# A split-mouth randomized controlled study to assess and compare the periodontal health of primary molars restored with Bioflex and prefabricated stainless steel crowns

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#### Abstract:

The preservation of oral function, the integrity of the arch, and the avoidance of early tooth loss all depend on restorative therapy for primary molars. Because of its strength and simplicity of installation, stainless steel crowns (SSCs) have long been regarded as the gold-standard material for full-coverage restorations in pediatric dentistry. But as aesthetic standards and biocompatibility issues have grown, new restorative materials like Bioflex crowns—flexible, aesthetically pleasing crowns that conform well to gingival contours—have emerged. This study aimed to assess the effects of Bioflex crowns and SSCs on primary molar periodontal health. During a three-month follow-up period, clinical measures including gingival index, plaque index were measured in children ages 4 to 8.

The result revealed that though both restorations successfully preserved tooth structure, SS crowns showed a greater gingival response and less plaque buildup, most likely as a result of their more flexible borders and improved gingival adaptation. On the other hand, Bioflex crowna were linked to a marginally increased risk of plaque retention and gingival irritation, especially in cases where marginal adaptation was less than ideal. The results indicate that Bioflex crowns are a feasible aesthetic and physiologically advantageous substitute for SSCs, but as we can not manipulate the crown by crimping and due to its surface texture it showed higher affinity for plaque accumulation than the stainless steel crown.

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### I. INTRODUCTION:

A key component of paediatric dentistry is the restoration of primary molars after pulp treatment, which is intended to maintain arch integrity, preserve tooth function, and guarantee long-term oral health. For primary molars with caries or structural abnormalities, restorative therapy is essential to preserving the primary dentition's integrity until natural exfoliation. The gold standard among restorative treatments has long been stainless steel crowns (SSCs), renowned for their exceptional durability, affordability, and high success rates in helping paediatric patients regain their function and form. SSCs work especially well after pulp treatment, in situations of severe caries, or in cases of developmental disorders such amelogenesis imperfecta. But even with their mechanical benefits and clinical endurance, SSCs have drawbacks, especially when it comes to periodontal health.

Problems including inadequate marginal adaptation, subgingival placement, and plaque retention can make the surrounding gingival tissues more prone to irritation and make it harder to maintain good dental hygiene. Even while SSCs are dependable, their metallic look is a cosmetic disadvantage, which has prompted the creation of more aesthetically pleasing substitutes such Bioflex crowns.<sup>4</sup>

Bioflex crowns are novel crown systems that have most recently been developed and introduced in response to the need for less intrusive, biocompatible, and aesthetically pleasing restorative treatment choices. Prefabricated, flexible, and tooth-colored, bioflex crowns are intended to maintain periodontal health while offering an aesthetic substitute for SSCs.<sup>5</sup> They are especially appealing in pediatric dentistry because of their versatility and low requirement for tooth preparation. Additionally, their material qualities—such as improved marginal integrity and decreased plaque accumulation—indicate a possibly positive effect on gingival health.<sup>6</sup>

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However, there is still no clinical data to support their long-term as well as short-term periodontal performance, despite their increasing popularity.

The tooth-colored, polymer-based materials used to make Bioflex crowns are intended to offer both mechanical strength and a more realistic look. Parents who were worried about dental aesthetics find these crowns very appealing, especially in the front and visible posterior areas. The long-term effects of these newer materials on periodontal health are yet unknown, though.<sup>7</sup> The surface roughness of Bioflex crowns may affect gingival response and plaque retention, and they cannot be crimped to a snug marginal fit like SSCs can.

Crown shape, marginal adaption, surface roughness, and ease of maintaining oral hygiene are some of the variables that affect periodontal health surrounding restorations.<sup>2</sup> Rough surfaces and poor adaptation of margines can cause gingival irritation and plaque buildup, which might shorten the restoration's and the tooth's lifespan. This study aimed to assess the effects of Bioflex crowns and SSCs on primary molar periodontal health. Specifically, we evaluate the Plaque Index and Silness and Loe Gingival Index at 1- and 3-months post-restoration.<sup>6</sup>

It is critical to assess and analyze the ways in which various crown systems affect the periodontal state of repaired teeth since maintaining periodontal health in young patients is important for both general oral health and the effectiveness of restorative procedures. The study aims to balance function, aesthetics, and periodontal health by offering evidence-based insights through this comparative analysis which will help doctor's make well-informed judgments about restorative alternatives for young patients.

## II. MATERIALS AND METHOD:

In a comparative research, 40 primary molars from children ages 4 to 9 years who reported with at least two decayed primary molars were recommended for pulp treatment and complete coronal restoration were considered. Using a randomized split mouth clinical design, 40 sites were selected from 20 patients (2 sites per patient). The sites for the study were then split into two groups, Group-I (Control group: 20 with SSC restorations) and Group-II (Test group: 20 with Bioflex crowns). To minimize variability, the same dentist placed all crowns, and same guidelines for oral hygiene were given. The ethical approval was obtained prior to the commencement of the study, and all parents or guardians provided their informed consent.

Two restorations were given to each child:

One tooth was rebuilt using a Bioflex crown; another molar was restored using a prefabricated stainless-steel crown (SSC).

After completing the standard pulp treatment procedures (pulpotomy or pulpectomy), the tooth was prepared.

The following indices were used to evaluate periodontal health:

The gingival index (Loe and Silness) and

The plaque index (Silness and Loe)

An examiner who was blind to the method of restoration took measurements at the one-month and three-month follow-up.

Inclusion Criteria	Exclusion Criteria		
Children aged 4–9 years	Systemic illness or medical conditions		
	affecting oral health		
At least two primary molars with Class II	Systemic illness or medical conditions		
carious lesions requiring pulpotomy or	affecting oral health		
pulpectomy			
Cooperative behaviour (Frankl rating 3 or 4)	Teeth with mobility or periapical pathology		



Fig. 1: Pre-op

Fig. 2: Stainless steel crown





Fig. 3: Bioflex Crown

Fig. 4: Post-op

# STATISTICAL ANALYSIS

Data analysis was done using appropriate statistical methods. Mean scores for plaque and gingival indices were compared between the SSC and Bioflex groups using the paired t-test. P-values less than 0.05 were regarded as statistically significant.

## III. RESULTS

In all, 40 primary molars from 20 children were repaired and assessed; 20 of these teeth received Bioflex crowns, and 20 received stainless-steel crowns (SSC). At one-month and three-month intervals, the Plaque Index and Gingival Index were used to evaluate periodontal health. The findings of the three-month follow-up were the primary focus of this study.

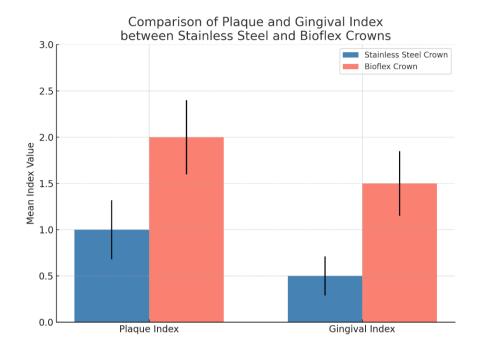
# The Plaque Index

SSC-restored teeth had a mean Plaque Index of 1.0 after three months, but Bioflex-restored teeth had a far higher mean score of 2.0. A statistically significant difference (p < 0.05) was found, suggesting that Bioflex crowns were more likely to accumulate plaque.

## The Gingival Index

Likewise, SSCs had a Gingival Index value of 0.5, whereas Bioflex crowns had a score of 1.5. A statistically significant difference (p < 0.05) was also observed, and the higher score for Bioflex crowns indicates greater gingival inflammation.

Index	Stainless Steel Crown	Bioflex Crown	p-value
Plaque Index	$1.0 \pm 0.32$	$2.0 \pm 0.40$	< 0.05
Gingival Index	$0.5 \pm 0.21$	$1.5 \pm 0.35$	< 0.05



Graph I: Comparison of Plaque and Gingival Index between Stainless Steel and Bioflex Crowns

## IV. DISCUSSION

In pediatric dentistry, the selection of the restorative material has a major impact on the surrounding periodontal health and also on the the durability of the restoration. Clinical metrics including as gingival index, plaque index, bleeding on probing, and probing depth are commonly used to measure periodontal health. § In this study, primary molars treated with prefabricated stainless-steel crowns (SSCs) showed a significant difference in periodontal response when compared to those restored with Bioflex crowns.

The manner that these characteristics evolved over time provided insight into how the different kinds of restorations interacted with the soft tissues According to the study's findings, primary molars restored with Bioflex crowns had significantly better periodontal health outcomes after three months than those restored with stainless-steel crowns (SSCs). The Bioflex group had substantially higher Plaque and Gingival indices, indicating that SSCs give young children a more periodontally pleasant experience. 9

Due to its proven mechanical strength, affordability, and convenience of placement, SSCs have long been the preferred material for replacing badly decayed primary molars. Still, their inflexible, prefabricated form might not precisely fit the unique shapes of each tooth and gingival border, particularly in young children with different anatomy. This frequently results in less than ideal marginal adaption, which might act as an area for plaque buildup. <sup>10</sup>

SSCs have long been used in pediatric restorative dentistry because of their exceptional marginal seal when appropriately crimped, longevity.<sup>4</sup> The decreased gingival inflammation and plaque retention seen in our research are probably caused by these variables. Conversely, Bioflex crowns have various drawbacks while being more visually pleasing and mechanically robust. Because they cannot be crimped, they are unable to adjust closely, which might lead to microleakage and plaque buildup at the crown-tooth contact.<sup>7</sup> This implies that improved gingival health is mostly dependent on the material's flexibility and biocompatibility.

Plaque retention also seems to be influenced by the surface roughness of Bioflex crowns. In contrast to SSCs' flat metallic surface, previous studies have connected a rougher surface of bioflex materials to increased bacterial adhesion. Furthermore, clinicians' capacity to personalize fit is limited by the difficulty to change Bioflex margins as accurately as SSCs, which may be a factor in the reported rise in gingival inflammation.

It is crucial to remember that although Bioflex crowns have obvious cosmetic benefits, particularly in areas of the posterior that are visible, their periodontal effects should not be disregarded, especially in kids having bad oral hygiene or a higher risk of dental cavities. The findings of this investigation align with other studies showing that the characteristics of restorative materials have a direct impact on periodontal health, particularly in young patients whose oral hygiene habits are still developing. If

Notwithstanding these results, there are certain limitations to this study, including its small sample size and short follow-up time. More reliable evidence to support clinical decision-making would come from further studies with larger samples and longer-term assessments. In our study, the Bioflex group had comparatively greater gingival and plaque indices, which suggests that increased plaque retention may make the gingiva more prone to inflammation.<sup>3</sup> By the conclusion of the follow-up period, the Bioflex group had more visible symptoms of mild inflammation, even if the periodontal parameters were still within clinically acceptable bounds.

Additionally, because Bioflex crowns are non-metallic and chemically inert, they may lower the risk of hypersensitivity and prevent the release of metal ions, which can occasionally be an issue with SSCs. It is crucial to remember that although Bioflex crowns showed periodontal compatibility in the short term, to determine their long-term performance in terms of resilience to wear, color stability, and durability, more research is still required.

The concept that Bioflex crowns provide a physiologically and aesthetically advantageous substitute for SSCs is generally supported by this study, especially where aesthetics are important considerations. The degree of tooth loss, the child's participation, the clinician's experience, and financial concerns should all be considered when choosing a material.

## V. CONCLUSION

In the restoration of primary molars, this study shows that stainless-steel crowns (SSCs) yield better periodontal health results than Bioflex crowns. Teeth replaced with SSCs exhibited considerably less gingival irritation and plaque formation during the 3-month follow-up, most likely as a result of improved marginal adaption and smoother surface properties.

Although Bioflex crowns have mechanical and cosmetic benefits, periodontal health may be jeopardized by their design flaws, especially their inability to be crimped.

When choosing restorative materials these factors should be carefully taken into account by dentist, particularly when periodontal health and long-term prognosis are at risk. The bioflex crown is both mechanically strong and aesthetically pleasing. Its inability to be crimped and its surface roughness, which causes more plaque retention than stainless steel crowns, are drawbacks.

#### Limitations

It is advised to do more research with larger sample sizes and greater observation times in order to confirm these results and investigate possible changes to the design of Bioflex crowns that could enhance their periodontal function.

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