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Comparative Assessment of Bioflex and Stainless steel crowns - In vivo Randomised controlled trial

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ABSTRACT:

Background: In Children Dental decay affects both primary and permanent teethis a serious global health problem. To maintain the integrity of the primary dentition, the damaged teeth may be restored with a full coronal restoration. Stainless steel crowns (SSC)werethe gold standard crowns used. In order to achieve aesthetics various tooth coloured crownshave been used .

Aim and objective: The study aim is to evaluate the clinical efficacy of recently developed tooth-colored Bioflex crowns and prefabricated stainless steel crowns. The study's primary goal is to assess the retention of the crown, gingival health, stainssurrounding the crown, and parental satisfaction during a 6 month follow-up.

Materials and methodology: The present in vivo study was conducted in 25 children aged4-9yrs as a split mouth design in maxillary and mandibular primary molars fordeep dental carious lesion and pulp involved teeth , where all the right side teeth were treated with Bioflex crowns and left side were treated with SSCrowns

Results and conclusion: The data was analysed using Ttest and the overall success rate with Bioflex crowns was 96% and SScrowns was 97.3%. Bioflex crownscan be option for posterior restoration when esthetics is of prime concern.

Key words: Bioflex Crowns, Esthetic Crowns, Primary teeth, Stainless steel crowns.

INTRODUCTION:

Early childhood caries, a global epidemic that affects most preschoolers, can cause degenerative conditions in the primary dentition even in very young children [1]. By restoringthe injured teeth with the full coronal restoration, the primary dentition can be preserved until its natural exfoliation. In addition to treating multisurface caries in the primary and earlypermanent dentition, stainless-steel crowns, also known as full coronal restorations, have been used as a post-endodontic restoration, an abutment for space maintainers, and a preventive restoration for special children [2]. Research reveals that stainless steel crowns are preferable to traditional restorations, even when utilized as a preventative measure forkids with developmental or medical disabilities [3]

Preformed metal crowns (ssc) was considered to restore full coronal restoration in earlier days [4]. According to a pediatric dentist survey, 87% of parents worry about the aesthetics of even posterior restorations because they believe it would affect their child's physical andmental health [5]. With these, there is emergence of tooth colored crowns and several typesof esthetic restorations have been produced (strip crowns, preveneered crowns). Each of these complete coronal restorations has benefits and drawbacks of its own [6]. Complete tooth-colored crowns (zirconia) are now possible because of recent technological advancements. They are useful, have a quick operating period, great resistance, and longdurability. These prefabricated crowns provide satisfaction to child's parents as a restoration they improve child's appearance and maintain oral health. Commercially available Zirconia crowns require increased amount of tooth reduction when compared to stainless steel crowns. They are also expensive. To overcome these disadvantages a newlydeveloped tooth Colored Bioflex crowns developed by KIDS E Dental which has the featuressimilar to stainless steel crowns with no additional amount of tooth reduction. However, limited knowledge available on literature search about its usage.An in vivo study was carried out to evaluate the clinical efficacy of Bioflex crowns against gold standard stainless steel crowns [7] .

MATERIALS AND METHODOLOGY: The present in vivo study was carried out in the pediatric dentistry department, Meghna Institute of Dental Sciences, Nizamabad. The Institutional Ethical Committee gave the study its approval with approval no: MIDS/MDS/PEDO/003

Sample size calculation**:** The study was conducted on 50 primary molars in 25 children aged 4-9 yrs where the sample size was calculated using 95% power and an alphaerror of 0.05. For each group, a sample size of 22 was established. It was determined that25 crowns would be examined overall for each group, accounting for a 20% loss to follow up(22+20%of 22).The design of the study was split-mouth ,intended to provide more precise results by eliminating individual variations that could influence the outcome of crowns. It was a randomized, controlled clinical trial [8].

GROUP I (N=25) – Stainless steel crowns **GROUP II** (N=25) – Bioflex crowns

Children who are categorized under ASA- Iand II , pulp therapy treated tooth, pair matched primary molars ,and caries involving more than two surfaces are included in the study . Thisstudy did not include teeth with developmental abnormalities, mobile primary molars or primary molars with root resorption. The clinical success rate of these crowns was assessed andcompared at an interval of 1 week , 3 and 6 months.

Treatment protocol: The child and parent was explained about the treatment procedure ina language that was most understandable to them and written informed consent has beentaken from parent or guardian and complete medical history was recorded.

Clinical procedure**:** Based on the inclusion criteria, pair matched primary molars were selected. Local anesthesia (infiltration) 2% lidocaine Hcl with 1:100000 adrenaline concentration was administered to both the groups. A trial fit was performed before cementation, with the crown size chosen based on the mesiodistal width. Start the timer instopwatch for both groups after the tooth preparation was done. Using a No. 330 bur, the occlusal surface of the teeth was prepared by reducing it to 1-1.5 mm. Using a No. 169L tapered diamond bur, interproximal reduction was carried out mesially and distally so that a straight probe could comfortably pass through the contact area. Every line angle ought tobe rounded, and the proximal surface's finish margin was achieved with a knife's edge. Avoid ledge formation. Using the crown pliers the selected crown was shaped and crimpedto get a snap fit and active fit for both the crowns. The prepared tooth was cleared of any saliva or blood. GIC-Type I (Global Company Corporation, Japan®) was used to lute the crown,after the passive fit and occlusion were examined. The crown was carefully positioned andheld there until the cement had fully set. Following crown cementation, all patients receivedinstructions on oral hygiene.

EVALUATION CRITERIA: The crown was evaluated at three intervals: one week, three months, and six months post-placement. Clinical assessment includes crown retention, gingival health, stains over the crown and patient satisfaction. Time taken for both the procedures also evaluated using stopwatch. The score was assessed visually and tactilelyusing a probe and explorer for gingival health and crown retention. Patient satisfaction wasmeasured using 5 point Likert scale based on color shape and size of crown.

For crown retention, United States Public Health System (USPHS) criteria was used where intact(alpha) was scored as 0, chipped/small but noticeable areaof loss(bravo) of material was score 1, and complete loss of crown (charllie) was scored as 2. Gingival health was scored based on Loe and Sillness Gingival Index 1963 [21] . Stainsover the crowns was also evaluated using Ryges criteria where Yes is marked for stains present and No if stains are absent on crown.

Statistical analysis: The T test was used to statistically estimate the collected data. For statistical significance, a probability value of $p < 0.05$ was established, and for statistically extremely significant relations, a value of $p \leq 0.000$.Inter group comparison between GroupI crowns and Group II crowns was assessed at end of 1 week, 3 months, and 6 months follow up.

Results:

Table 1**:** On inter group comparison 100 % crown retention is observed with GroupA crowns at the end of follow up period and 16.4% Group B crowns showed loss of retention at the end of 1 week and 4% crowns lost at 3 months follow up but there was no significant difference observed between the crowns at the end of follow up.

Table 1: Inter group Comparison of Retention with Group I and Group IIcrowns at 1 week, 3 months and 6 month follow-up

Category	**Stainless steel crown**			**Bioflex crowns**		
Crown Retention	**1 week (25)**	**3 month (25)**	**6 month (25)**	**1 week (25)**	**3 month (25)**	**6 month (25)**
Intact	25/25 100%	25/25 100%	25/25 100%	21/25 84.81%	23/25 92.9%	25/25 100%
Lost	-	-	-	4/22 16.19%	2/25 7.1%	-
Chipped	-	-	-	-	-	-
P value	0.589 **NS**					

Unpaired T-Test NS – Non significant

Table 2: On Intergroup comparison of gingival health it revealed that, during the study period, Group B crowns had 100% healthy gingiva, while Group A showed 90.1% healthy gingiva and 9.9% mild inflammation during the three- and six-month follow-up intervals, but there is no significant difference was found between the two groups

Table 2: Inter group Comparison of Gingival health with Group I andGroup II crowns at 1 week, 3 months and 6 month follow-up visit

Category	**Stainless steel crown**			**Bioflex crowns**		
Gingival Health	**1 week (25)**	**3 month (25)**	**6 month (25)**	**1 week (25)**	**3 month (25)**	**6 month (25)**
No Inflammation	25/25 100%	22/25 88.3%	23/25 90.9%	25/25 100%	25/25 100%	25/25 100%
Mild Inflammation	-	3/25 13.64%	2/25 9.1%	-	-	-
Moderate Inflammation	-	-	-	-	-	-
Severe Inflammation	-	-	-	-	-	-
P value	0.471 **NS**					

Table 3- on inter group comparison it showed that only 4.6% of Group B crowns showed a slight yellowish discoloration at 3 rd month follow up and no significant differenceobserved between both the crowns

Table 3: Inter group Comparison of Stains over the Group I and Group IIcrowns on 1 week 3 months and 6 months follow up visit

Category	**Stainless steel crown**			**Bioflex crowns**		
Stains	**1 week (25)**	**3 month (25)**	**6 month (25)**	**1 week (25)**	**3 month (25)**	**6 month (25)**
Yes	-	-	-	-	1/25 4.6%	-
No	25/25 100%	25/25 100%	25/25 100%	25/25 100%	24/25 95.4%	25/25 100%
P value	0.478 **NS**					

Table 4: on intergroup comparison between two groups it showed that at a 3 and 6 month follow up there is a clinical significant difference noticed with a (p=0.001) in respect to parental satisfaction

Table 4:Intragroup Comparision on Parental overall satisfaction forGroup I and Group II crowns at 1 week 3 months and 6 months follow up

Category	**Stainless steel crown**				**Bioflex crowns**			
Patient Satisfaction	**Baseline (25)**	**1 wk (25)**	**3 mo (25)**	**6 mo (25)**	**Baseline (25)**	**1 wk (25)**	**3 mo (25)**	**6 mo (25)**
5	10/22 45.5%	13/22 59.1%	11/22 50%	10/22 45.5%	16/22 72.7%	14/22 63.6%	15/22 68.2%	17/22 77.3%
4	12/22 54.5%	9/22 40.9%	11/22 50%	12/22 54.5%	6/22 27.3%	8/22 36.4%	5/22 22.7%	5/22 22.7%
3	-	-	-		-	-	2/22 9.1%	-
P value	0.239 **NS**				**0.001* HS**			

Paired T-Test HS- Highly Significant , NS-Non significant

Table 5: On comparison between two groups it showed that the time taken for crown placement for both group of crowns and there is no clinical significant difference noticed.

Table 5: Inter group Comparison of Time taken for Group I and Group IIcrowns placement

Time Taken	**Stainless Steel crown**	**Bioflex crown**
30 min	3/25 13.6%	-
40 min	11/25 50%	5/25 22.7%
45 min	1/25 4.5%	-
50 min	3/25 13.6%	10/25 45.5%
60 min	4/25 18.2%	5/25 22.7%
80 min	-	1/25 4.5%
90 min	-	1/25 4.5%
P value	0.397 **NS**	

Discussion:

A child's overall health and wellness are greatly influenced by their oral health. Poor oral health leads to numerous conditions including dental caries, early childhood caries, gingivitis, periodontitis, tooth discolouration, halitosis, and premature primary tooth loss [9] The presence of caries in primary teeth increases the risk of caries developing in permanent teeth [10] .

Full coverage restorations completely cover the damaged tooth, preventing additional deterioration. Stainless steel crowns, also called as prefabricated metal crowns, were the preferred option for complete coronal restorations due to its accessibility. The sole drawback of SSC was its unsightly appearance.

Children's interest to participate in social and academic activities, their self-esteem[11], andtheir social interactions[12] can all be greatly impacted by pleasing esthetic restorations.

According to Alrashdi M. et al. (2013)[13] prefabricated zirconia crowns seem to be an excellent aesthetic substitute for prefabricated metal crowns, while research indicates thatzirconia crowns require more tooth reduction and long time. Therefore, in patients who areapprehensive and recalcitrant, these crowns are generally not advised.

With this in mind the current study was conducted to know the clinical effectiveness of newly available Bioflex crowns, which are tooth-colored, modern crowns composed of a high- strength hybrid resin polymer material. They are easy to place, requiring less removal of enamel or dentin, and their tooth preparation is comparable to that of prefabricatedstainless-steel crowns[13].According to Ishani Rahate et al[14]. (2014), the Bioflex crown is a synthetic alternative to traditional crowns that provides better adaptability, durability, handling ease, and enhanced cosmetic attributes in pediatric dentistry.

Retention of the crown being an important factor in determining the success of the crown. In primary teeth, the retention of the crowns depends on both mechanical and chemical retention[15] . The current study results showed that at the end of 1 week and 3 months the bioflex crownswere lost and recemented , followed till the end of the study and found that teeth were asymptomatic. The present study findings were in consistent with Rupal Agrawal et al [7] also reported that at the third month follow-up, the stainless steel crown outperformed thezirconia crown in terms of retentivity.

The results of the present study were in accordance with Gayathri etal.[16] who found that ata 12-month follow-up, prefabricated zirconia crowns retained 93.77% of their strength whilestainless steel crowns retained 96.7%crowns . Loss of cement and retention may be the causes of Occlusal stresses can gradually promote fracture propagation The voids in the setcement, known as micro structural porosity, can cause cement to lose its strength over time and cause retention loss [16] .

According to the studies conducted by A. Heidari et al[17] primary crimping is required to allthe stainless steel crowns to enhance the retention of the crown. The present study used Type I-GIC (luting) cement for both the crowns. As the studies from Samuel Raj Srinivasan et al [18]

demonstrated that traditional GIC is preferable to BioCem™ and resin cement (APC) for cementing prefabricated PZC for long-term retention of zirconia crownsin routine pediatric practice.

Prefabricated crowns must have their gingival health maintained for the restoration's overall success as well as the wellbeing of the neighboring teeth and gums[19] .Poorly fitting crowns can cause gum irritation and plaque accumulation, crown material also has a role in plaque accumulation and gingival inflammation[20] .

The findings of this study support those of Tarans et al.[20] and Wakwak et al. [21], who reported 75% healthy gingiva for stainless steel crowns and 100% healthy gingiva for prefabricated zirconia crowns in a 12-month follow-up. Mathew et al. [22] stated that ultra- smooth surfaces hinder the processes of bacterial adhesion and biofilm deposition, whereas flaws in polymeric surfaces promote these processes.

When compared to zirconia or ceramic crowns, metal borders made of nickel-chromium-molybdenum (Ni-Co-Mo) alloy exhibited more gingival discomfort, as demonstrated by Ozen et al. (2014) . Metal borders with irregular shape and adhesive residues in the sulcusin cases of SSCs were found to be primary sources of gingival irritation in studies by Maclean et al.[23]. This led to further plaque deposition and subsequent gingival inflammation. Bioflex crown showed a light Yellowish discoloration on 3rd month follow up. Inthe next 1 week follow up there is no discoloration observed. Thus it could be due to chromogenic food which may have an effect of temporary discoloration of crown and resolved on its own.

Mathew et al [24] in his study concluded that the existence of micro porosities is the primary cause of stains on newly placed restorations. SSC crowns are resistant to staining due totheir glossy appearance and polished surface. Zirconia crowns feature an extra glaze layerthat keeps the surface ultra-smooth and inhibits the formation of porosities.

We must counsel the patient to brush twice daily with a toothpaste and to floss every day in order to get rid of plaque and stop stains.

Expert cleaning can assist in keeping the crowns in good condition and removing surface stains. Encourage limiting the amount of foods and drinks that cause stains. Esthetic restorations are gaining more demand and parental acceptance rate has been increased for these kind of

restorations.Fishman et al [11] investigated the preferences of children for posterior restoration, based on the appearance. Strip crowns have been shown to have high parental acceptance but, there are studies which shows that gingival inflammation noticed with stripcrowns [25] .

Recent technological advances led to introduction of Zirconia crowns but they require increased amount of tooth reduction. To overcome these disadvantage newly available tooth colored (Bioflex) crowns have been used.

Parental satisfaction measured using a 5-point Likert scale indicated that Group II crowns produced better results (mean score) and that parents were generally satisfied with the size,form, and color of both crowns. The results of the current study were marginally greater than those of Holsinger et al. [26]. Zirconia outperformed stainless steel (2.9) in terms of color, with a mean score of 5. When it came to parents' assessments of durability, zirconiaand stainless steel crowns fared similarly, with mean scores of 4.8, which was somewhat higher than Wallia et al.'s [5] results (4.7). Parental satisfaction with zirconia crowns was found to be higher than that of other restorations, according to Harshitha et al [27]. The meanoverall satisfaction was 4.6 on a five-point Likert scale.

According to our research, the Bioflex crown had a higher overall satisfaction rating (4.8) than the stainless steel crowns (4.2). Additionally, a notable variation has been noted in patient satisfaction with Bioflex crowns. The preparation time for prefabricated stainless steel crowns and their role in comparisonto zirconia crowns can vary based on several factors. The time taken also has an impact on selection of the crown required by the patient. As SSCrowns preparation involves minimal tooth reduction, typically focusing on removing decay and shaping the tooth. The present study results showed that Time taken for crown placement in Bioflex crowns andstainless crowns was around 30-50 min. There is no clinical significant difference observedbetween placements of these two different types of crowns. The tooth preparation was similar to both types but on evaluation Bioflex crowns required more amount of time to place in comparison to stainless steel crowns.

Limitation of the current study were a long term follow up is required with increased amountof sample. It is advised that more research be done to evaluate the effectiveness of crowns in situations such as multiple crown placement, crowded dentition, and dentition with occlusal variation.

Every parent was intended to choose Bioflex crowns because of its esthetic appearance and decreased amount of plaque accumulation when compared with stainless steel crowns.But there is no clinical significant difference noticed in terms of retention, gingival health andstains over the crown. Therefore, when aesthetics is the main consideration, Bioflex crownsmay be the best option for a post-endodontic repair.

Conclusion: When compared to both the crowns it demonstrated a good clinical success rate; nonetheless, no discernible difference was seen between the two groups. Compared to stainless steel crowns, Bioflex crowns dramatically increased parental satisfaction.As Bioflex crowns were esthetic in appearance and with goodclinical success rate most of the parents prefer to choose this newer crowns. The crowns chosen for each child during the treatmentplan may be tailored based on the demands of the parents and the clinical circumstances.