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Clinical Evaluation and Comparison of Stainless Steel Crowns and Zirconia Crowns in Primary Molars- A Study Protocol

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Aim: The present study will be undertaken to evaluate and compare the clinical success of stainless steel crowns and zirconia crowns in carious primary molars.
Study Design: Randomized controlled trial.
Place and Duration of the Study: Department of Pedodontics & Preventive Dentistry, Sharad Pawar Dental College & Hospital, Duration- One year
Methodology: In this Split-mouth, 12 months study, set of primary molars in 4-9 years old children will be restored with stainless steel crown and zirconia crown. The primary objective is the assessment of clinical success by evaluating pain, swelling and pathologic mobility at baseline, 1, 3, 6 and 12 months interval. The secondary objectives are to assess the level of parental satisfaction by applying fivepoint likert scale and evaluate the gingival condition by recording Sillness and Loe Plaque index (PI) and Loe and Silness Gingival Index (GI) of study groups at periodic interval of 1, 3, 6 and 12 months.
Results: The results of the present study will investigate the effectiveness of two types of pediatric full coverage restorations for management of extensive caries in primary molars.
Conclusion: The findings of the present research would help the patient and practitioners to select appropriate therapeutic option.

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Keywords: Primary molars; stainless steel crowns; zirconia crowns.

1. INTRODUCTION

Dental caries is one of the commonest chronic infectious diseases of childhood caused by interaction of bacteria flora, mainly Streptococcus mutans and carbohydrates on tooth enamel. The condition is characterized by an overwhelming infectious challenge and is associated with lack of oral hygiene maintenance, unusual dietary practices and low salivary flow rates [1]. S. mutans can reach from mother to newborn and can begin to colonize even pre-dentate infants. These bacteria produce an array of enzymes, breaking down complex sugars into monosaccharides for energy, causing an acidic environment in the mouth and result in tooth demineralization and dental caries. Children experiencing decay in primary dentition are more prone to developing subsequent caries in permanent dentition [2].

Despite the implementation of various preventive programs for dental caries, data suggest that around 50% of children still have carious primary teeth in need of treatment. The presence of carious lesions in primary teeth leads to a negative impact on child's oral health-related behavior, functional and emotional well-being and overall quality of life [3,4].

Retention of pulpally involved primary tooth until the time of exfoliation is preferable to space maintainer. The reasons to maintain the intact arch are as follows; the normal healthy primary dentition play a vital role in mastication, proper speech development, contribute to aesthetics and serve as a guide for the eruption of permanent dentition [5]. Hence, maintenance of deciduous teeth until their normal exfoliation is critical in pediatric dentistry.

In cases of deep carious lesions, absolute management of primary dentition with stainless steel crown has been in practice for many years. Stainless steel crowns (SSC) provide durable and reliable complete coverage restorations and are retained for the lifetime of a primary tooth [6]. Although SSCs are low maintenance restorations, their metallic appearance has been an issue for the esthetic perceptions of parents [7]. In addition to esthetic concerns of stainless steel crowns, studies have concluded that inadequate oral hygiene and poorly adapted crown margins in children were associated with gingivitis [8]. Another study [9] reported that primary molars restored with SSC, veneered SSC, or open-faced SSC are associated with gingivitis. The recently developed pediatric zirconia crowns (ZC) are a fairly new treatment option that enables practitioners to provide better esthetic results.

Although zirconia is a well-accepted treatment modality for permanent dentition, its usage in primary dentition started in 2008 [10,11]. Studies have not reported any significant local or systemic adverse reactions or cytotoxic effects of zirconia material. Bacterial colonization over zirconia is not to the similar extent as to other restorative materials [12-16].

Though many in vitro studies have been conducted with zirconia crowns, clinical trials in primary dentition are scanty. Hence, the purpose of the present study is to compare the clinical success and gingival health of children after restoring primary molars with stainless steel crowns and zirconia crowns. The study will also investigate parental satisfaction on five-point likert scale.

1.1 Rationale

The gingival health and plaque formation in primary teeth is a major oral health concern. SSCs are highly retentive and viable restorative options, however they don't give esthetic appeal. On the contrary, zirconia crowns are highly esthetic, biocompatible and provide excellent mechanical properties. Both crowns have their own set of advantages and disadvantages. Many treatment options exist to restore primary molars but it needs to satisfy the demands of the society. Therefore, the present study is designed to evaluate and compare the highly esthetic zirconia crowns with the time tested stainless steel crowns in primary molars.

1.2 Objectives

The main aim of the study is to assess the effectiveness of highly esthetic zirconia crown in carious primary molars in comparison with stainless steel crowns. The control treatment is SSCs since this is the standard crown option.

The primary objectives include assessment of clinical success by evaluating pain, swelling and pathologic mobility in primary teeth restored with zirconia crowns and Stainless steel crowns at

baseline, 1month, 3months, 6months and 12 months interval. The secondary objectives are to assess parental satisfaction on five point likert scale and evaluate the gingival condition by recording Sillness and Loe Plaque index (PI) and Loe and Silness Gingival Index (GI) of study groups with 12 months follow-up.

1.3 Research Question

Are preformed zirconia crowns better choices than traditional stainless steel crowns with respect to overall clinical success and parental satisfaction in primary molars?

1.4 Hypothesis

Considering the biocompatibility and esthetic superiority of zirconia crown over SSCs, we hypothesize that the success rates between zirconia crowns and SSCs are equivalent given the absence of any major symptoms such as pain, swelling and pathologic mobility.

2. METHODS

2.1 Study Design

We plan to recruit 10 patients with each having two matched bilateral carious mandibular primary molars indicated for pulpectomy. The study will be a split-mouth randomized controlled trial where each subject will form its own control. Following pulpectomy, the two primary molars will be assigned to the experimental group and control group for crown placement.

2.2 Blinding

The statistician, analyzing the data will be blinded to the study arms. It is not possible, however to blind trial participants, investigator and assessor because each crown type has its own specific color.

2.3 Setting

The study will be carried out in Sharad Pawar Dental College & Hospital, Department of Pedodontics & Preventive Dentistry, Wardha.

2.4 Study Population

The participants and eligibility criteria are shown in Table 1.

2.5 Study Size Estimation

10 patients (20 primary molars, Split-mouth design)

- Significance level Type I error rate, α= 0.05
- Power (1-beta) = 0.8
- Z alpha value = at 90% 1.645
- Z beta value = at 80% 0.842
- Ratio of sample size, Treatment /control =1
- Allowable difference, d=μT− μC= 0.3
- Expected population standard deviation, SD = 0.9
- δ(>0), Margin = 1.5
- Drop rate (%) = 7
- Sample Size n_1 - Treatment = 10
- Sample Size n_0 - Control = 10
- Total sample size = 20

$$n_1 = \left\lceil \frac{(z_\alpha + z_\beta)^2 (\sigma_1^2 + \sigma_0^2 r)}{(d-\delta)^2} \right\rceil.$$

$$n_0 = \left\lceil \frac{(z_\alpha + z_\beta)^2 (\sigma_1^2/r + \sigma_0^2)}{(d-\delta)^2} \right\rceil.$$

With above mentioned calculation, sample size determination is 20 considering the drop outs, sample size has been estimated 10 samples in each group. The total minimum sample size with 90% of confidence interval is 20.

2.6 Recruitment Procedure

Participants will be recruited from the OPD of Department of Pedodontics & Preventive dentistry, Sharad Pawar Dental College & Hospital, wardha from October 2021 to December 2021. At the first visit, eligibility criteria mentioned in Table 1 will be verified by the operator following clinical and radiographic evaluation. Potentially eligible patients and their parents/guardians will receive detailed information about the study.

2.7 Randomization

Each subject with two matched carious primary molars will receive crowns of test and control group. Primary molar will first be allocated to the gold standard treatment i.e. SSCs. One-week later, the contralateral tooth of the same patient will be restored by zirconia crown. Computer generated randomized sequence list will be used for random allocation of patients.

Table 1. Eligibility criteria

Inclusion Criteria
- Children aged 4 to 9 years (American Society of Anesthesiologists (ASA) class I, having deep occlusal caries indicated for pulpectomy followed by full coverage restoration - Patients diagnosed with irreversible pulpitis of at least two matched bilateral carious mandibular primary molars. - Healthy cooperative children free of any systemic ailment or any developmental disturbances of the teeth and jaws that would affect patient's diet, caries susceptibility or the selection of restorative material - Presence of antagonist tooth, willingness to participate in the study and to continue with the follow-up appointments - History of spontaneous pain - Teeth with Radiographic evidence of pulpal/periradicular pathology
Exclusion criteria
- Teeth with internal resorption - Teeth with physiologic root resorption more than one- third of the root length - Teeth that are non-restorable - Patients with compromised general health due to systemic disease - Mechanically/traumatically exposed teeth - Excessive hemorrhage encountered during the clinical procedure - Teeth with Radiographic evidence of pulp chamber calcification - Exposures with purulent discharge or serous exudate - Teeth with fistula - Teeth with pathological mobility.

2.8 Intervention

A single operator, specialist in pediatric dentistry would place SSCs and Zirconia crowns to reduce operator variability. The tooth preparation will be done by occlusal and proximal reduction; an SSC of appropriate size will be tried and contoured so as to adapt to the tooth. Occlusion will be checked and crown will be cemented using luting glass ionomer cement.

At the next visit (One week later), restoration of the contralateral tooth with zirconia crown will be completed. Under local anesthesia, 1.5–2 mm of occlusal reduction will be performed using marginal ridge of the adjacent teeth as a reference point. The tooth structure around the entire crown circumference will be reduced by 0.75–1.75 mm following the natural anatomy and contours of the tooth.

Tooth preparation will be extended subgingivally by 1-2 mm down the CEJ while carefully avoiding damage to the gingiva. All sharp angles will be removed and the preparation will be rounded off. The crown will be placed over the prepared tooth to check for trial fit, final cementation of zirconia crown will be done using glass ionomer cement.

2.9 Study Outcomes

The primary outcome is the assessment of clinical success of the treatment. Success will be defined by absence of pain, swelling, and periapical pathology evident on the radiograph. The secondary outcomes are parental satisfaction and evaluation of gingival state using Sillness and Loe Plaque index (PI) and Loe and Silness Gingival Index (GI) on the crowned teeth at 1, 3, 6 and 12 months interval. Parental satisfaction will be recorded on a five-point likert scale. Independent evaluators will evaluate primary and secondary outcomes clinically and radiographically.

2.10 Assessment and Data Collection

2.10.1 First (Baseline) visit

At the first visit, before commencement of treatment, characteristics of participants (e.g. age, gender) will be noted. Each index tooth will be divided in four parts i.e. distofacial papilla, mesiofacial papilla, midfacial papilla and entire lingual gingival margin. Baseline scores of plaque index and gingival index will be recorded.

2.10.2 Follow – up visits

After 1, 3, 6 and 12 months of follow-ups, the primary and secondary outcomes will be assessed by independent evaluators. Evaluators will be trained and calibrated for assessment of the study outcomes by means of repeated exercise on routine patients reporting to OPD for treatment. In case of disagreement, the case will be reviewed again to reach the final judgment. If disagreement persists, a third evaluator will be consulted.

3. DISCUSSION

Despite chronic infection, maintenance of primary teeth is imperative to maintain arch form and function. Pulpectomy followed by stainless steel crown placement has been a valuable treatment option in such cases [17]. Stainless steel crowns have been highly successful restorations in treatment of multi-surface carious lesions in primary molars, and no other restorative material in pediatric dentistry has been as effective as SSC due to its durability and resiliency [18]. However, SSC have to be adjusted and manipulated by trimming, contouring and crimping for proper marginal adaptation, which as a result causes surface defects and roughness endangering plaque accumulation and bacterial colonization.

Furthermore, the growing patients' interest towards visually appealing restorations limits its usage. Thus, the zirconia crowns being highly esthetic restorations can be considered an acceptable alternative to SSC [19].

To date, very few studies have compared the clinical efficacy of SSC and Zirconia crowns in primary molars. A search of PubMed and Cochrane reveal very few randomized clinical trial. In the present study, the assessment criteria for the primary outcome will be based on the systematic review by Innes et al [20]. The success of restoration would take into consideration the gingival health and parental satisfaction.

4. CONCLUSION

In present time, when esthetic restoration of deciduous teeth is becoming as important as their durability, the results of the present study will help clinicians to select the appropriate treatment option for severe dental decay affecting most children. The results will also help us to know parental preference for the type of restoration, thereby benefitting the patients, practitioners and healthcare system as a whole.

CONSENT

The participants will be formally included in the study after obtaining verbal assent from children and documenting written informed consent from parents/guardians.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval will be collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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