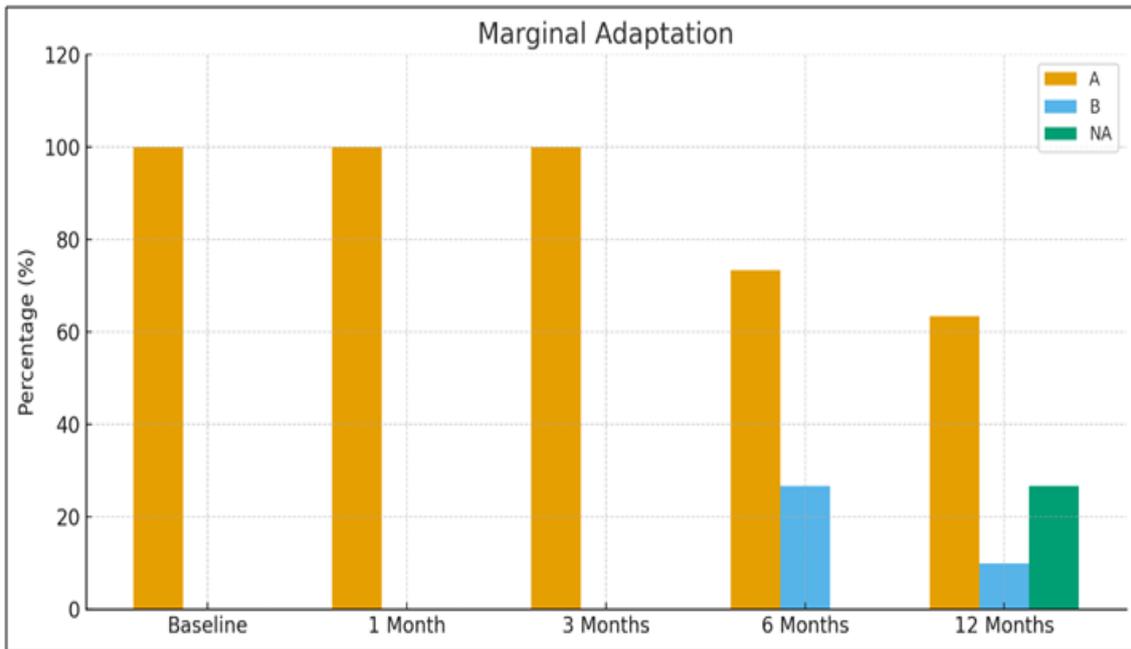


Graph 1. The bar chart depicts distribution of mean gingival scores at baseline, 1 month, 3 months, 6 months and 12 months of Bioflex crowns.

The mean of gingival scores was found to be **0, 0.23, 0.57, 1.27 and 1.4** at baseline, 1 month, 3 months, 6 months and 12 months respectively.

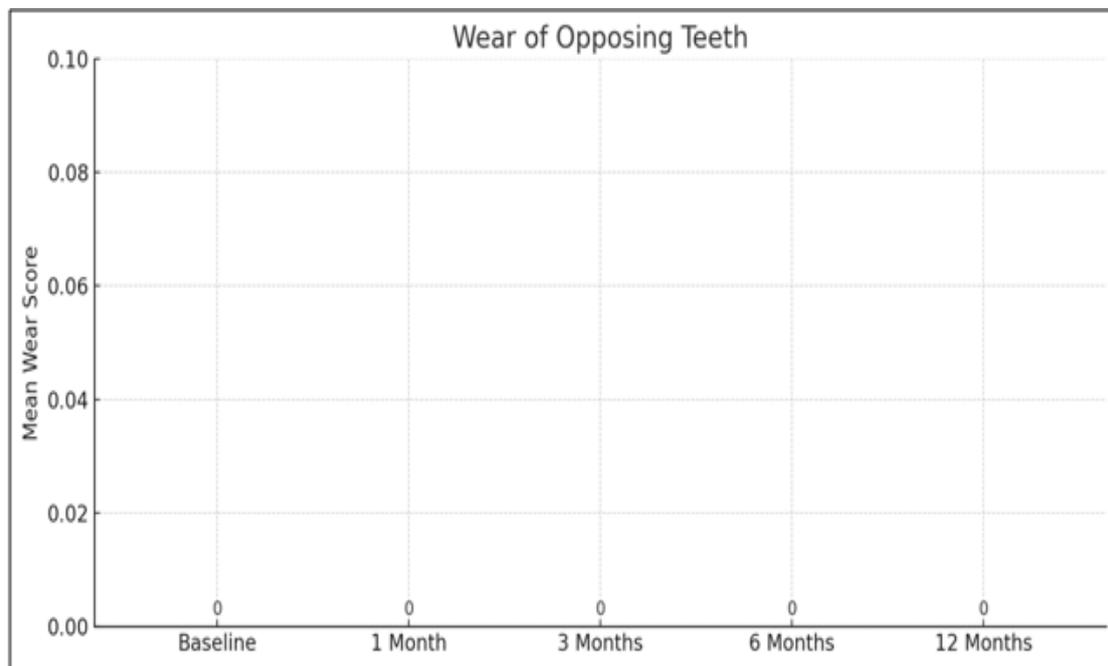


Graph 2. The bar chart depicts distribution of mean plaque scores at baseline, 1 month, 3 months, 6 months and 12 months of Bioflex crowns. The mean plaque scores were found to be 0, 0.37, 0.77, 1.7 and 1.87 at baseline, 1 month, 3 months, 6 months and 12 months respectively.

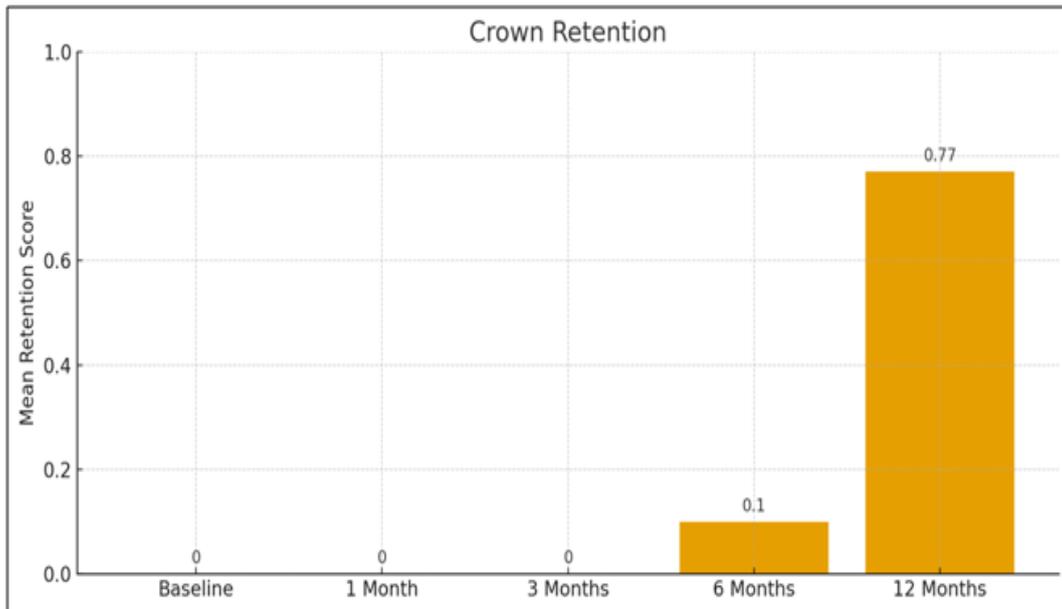


Graph 3. The bar chart shows distribution of percentage of marginal adaptation scores at baseline, 1 month, 3 months, 6 months and 12 months in Bioflex crowns.

100% of the cases exhibited Alpha scores at baseline, 1 month, and 3 months. At 6 months, only 73.33% exhibited A (Alpha) scores, while the remaining 26.66% demonstrated B (Bravo) scores. Similarly, at the 12-month follow-up, 63.33% in the Bioflex group exhibited A (Alpha) scores, while 10% recorded B (Bravo) scores.



Graph 4. The bar chart depicts the distribution of mean scores of crown retention at baseline, 1 month, 3 months, 6 months and 12 months in Bioflex crowns. The mean score of crown retention was 0 at baseline, 1 month, and 3 months; however, it increased to 0.10 at 6 months and 0.77 at 12 months.



Graph 5. The bar chart depicts the mean scores of wear of opposing teeth at baseline, 1 month, 3 months, 6 months and 12 months in Bioflex crowns. The mean scores for opposing teeth were 0 at baseline, 1 month, 3, 6 and 12 months.



Figure 1 – BIOFLEX CROWNS



Figure 2 – PRE OPERATIVE PICTURE



Figure 3 – 1 MONTH FOLLOW UP



Figure 4- 3 month follow up



Figure 5- 6 month follow up



Figure 6. – 12 months follow up

DISCUSSION

Restoring pulpctomized primary molars is essential in pediatric dentistry, as these teeth play a pivotal role in maintaining arch integrity, mastication, phonetics, and guiding the eruption of permanent successors. Premature loss or inadequate restoration of such teeth may lead to drifting of adjacent teeth, loss of space, and altered occlusal development, making full-coverage restorations the preferred modality in cases involving extensive structural loss or endodontic therapy [2]. Traditional options such as stainless steel crowns have been widely used due to their durability; however, the increasing emphasis on esthetic dentistry has encouraged the adoption of tooth-colored alternatives, including zirconia, pre-veneered SSCs, and more recently, polymer-based crowns such as Bioflex [7]. Bioflex crowns were introduced as a solution to overcome limitations associated with rigid esthetic crowns, aiming to provide a balance of flexibility, biocompatibility, reduced tooth preparation, and improved appearance. Although promising, scientific evidence supporting their long-term behavior remains sparse, thereby necessitating clinical evaluation such as the present study, which assessed their performance over 12 months.

In the present study, gingival and plaque index scores demonstrated a gradual increase across different follow-up intervals. At baseline and early recalls, the gingival tissues appeared healthy; however, by 6 and 12 months, mild to moderate inflammation was evident. These findings are consistent with previous reports that composite-based or polymeric crowns tend to accumulate plaque as time progresses due to changes in surface topography [11]. Surface roughness is known to influence bacterial adhesion significantly, with roughened or irregular surfaces enabling more robust plaque biofilm retention [12]. Since Bioflex crowns are fabricated from bis-acrylate hybrid resin material, their initially smooth surfaces may undergo micro-abrasion from tooth brushing, dietary habits, and normal masticatory forces.

Additionally, chairside adjustments performed during trimming and contouring may introduce microscopic irregularities at crown margins. Even minor discrepancies at the cervical margins of preformed crowns can hinder effective self-cleansing and increase susceptibility to gingival inflammation [13]. Nevertheless, the gingival inflammation observed in this study remained within clinically acceptable limits. No cases demonstrated suppuration, hyperplastic gingival response, or bleeding on simple contact, indicating that despite increased plaque retention, the Bioflex material itself does not provoke an adverse inflammatory reaction. The overall soft-tissue compatibility may be attributed to the metal-free, biocompatible polymer composition of the crowns. The findings underscore the importance of adequate oral hygiene instruction, especially in pediatric patients where plaque control may be inconsistent. Parents must be educated regarding the need for meticulous brushing around crown margins, as the material's intrinsic properties alone cannot prevent plaque accumulation without proper maintenance. Marginal adaptation is another critical determinant of long-term restorative success. In this study, Bioflex crowns exhibited excellent marginal adaptation during the early follow-up phases, with 100% of restorations scoring Alpha up to 3 months. This can be attributed to their flexible nature, which allows them to seat more intimately against the prepared tooth structure, potentially compensating for minor discrepancies in preparation or crown shape. However, by 6 and 12 months, marginal adaptation declined markedly, with Alpha scores decreasing to 73.33% and 63.33%, respectively. Such deterioration is consistent with findings from studies on polymer-based crowns, where marginal distortion and cement degradation occur over time [14]. The relatively lower modulus of elasticity of bis-acrylate materials may render them more susceptible to deformation under cyclic occlusal forces compared to more rigid materials like zirconia.

Although some crowns exhibited marginal deterioration, important to note is that none showed recurrent caries or radiographic pathology. This suggests that while marginal discrepancies increased, they did not reach a threshold capable of compromising the underlying tooth structure within the 12-month period. Continued monitoring remains critical, as longer follow-up intervals may reveal whether these early marginal changes could predispose crowns to leakage or caries in the future. Nonetheless, the results indicate that Bioflex crowns maintain clinically acceptable marginal integrity within the first year after placement.

Retention of esthetic pediatric crowns is a vital parameter influencing treatment success. Bioflex crowns displayed excellent retention during the early months, with no dislodgment recorded up to 3 months. A slight loss of retention was noted at 6 months, becoming more apparent at 12 months. These trends are coherent with the behavior of polymer crowns documented in earlier studies [15,16]. Several factors may contribute to this pattern. Initially, the crown's flexible internal walls adapt closely to the prepared tooth, creating mechanical interlocking. Resin-modified glass ionomer cement also enhances early retention by bonding chemically to tooth structure and mechanically to the crown interior. Over time, however, occlusal stresses may lead to deformation of the crown walls, while cement may undergo dissolution or fatigue. Pediatric patients may also exert unpredictable chewing forces, further influencing esthetic crown retention.

Despite the decrease in retention after 12 months, the overall performance remained acceptable, with no catastrophic failures. These findings suggest that Bioflex crowns can withstand functional forces during mastication in young children, though periodic recalls remain essential for early detection of retentive issues. One of the noteworthy strengths of Bioflex crowns observed in this study was their complete lack of abrasive effect on opposing dentition. Throughout the entire follow-up period, opposing natural teeth showed no wear, confirming that the relatively low hardness and flexible polymeric composition of Bioflex material imposes minimal risk to occlusal antagonists. This finding corresponds with wear studies that demonstrate considerably lower antagonist abrasion with resin-based crowns compared to ceramic or metal restorations [10,17]. The slight occlusal wear visible on the crowns themselves may even be advantageous, as it allows natural equilibration within the child's occlusal scheme without creating high points or inducing occlusal trauma. Importantly, no child reported discomfort, difficulty chewing, or sensitivity, reinforcing the clinical stability of these crowns during functional use.

Radiographic findings throughout the 12-month period further support the suitability of Bioflex crowns for use in primary molars. No pathological

changes such as bone loss, periodontal ligament widening, or periapical abnormalities were observed. The CEJ-crest distance remained within normal limits at each interval, indicating that the crowns did not induce adverse periodontal responses. These findings align with earlier studies where esthetic pediatric crowns showed stable bone levels when margins were properly contoured and oral hygiene maintained [18]. Collectively, the outcomes of this study reinforce that Bioflex crowns serve as a viable esthetic and functional alternative for restoring primary molars, especially when metal-free options are preferred. Their minimal tooth preparation requirements, favorable esthetic outcomes, biocompatibility, and negligible opposing tooth wear make them well-suited for children and parents seeking non-metal restorative options. While Bioflex crowns performed satisfactorily in the short term, the progressive increase in plaque and gingival scores and the gradual decline in marginal integrity highlight the need for periodic clinical assessment and reinforcement of oral hygiene measures. The retention patterns observed after 12 months also suggest that careful monitoring is advisable beyond the first year. Given the limited literature available, further research with larger sample sizes and long-term follow-up is necessary to fully evaluate the performance and durability of Bioflex crowns in pediatric dentistry.

CONCLUSION

Bioflex crowns demonstrated acceptable clinical performance over a 12-month period, with good early retention, satisfactory marginal integrity in the initial months, and excellent compatibility with opposing teeth. Mild to moderate increases in gingival inflammation and plaque accumulation were observed over time, along with gradual deterioration in marginal integrity and retention. Bioflex crowns represent a viable esthetic option for restoring primary molars, particularly when esthetics are prioritized, regular follow-ups and oral hygiene maintenance are ensured.

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