Evaluation of Clinical Performance, Parent's Satisfaction, Gingival Health and Bacterial Effects of Bioflex Crowns & Endocrowns Compared to Ready-Made Zirconia Crowns on Pulpotomized Primary Molars: A Randomized Clinical Trial

A Protocol submitted to the Faculty of Dental Medicine (Boys, Cairo), Al-Azhar University, in the partial fulfillment of the requirements of Doctor Degree in Pedodontic and Oral Health

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Introduction

Dental caries is the most prevalent disease, affecting 60–90% of children worldwide. If left untreated, tooth structure would be progressively damaged lead to pulpal inflammation which require pulpal therapy. Primary dentition commonly affected by caries because of improper oral hygiene and increased intake of sucrose. Nowadays, repairing and restoring primary teeth rather than extraction is receiving attention to maintain appropriate articulation and preserve the space required for the eruption of permanent teeth [(1)].

Selecting a suitable final restoration for Pulpotomized primary molars is the key element that affects success of treatment. Stainless steel crowns (SCCs) are known to be the most protective, and durable restorations of the primary dentition with the advantages of maintaining morphologic form, superior clinical performance, effortless placement and time-efficient [(2)]. Despite superior qualities of (SSCs), their use is not popular nowadays due to poor esthetic appearance, parents and child's demanding more esthetic restoration. So, several treatment options have been developed for treatment of primary teeth such as strip crowns, pre-veneered stainless-steel crowns and zirconia crown[(3)].

Zirconia is being used successfully in general dentistry, due to its superior toughness and fracture resistance compared with other types of ceramics, it is a crystal-like dioxide of zirconium that possess a metal like mechanical properties and a tooth like color, that are available to use for primary teeth treatment. Pediatric zirconia crowns were introduced by EZ-pedo and became commercially available in 2008[(4)].

Pediatric zirconia crowns are preformed and made completely with ceramic materials (tetragonal zirconia). It have high flexural strength, allowing them to resist crack propagation, high strength, toughness, higher resistance to chemicals, and superior erosion resistance, so it provided a more durable and esthetic alternative for the management of dental caries in primary molars [(5)].

The clinical performance, gingival status and periodontal health of pediatric zirconia crowns versus stainless steel crowns were evaluated in several studies [(6-9)] ,and showed that zirconia crown had more clinical performance, gingival and periodontal health than that of stainless steel crowns, However, the amount of tooth reduction needed to receive zirconia

crown (determinant factor for passive fitting) is more aggressive than that required for stainless steel crowns by approximately 20 to 30% So there are need for developing more flexible esthetic restorations [6].

Bioflex crowns are available as aesthetic preformed pediatric crowns that are flexible, durable, and adaptable offering properties of both stainless steel and zirconia crowns. There is a lack of literary evidence for assessment of the properties of Bioflex crowns and their effect on clinical outcomes and parental satisfaction compared to traditionally available options [10].

More conservative treatment modalities preserving natural tooth structure (minimal intervention dentistry) have been considered aided by simultaneous progress in biological research and development of adhesive materials. Endocrowns were first described in 1999 by Bindl and Mörmann considered one of these strategies [11]. Endocrowns are monolithic adhesive ceramic restorations give the opportunity of color matching, and shade selection that is not available in ZC [12].

Endocrowns need a special preparation design with less circumferential tooth reduction including a butt joint preparation at the cervical margin that end supragingival so eliminates any possible discomfort or gingival trauma during tooth reduction offering healthier periodontal tissues, more peripheral enamel preservation, and an increase in the surface area for bonding. In contrast, the finishing line of ZC must extend for 1 to 2 mm subgingivally. But the occlusal surface reduction is similar for both restorations [4]. Endocrown retention is gained macro-mechanically by friction with the pulpal walls, and micromechanically through adhesive cementation **[12]**.

Endocrowns are considered as effective restorations for molars that have undergone endodontic treatment offering better fracture resistance and stress distribution, offer excellent strength for cuspal overlays, it can be used as a final restoration for primary molars preserve tooth structure, and maintain periodontal health[13].

Up to our knowledge, there is no study evaluate the clinical performance, bacterial adherence, assessment of dental plaque and gingival status of endocrowns and Bioflex crowns as a new restorative modality in Pulpotomized primary molars compared with prefabricated ZCs, and the parental satisfaction toward the three restorations at the end of the12 month follow-up

Aim of the study

This study will be conducted to evaluate clinical performance, parent's satisfaction, gingival health and bacterial effects of Bioflex crowns &Endocrowns compared to ready-made zirconia Crowns on Pulpotomized primary molars

Patients and Methods

Study Design:

This study will be designed as a randomized clinical trial

Sample Size calculation: [7,13]

This study will be conducted to evaluate Clinical performance, bacterial adherence, assessment of gingival health and patient satisfaction of LS2 endocrowns and Bioflex crowns compared with prefabricated zirconia

crowns as a restoration of Pulpotomized primary molars. Assuming there is no difference between groups (equivalence trial), if there is truly no difference between the standard and experimental treatments, then 22 patients in each group are required to be 80% sure that the limits of a two-sided 95% confidence interval will exclude a difference in means of more than 0.6. This number is to be increased to 24 in each group to compensate for possible losses during follow up. Sample size was calculated by sealed envelope power calculator.

Study Setting and Population:

This study will involve children with 72 primary molars who require Pulptomy treatment at the Pedodontics and Oral Health Department, Faculty of Dental Medicine (Boys, Cairo), Al-Azhar University.

Subject grouping:

The involved primary molars (n= 72) will be divided randomly into 3 groups (n=24) according to the type of the final restoration for Pulpotomized molars as the following

- **Group A:** will be restored with endocrown (study group)
- **Group B:** will be restored with prefabricated Bioflex crown (study group).
- **Group C:** will be restored with prefabricated zirconia crown (control group).

Eligibility criteria for the study:

Inclusion criteria: [12]

- Parents' and patients' acceptance and cooperation (franklel scale +ve.++ve)

- Apparently Healthy children.
- Child's age ranging from 4 to 8 years old.
- Primary 2nd molars with deep carious lesion indicated for vital Pulptomy
- No periapical pathological lesion
- No root resorption exceeding more than 2/3 of root length.

Exclusion criteria [12]

- Medically compromised children (bleeding disorders, cardiac patient and any systemic diseases could affect oral and gingival health.
- Presence of para-functional habits. Such bruxism.
- Non-restorable tooth.
- Teeth with non-vital pulp

Ethical Consideration:

- This study will be carried out after approval of the Ethical Committee, Faculty of Dental Medicine (Boys, Cairo), AL-Azhar University.
- All children's parents/ guardians will be informed in a verbal and written manner about the aim of these research. A written informed consent will be signed by the parents before starting the study

Intervention:

Pulptomy Procedures [12]

- The tooth will be anaesthetized. Then, it will be isolated using a rubber dam.
- Caries will be removed with a sterile non-end cutting bur # 558 to complete the removal of the pulp chamber roof under copious water coolant spray. Coronal pulp tissue remnants will be removed with a sharp, sterile excavator. A piece of cotton soaked with formocresol will be inserted into the pulp chamber for 5 minutes.

- After removing the formocresol pellet, a thick mix of zinc-oxide/eugenol paste will be packed into the pulp chamber to seal the orifices.

Restoration of the tooth:

According to the groups restoration will be as the following:

Group A: Endocrowns tooth preparation, scanning, cementation:

For the endocrowns [12, 13]

- A layer of light -cured glass ionomer cement ° of 1 mm thickness will be applied over the ZOE- to isolate it from the successive resin based restorations and adhesives- leaving a minimum of 3 mm of the pulp chamber to provide an adequate thickness for the endocrown core.
- Round-end tapered stone will be used to achieve depth cuts of 1.5 mm for occlusal clearance
- A wheel stone will complete the occlusal reduction and making butt joint finish line.
- Tapered stone of 8-degree angle will be used to prepare axial wall flared, the pulp chamber walls to a standard degree of divergence.
- Abrasive rubber tip will be used to smoothening and rounding the internal angles giving a polished and smoothed preparation.
- Endocrown will be manufactured using CAD/CAM technology
- internal wall of crown will be treated with etchant material, rinsed, dried then silane coupling agent

- Dual-cure resin cement will be applied on the crown fitting surface for endocrown cementation.

Group B: Preformed Bioflex crowns [10]

According to manufacturer instruction the preparation will be as the follow:

- Light -cured glass ionomer filling of adequate thickness will be applied over the ZOE to seal the cavity before preparation
- A digital caliper will be used to measure a mesio-distal dimension of tooth then suitable sized preformed crown will be selected.
- Tooth preparation will be carried out with a tapered diamond bur for occlusal reduction by 1–1.5 mm, including the central groove.
- The proximal preparation will be around 0.5 mm to clear the contact area
- Placement of the crown will be achieved by a snug fit followed by contouring using a Hover's plier.
- Crown cementation will be carried out using glass ionomer cement and removal of excess cement using floss or explorer.

Group C: performed zirconia crowns [10, 12, 13]

- Light -cured glass ionomer filling of adequate thickness will be applied over the ZOE to seal the cavity before preparation.
- A digital caliper will be used to measure a mesio-distal dimension of tooth then suitable sized preformed crown will be selected.

- A diamond bur will reduce the occlusal surface by 1.5–2 mm
- Interproximal contacts will be prepared with a tapered fissure bur. About 1–2 mm sub gingival preparation will be performed
- The selected crown will be placed and checked.
- The passive fit of the crown will be assessed and will be luted with glass ionomer cement.
- Consistent firm finger pressure will be applied during cementation.

Observations:

Clinical Performance Assessment [10,12]

- Retention, marginal adaption, fracture of the restoration were scored using a modified United States Public Health Service (USPHS) criterion.
- Dental plaque accumulation and gingival condition were assessed using plaque index (PI) and GI.
- Preparation time and cementation assessment using stop watch to record time from preparation start till final restoration cementation.[15]
- Clinical performance and oral status will be assessed at follow-up periods of 3 (T1), 6 (T2), and 12 (T3) months. At the end of the follow-up (T3), parent's satisfaction analysis toward the color, shape, and size of three restorations will be adopted to directly evaluate their satisfaction toward their children's restorations. Parents' responses were rated on a 5-point Likert-type scale.

Microbiological analysis: [9]

- The swabs will be collected before preparation of crowns, 3 months, 6 months and 12 months after cementation.
- The number of Streptococcus Mutans, lactobacillus will be digitally counted.
- Swabs will be taken from occlusal surface by means of the tips of sterile cotton
- All specimens were transported immediately to microbiological lab.
- Swabs will be taken from occlusal surface by means of the tips of sterile cotton.
- Samples will be preserved in a transporting medium tube containing 9ml thioglycolate broth medium.
- The number of Streptococcus Mutans, lactobacillus will be digitally counted.

Data Management and Analysis

Data will be analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 27 (SPSS Inc., Chicago, IL). Numerical data will be described as mean and standard deviation or median and range. Data will be explored for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. Comparisons between 3 groups for normally distributed numeric variables will be done using the ANOVA while for non-normally distributed numeric variables will be done by Kruskal Wallis test. An equivalence limit will be checked in the difference between groups. Categorical data will be described as numbers and percentages and comparisons will be done by chi square test or fisher exact as appropriate. A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

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