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EVALUATION OF CLINICAL PERFORMANCE, GINGIVAL HEALTH AND BACTERIAL EFFECTS OF BIOFLEX CROWNS COMPARED TO READYMADE ZIRCONIA CROWNS ON PULPTOMIZED PRIMARY MOLARS: A RANDOMIZED CLINICAL TRAIL

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Abstract

Background: Dental caries in children often require crowns for restoration, with options like stainless steel, zirconia and Bioflex enhance accuracy, efficiency, and patient satisfaction, offering a modern alternative to traditional methods. **Objectives**: The current trial aimed to determine the clinical outcomes, gingival health, and microbiological impacts of Bioflex crowns in comparison with prefabricated zirconia crowns (ZRCs) on Pulpotomized primary molars. **Patients and methods:** This study was conceived as a randomized controlled clinical trial. A total of 48 Pulpotomized mandibular second primary molars from 48 children were randomly allocated into two equal groups. 24 molars were re-established with prefabricated primary ZRCs (Control group), and an equal number were re-established with Bioflex crowns (study group). The Modified California Dental Association (CDA) protocol was applied to assess clinical performance, while gingival status was evaluated using the gingival and plaque indices. The bacterial effects were determined through microbial analysis. **Results:** Both types of restorations demonstrated comparable gingival health status throughout the follow-up period. For Marginal integrity and morphology both groups showed comparable results with non-significant differences at the follow-ups. Surface characteristics for Zirconia and Bioflex crown at the ends of follow up was 100%, 81.8% respectively (P=0.030). For bacterial adhesion Zirconia crown shows sustained anti-microbial effects over Bio-flex crown. **Conclusions:** The clinical performance and gingival health outcomes of Bioflex crowns were comparable to those of ZRCs, except for surface characteristics, which favored the ZRCs. However, *Streptococcus mutans* and *Lactobacillus* adhesion was significantly elevated on Bioflex crowns than on ZRCs.

Keywords: Gingival Health, Bacterial Effects, Bioflex Crowns, Zirconia Crowns, Pulptomized Primary Molars.

INTRODUCTION

For several decades, stainless steel crowns (SSCs) have constituted the primary choice option for restoring severely damaged and pulpally treated primary teeth and are considered among the most efficacious and resource-efficient restorative approaches in

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pediatric dentistry since their first use in children by Humphrey in 1950[1]. SSCs are inexpensive, are straight forward to apply and demonstrate a high rate of clinical success. However, their non-esthetic appearance represents a notable limitation, which has increasingly become a concern in pediatric dentistry [2].

Prefabricated zirconia crowns (ZRCs) were launched in 2008 as a substitute restorative option, offering an esthetically pleasing option with acceptable mechanical properties. Nevertheless, ZRCs present certain clinical limitations, including the need for extensive tooth reduction, higher cost, and the incapacity to crimp or modify the crown, coupled with the necessity to tailor the tooth preparation to fit the crown rather than adjusting the crown to accommodate the preparation. [3].

Bioflex crowns constitute a recent advancement in pediatric dentistry, integrating the advantageous properties of both stainless steel and ZRCs. Fabricated composed of a high-impact, high-strength hybrid resin polymer that is free from bisphenol A-glycidyl methacrylate (Bis-GMA), these crowns are pre-contoured and pre-crimped, metal-free, and monochromatic tooth-colored restorations. They exhibit high flexibility and require less tooth reduction compared with ZRCs. [4, 5]

Bioflex has a similar or better wear resistance better than that of SSCs with self-adaptive technology allow crown to modify in areas of slightly high occlusion, unlike zirconia crown If When Bioflex crowns are susceptible to contamination by blood or saliva during try-in, they can be rinsed with water, dried, and subsequently cemented without significantly affecting the quality of cementation. Their internal surfaces are sandblasted to enhance retention when used with self-setting resin-modified glass ionomer (RMGI) or conventional glass ionomer (GI) cements [5]

Numerous reviews have examined the application and therapeutic efficacy of prefabricated ZRCs in the restoration of primary molars. [6-10] In contrast, the use of Bioflex crowns for restoring Pulpotomized primary molars represents an innovative strategy.

This clinical trial was conducted to assess the clinical outcomes, plaque accumulation, gingival health, and microbial adherence associated with Bioflex crowns, as an innovative restorative option for pulpotomized primary molars, in comparison with prefabricated ZRCs.

MATERIALS AND METHODS

Ethical Considerations

The study was reviewed and authorized by the Ethics committee, Faculty of dental Medicine (Boys, Cairo) Al-azhar University, Cairo, Egypt with code (966/5604). A documented consent was gathered from all the children’s caregivers or guardians. The trial was registered at ClinicalTrials.gov PRS (Protocol registration and Result System) with an ID of (NCT 06433141).

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Study Design and Setting

Randomized clinical controlled trial was conducted on both sexes of children selected from Paediatric Dentistry Clinic, Faculty of dental medicine (boys, Cairo), Al- azher University.

Sample Size & Randomization

This study was conducted on 48 children with total of 48 molars with 24 in each group. A sample of 22 participants in each group was necessary to provide 80% power to ensure that the two-sided 95% confidence interval would exclude a mean difference greater than 0.6. To account for potential attrition during follow-up, the sample size was increased to 24 participants per group. The calculation was conducted using the Sealed Envelope power calculator.

Eligibility criteria: [11,12]

Inclusion Criteria

- Apparently healthy children with no record of systemic disease
- Children acceptance and cooperation (franklel scale +ve.++ve)
- Parents acceptance and cooperation
- Children aged 4–8 years.
- No record of antibiotic intake during the preceding two weeks.
- No record of fluoride treatment during the preceding two weeks.
- Mandibular second primary molars with deep carious lesions indicated for vital pulpotomy.
- Absence of periapical pathological lesions.
- No root resorption exceeding two-thirds of the root length.

Exclusion Criteria

- Medically compromised children (e.g., those with bleeding disorders, cardiac conditions, or any systemic disease that could affect oral or gingival health).
- Presence of para functional habits, such as bruxism.
- Non-restorable teeth.
- Teeth exhibiting tenderness to percussion.

Group assignment:

Groups were divided randomly using (**Random allocation software)**

Group A (study group: received performed Bio-flex crown as a final restoration.

Group B (control group) received performed ZRCs as a final restoration

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Intervention

History Taking and Documentation

All participants underwent a comprehensive history taking, clinical examination and radiographic examination to evaluate peri-radicular, furcation areas, pulp canals, periodontal space, and developing succedaneous teeth [13,14] preoperative clinical photos were taken using digital camera. An introducery visit was performed to assess patient's co-operation, steps of the procedure were re-explained to the guardian and the child.

Tooth Isolation and Pulptomy Procedures [11,15,16]

Profound local anesthesia was achieved using 4% articaine hydrochloride with 1:100,000 epinephrine (Artinibisa 1.8 ml, inbisa dental S.L.U, Spain). The tooth was rendered isolated by means of a rubber dam following caries removal, a non–end-cutting bur (#558) was utilized under copious water coolant to complete removal of the pulp chamber roof. Any remaining coronal pulp tissue was eliminated with a sharp, sterile excavator. A moist sterile cotton pellet was then kept in the pulp chamber for 60 seconds to achieve hemostasis. Subsequently, a 1.5-mm layer of mineral trioxide aggregate (ProRoot®, Dentsply, Tulsa Dental, Tulsa, OK, USA) was placed and compressed into the pulp chamber to seal the orifices. An adequate thickness of light-cured GI cement (light-cured resin, SDI, Germany) was then applied over the MTA to seal the cavity before crown preparation.

Bioflex Crown Preparation, Cementation (group A) [5, 17]

Crown size was selected for a tight snap fit, guided by mesio-distal measurements, ensuring proper margin adaptation into undercuts. Tooth preparation for Bioflex crowns included occlusal reduction (1–1.5 mm following tooth contours), buccal and lingual reduction of the occlusal half with a 45° bevel, and proximal reduction while preserving adjacent teeth and avoiding marginal overhangs; all line angles were rounded and cervical margins finished smoothly.

Crowns were cemented with GIC, with careful removal of excess cement interproximally using knotted floss and around the tooth with an explorer after full setting, without dislodging the crown.

Zirconia Crown Preparation, Cementation [11,12,18,19]

Crown size was selected using mesio-distal measurements and Nusmile try-in crowns to ensure a passive fit and prevent fracture. Tooth preparation involved an occlusal decline of 1.5–2 mm was executed via a tapered diamond bur. (more extensive for thicker ZRCs), full circumferential buccal and lingual reduction supra-gingivally, and careful proximal preparation to preserve adjacent teeth and avoid overhangs, finishing with smooth feather-edge sub-gingival margins (~1.5 mm depth) and rounded line angles.

A NuSmile pink try-in crown was used to verify the fit and occlusion, and necessary adjustments were performed as required before washing and drying the tooth to ensure it was free of blood or debris.

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Crowns were cemented with GIC, the crown was positioned accurately, and excess cement was removed from all visible surfaces. With careful removal of excess cement interproximally using knotted floss and around the tooth with an explorer after full setting, without dislodging the crown.

Outcome's Measurement

Oral Hygiene Measure Protocol: All children were instructed to perform oral hygiene measures such as tooth brushing in morning and before sleeping, with the aid of oral hygiene logbook containing daily check list about tooth brushing

Clinical Performance Assessment [20-22]: A mouth mirror, a sickle probe (No. 23) and sufficient overhead lighting were used for proper examination, the clinical performance was assessed with respect to marginal integrity, surface, and morphology was scored using Modified California Dental Association (CDA) Protocol. Romeo (excellent), Sierra (acceptable) and Tango (retrievable) scores were considered a success. While Victor (not acceptable) was a failure as shown in **appendix (1)**

Appendix 1: Modified CDA Protocol.

Rating		Marginal integrity	Surface	Morphology
Romeo (Excellent)	**Success**	No visible evidence of ditching along the margin into which the probe can penetrate. No discoloration between the crown and the tooth.	Smooth surface of restoration. No irritation of adjacent tissue.	Continuous contour with existing anatomical form of the adjacent and contralateral teeth
Sierra (Acceptable)	**Survival**	Detectable slight marginal discrepancy, repair is unnecessary. Discoloration between the crown and the tooth	Surface of restoration is slightly rough or pitted, can be polished but is not necessary.	As above but with minor deviations.
Tango (Retrievable)	**Survival**	Faulty margins that cannot be properly repaired. Penetrating discoloration between crown and tooth. Retained excess cement or cement deficiency	Surface deeply pitted irregular grooves with no change in functional anatomy. Can be polished	Deviations that create discomfort. Can be adjusted.
Victor (Not acceptable)	**Failure**	Restoration is mobile, lost, or fractured or caries contiguous with the margin or restoration or tooth structure fractured	Gross porosities or fractures that cannot be corrected by polishing Anatomical form functionally insufficient.	Restoration causes pain in tooth or adjacent tissue.

Gingival Health [15,23]

Dental plaque accumulation and gingival condition were determined via the Plaque Index (PI) (Appendix 2) and the Gingival Index (GI) (Appendix 3)

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Appendix 2: Turesky Modification of The Quigley-Hein Plaque Index.

Scores	Criteria
0	No plaque
1	Isolated areas of plaque at the gingival margin
2	Thin band of plaque at gingival margin (≤1 mm)
3	Plaque covering up to one third of the tooth surface
4	Plaque covering between one thirds to two thirds of the tooth surface
5	Plaque covering more than two thirds of the tooth surface

Appendix 3

Scores	Presenation
0	Normal gingiva; absence of inflamation, bleeding; or swelling.
1	Mild inflammation, slight edema and color change, but no bleeding.
2	Moderate inflammation, redness, swelling, and bleeding on probing.
3	Severe inflamation, marked redness and edema, spontaneous bleeding of the gingiva

Microbial Analysis [24,25]

Swabs were obtained from the occlusal and buccal surfaces before crown preparation, immediately after preparation, and at 1- and 6-months following cementation. Sterile cotton tips were used under complete aseptic conditions, and the samples were transferred to tubes containing 9 mL thioglycolate broth medium capable of maintaining the viability of aerobic and anaerobic microorganisms.

All specimens were promptly transported to the Microbiology Laboratory, Department of Botany and Microbiology, Faculty of Science, Al-Azhar University, for culture on selective media. Streptococcus mutans counts were determined using mitis salivarius agar supplemented with bacitracin, based on the manufacturer's protocol.

Each specimen in normal saline was homogenized by agitation using a vortex mixer at maximum speed for 60 seconds, and the resulting suspension was serially diluted up to 10^{-6} in sterile normal saline. The inoculated plates were subsequently incubated in an anaerobic jar with a gas pack at 37 °C for 3 days. The same procedure was applied to quantify Lactobacillus counts, using selective MRS agar in place of the standard medium.

Statistical Analysis

Data were analyzed via IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 27 (SPSS Inc., Chicago, IL). Numerical data were shown as mean and standard deviation or median and range. Data was explored for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. Comparisons among 3 groups for normally distributed numeric variables were done via the ANOVA while for non-normally distributed numeric variables were conducted by Kruskal Wallis test.

An equivalence limit was checked in the difference between groups. Categorical data were shown as numbers and percentages and comparisons were done by chi square test or fisher exact as appropriate. A p-≤to 0.05 were statistically significant. All tests were two tailed.

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RESULTS

Participant recruitment commenced in January 2023 and was completed in October 2023, with a total of 48 participants selected for inclusion in the trial, participant age revealed comparable mean values across the groups: Group A (7.0 ± 1.0 years), and Group B (6.8 ± 0.9 years) (P value = 0.711). Gender distribution Group A consisting of 12 girls (54.5%) and 10 boys (45.5%). and Group B including 8 girls (36.4%) and 14 boys (63.6%) **table 1**

Marginal integrity and morphological stability, were comparable among the two groups throughout the follow-up period. At the 1-month evaluation, all restorations in both the control and intervention groups received identical rankings as ("Romeo." =100%). At 6-month ZRCs group were ranked "Romeo", but Bioflex group show ("Romeo =95.5%), Sierra= 4.5%) for marginal integrity, (Romeo=90.9%, Sierra=9.1) for morphological stability.

Surface characteristics were identical for both group at 1 month ranked "Romeo". At the 6-month evaluation, a significant variation was observed among the two groups: the ZRC group demonstrated 100% ratings of 'Romeo,' whereas the Bioflex group showed 81.8% 'Romeo' and 18.2% 'Sierra' (Table 1) (figure 1, 2).

Throughout the follow-up period, no statistically significant differences were detected among the two groups in mean PI and GI scores (p > 0.05). The mean dental plaque accumulation on Bioflex crowns remained nearly constant across follow-ups and was greater than that recorded for ZRCs.

Table 1: Demographic data and clinical outcomes at 1- and 6-month follow-ups among the two studied groups

			Group A (n=24)	Group B (n=24)	P
Demographic Data					
Age(years)			7.0±1.0	6.8±0.9	0.711
Sex	**Female**		12(54.5%)	8(36.4%)	**0.453***
	Male		10(45.5%)	14(63.6%)	
Clinical outcomes					
Marginal integrity	**1 Month**	**Romeo**	(100%)	(100%)	--
	6 Months	**Romeo**	(95.5%)	(100%)	1.000
		Sierra	(4.5%)	(0%)	
Surface	**1 Month**	**Romeo**	(100%)	(100%)	--
	6 Months	**Romeo**	(81.8%)	(100%)	**0.030***
		Sierra	(18.2%)	(0%)	
Morphology	**1 Month**	**Romeo**	(100%)	(100%)	**--**
	6 Months	**Romeo**	(90.9%)	(100%)	0.323
		Sierra	(9.1%)	(0%)	

Data are shown as mean ± SD or frequency (%). *: P<0.05 is statistically significant, NA: not applicable. Analysis done by chi square test and fisher exact test.

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Figure 1: Clinical performance photograph of Bioflex group follow up 6 months

Figure 2: clinical performance of zirconia group follows up 6 months

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Regarding to microbial adhesion **(table 2),** Longitudinal *S. mutans* counts and lactobacilli count (×10³ CFU) were similar across groups A and B at baseline with no significant differences. Post-intervention, both groups showed modest reductions, though only *Lactobacilli* counts differed significantly (P=0.014). By 1 month, Group B exhibited a marked decline in both bacterial measures, while Group A remained elevated (P<0.001). This significant difference persisted over 6 months, indicating a sustained antimicrobial effect in Group B over time (P < 0.001).

Table 2: Longitudinal analysis of *s.mutans* and *lactobacilli* counts pre-treatment, post-intervention, and at 1- and 6-month follow-ups in groups A, and B

	Group A	Group B	P_1
***S.mutans* (x103)**			
Before treatment	61±6.2	59.9±6	0.808
at work	24.4±3.4	23.6±4.2	0.211
1 Month	28.2±3.4	12.5±3.8	**<0.001***
6 Months	29.8±3.1	14.7±3.9	**<0.001***
P_2	**<0.001***	**<0.001***	
***Lactobacilli* no (x10^3)**			
Before treatment	47±6	46.7±5.6	0.960
at work	25±4.5^{A}	24.2±3.6	**0.014***
1 Month	25.7±4.9^{A-B}	11.8±2.1	**<0.001***
6 Months	26±5^{B}	13.9±2.1	**<0.001***
P_2	**<0.001***	**<0.001***	

Data are shown as mean ± SD.*: P<0.05 is statistically significant, P1: Analysis done by on way ANOVA followed by Bonferroni post hoc test, p2: comparison overtime by RM-ANOVA followed by Bonferroni-Adjusted Paired *t*-Tests

DISCUSSION

Restoring pulpotomized primary molars continues to represent a marked challenge in pediatric dentistry. Although SSCs are regarded as the reference standard for the restoration of pulpotomized primary molars, the increasing emphasis on esthetic dentistry has led young patients and their custodial guardians to seek more aesthetically pleasing alternatives to SSCs.[26] Prefabricated ZRCs provide an option with superior esthetic outcomes but involve relatively complex manipulation during placement. [6.26]

Bioflex crowns have recently have been launched in the dental market, combining desirable features of both stainless steel and ZRCs. They offer an esthetic benefit comparable to ZRCs, providing a natural appearance while requiring less tooth reduction. (4) Our study was undertaken to evaluate and contrast the clinical outcomes, gingival health, and bacterial effects of Bioflex crowns with prefabricated ZRCs in pulpotomized primary molars over a 6-month follow-up period. The clinical outcomes of restorations were determined using the Modified CDA protocol, with criteria encompassing marginal integrity, anatomic form (morphology), and surface luster.

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Regarding marginal integrity, only one restoration in the bio-flex group showed slight marginal ditching (score= sierra in CDA) which was clinically acceptable. No marginal discrepancies were observed in Zirconia groups. However, the variations among two groups were insignificant. Previous study [27,28] showed that ZRCs had high marginal integrity and were clinically acceptable. The data of our study was in line with the data of Khattab et al. [11] where 100% of prefabricated ZRCs in restoration of pulpally treated molars showed marginal continuity at 6,12- and 24-months intervals.

Regarding the surface of the restoration, the result of our study revealed that the surface of Bioflex restorations was more pitted and rougher than ZRCs groups. Concerning morphological stability ZRCs group have optimum stability in morphology, Bioflex group show less stability, however the difference was not significant among two groups.

Through evaluation of gingival health and oral hygiene, scores of GI and PI were taken for Bioflex and ZRCs after 1 month and after 6 months. The GI and PI were employed owing to their greater sensitivity in evaluating clinical variables. These indices quantify conditions at each site on an incremental scale, thereby providing more detailed information required for detecting minor variations between the materials under investigation. [29]

Concerning PI, at 1 month all groups achieved perfect plaque-free status, but at 6-month Bioflex group show increase in score each maintained 90.9% plaque-free participants (n=20) with 9.1% (n=2) developing plaque *in situ,* this may be a result of inadequate oral hygiene or rough surface of the restoration which increase adherence of food debris. Zirconia showed marginally superior outcomes with 95.5% plaque-free (n=21) and only 4.5% (n=1) exhibiting plaque *in situ*, however Intergroup differences remained non-significant Also, these results were in line with study conducted by Elheeny AA. [30] who reported that gingival health and plaque accumulation for ZRCs is better than that for resin-bonded composite strip crowns (RCSC) after 6 months follow up. This result is in line with a study conducted by Abdelhafez A (52)., conducted a study evaluating gingival health and plaque accumulation between three group ZRCs, Bioflex and StSt, he documented that there is no significant difference in gingival health among three groups after 12 month follow up.

For the microbiological evaluation, *S. mutans* and *Lactobacillus* species were selected as representative oral bacteria, as they are among the most prevalent microorganisms in the oral cavity [32]. *S. mutans* is the principal microorganism implicated in the initiation of dental caries. Its capacity to adhere to restoration surfaces is pivotal in the early stages of secondary caries development. *Lactobacillus* species are also important in the progression of carious lesions, particularly within dentinal tissue [33].

In this study, swabs were obtained from the occlusal and buccal surfaces, as these areas harbor higher microbial loads and are more susceptible to caries development [34].

With respect to the findings of microbial adhesion to the crowns, no statistically significant difference was documented among the two groups pre- treatment, immediately post treatment there dramatically reduction in bacterial count for all groups, also the difference

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is non-significant, but after 1 month zirconia group show the highest reduction in bacterial count when compared to Bioflex group, also after 6 month zirconia group still had lowest bacterial adhesion when compared to Bioflex groups. These findings may be attributed to the material's chemical constituents' surfaces, which plays a crucial role in bacterial colonization. This result agreed with study conducted by Wakwak MA et al. [24], Elizabeth JA et al. [35] reported that ZRCs had low bacterial adhesion when compared to SSCs.

CONCLUSIONS

ZRCs remain a highly suitable choice for full-coverage restorations of primary posterior teeth. Bioflex crowns also represent a valuable alternative for restoring primary molars. However, ZRCs demonstrated relatively superior outcomes compared with Bioflex crowns in terms of clinical performance, gingival response, and resistance to plaque accumulation. Moreover, ***S. mutans*** and ***Lactobacillus*** adhesion was significantly elevated on Bioflex crowns than on ZRCs.

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Nil.

Conflict of Interest

Nil.

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