

Comparative Evaluation Of Periodontal Health In Primary Molars Restored With Stainless Steel Crowns And Figaro Crowns - A Randomised Controlled Trial

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INTRODUCTION:

Preformed stainless steel crowns (PSSCs), which was introduced seven decades ago, have become the gold standard in restoring primary molars with multi surface or severe carious lesions and with pulpal treatment (1). American Academy of Pediatric Dentistry and British Society of Pediatric Dentistry also recommend the usage of PSSCs . This could be due to its longer clinical success compared to conventional restorations like amalgam, glass ionomer cement or composite resin (2,3). Although there is a compromise in esthetics, the PSSCs provide better adaptation, better retention, higher strength, lower microleakage and thereby improve the functionality of primary molars until they physiologically resorb (4–7).

Esthetic alternatives to PSSCs, Zirconia crowns made its debut in 1991 creating a paradigm shift in pediatric esthetic dentistry. Although the metallic appearance was replaced, the reduction of tooth

structure was comparatively very high when compared to PSSCs (8). Fibreglass crowns i.e. Figaro crowns (Figaro Crowns, Inc.; USA) entered the market in 2018 with the idea to overcome the odds of both PSSCs and Zirconia crowns (9). They were made of fiberglass, titanium oxide and ferrous oxide providing the strength similar to PSSCs with no compromise in the esthetical component. An in-vitro study demonstrated that Figaro crowns needed lesser crown reduction when compared to Zirconia crowns (10). Whilst results from a recent randomised controlled trial has shown that Figaro crowns lacked the strength and were not esthetically durable by the end of 6-month follow up (11).

Preserving the hard tissue regions of primary dentition is as important as maintaining the soft tissue components i.e. the periodontium. Properly contoured and well crimped PSSCs, minimises plaque and debris accumulation thereby maintaining gingival health. Gingivitis was noticed in poorly adapted crown margins along with improper oral hygiene (12,13). A recently published in-vivo study showed that gingival and periodontal health were better with teeth restored with Zirconia crowns when compared to PSSCs (14). The periodontal health around the newly introduced fibreglass crowns were not yet reported. Hence this study was aimed to evaluate the periodontal health status of primary molars restored with PSSCs and Figaro crowns.

MATERIALS AND METHODS

This split mouth randomised clinical trial was conducted in a university setting. The study protocol was approved by the institutional ethical committee and provided clearance for this human clinical trial (SRB/2020/012). Children attending the out-patient department of Pediatric and Preventive Dentistry from January 2019 to January 2020 were taken for the clinical trial.

Inclusion criteria were healthy children with ASA physical status I between the age group of 6-9 years of age, children who required bilateral pulp therapy in primary mandibular second molars, children with no recent preventive dental treatments like topical fluoride applications, children not under antibiotic coverage for at least 1 month prior to the study and children without regular usage of mouthrinses. Exclusion criteria were uncooperative children, children with poor oral hygiene maintenance, children with decayed primary mandibular second molars indicated for extraction, children with allergy to nickel and presence of any periodontal disease or internal resorption or dentoalveolar abscess. Parent(s) or caretaker(s) or legal guardian was explained in their local language about the protocols of the clinical trial and if they agreed to comply, informed consent was obtained from them.

The sample size was calculated based on our pilot study with 5 children. With a significance level of 5%, a test power of 80% and 15% loss to followup, a sample size of 50 teeth were obtained. So 25 children who met the inclusion criteria were recruited for the study. Following pulp therapy of both the mandibular primary second molars, teeth were randomly allocated into either PSSC (3M ESPE, Minneapolis, USA) or Figaro crown group (Figaro Crowns, Inc.; USA). Randomisation was done by coin toss method after completion of the first pulp therapy. During the second pulp therapy visit, the other crown was placed.

A single operator performed the treatment procedures for all the children to avoid operator variability. The operator performed the tooth reduction as per the proposed manufacturer instructions. For placement of PSSCs, 1.0-1.5 mm of occlusal reduction was done followed by 1 mm of proximal reduction. Any cervical shoulders were removed to obtain a feather edge finish line, 0.5mm below the marginal gingiva. Line angles and point angles were rounded. Crimping and contouring of the PSSCs were done with respective pliers until proper active fit of the crown was obtained. For placement of Figaro crowns, 1.0-2.0 mm of occlusal reduction was done followed by 1.0-1.5 mm of circumferential axial reduction. 1-1.5 mm subgingival preparation was done to provide a feather margin circumferentially. Line angles and point angles were rounded. Slightly active fit of the crown was obtained due to the Flex-fit nature of the crowns. All the crowns were luted using glass ionomer cement (Ketac, 3M ESPE). All the children were given post operative instructions and also were taught Fone's brushing technique. The children were recalled at 3, 6, 9 and 12 month intervals for assessment of periodontium.

A research scholar who was not involved in the treatment procedure performed the periodontal assessments in the followup visits. Plaque accumulation was recorded using the criteria provided by Sillness and Loe (PI)(15), and gingival inflammation was recorded using Loe and Sillness Index (GI) (16). Neither the patient, nor the operator, nor the research scholar, were blinded as the appearance of the crowns cannot be hidden.

STATISTICAL ANALYSIS

The tabulated data (mean values of GI and PI) that were obtained were subjected to statistical analysis using SPSS (version 23, Illinois, Chicago). Within-group assessment over the four follow-ups until 12 months was performed using repeated measures ANOVA, and between-group assessment was performed using independent T test. The level of significance was set at 5%.

RESULTS:

This split mouth clinical trial was conducted among 25 children. The mean age of children in the PSSCs group was 7 ± 1.1 years while in the Figaro crowns group was 8 ± 1.5 years. Among 25 children who received PSSCs, 13 were males and 12 were females. At baseline, the mean PI score was 1.08 ± 0.6 and the mean GI score was 0.56 ± 0.7 . Among 25 children who received Figaro Crowns, 16 were males and 9 were females. At baseline, the mean PI score was 1.12 ± 0.5 and the mean GI score was 0.6 ± 0.6 . (Table 1) There was no significant difference at baseline between the groups ensuring effective baseline randomization.

At 3 months, 6 months, 9 months and 12 months follow ups, the mean PI scores and mean GI scores of the participants for PSSCs were slightly lower than Figaro crowns. However this difference was not statistically significant. ($p > 0.05$)(Table 2)

Table 1: Baseline characteristics of children included in the study

	PSSCs		Figaro Crowns	
	Mean PI (SD)	Mean GI (SD)	Mean PI (SD)	Mean GI (SD)
Baseline	1.08 (0.6)	0.56 (0.7)	1.12 (0.5)	0.6 (0.6)
Mean Age	7 ± 1.1 years		8 ± 1.5 years	
Gender	Male	13	Male	16
	Female	12	Female	9

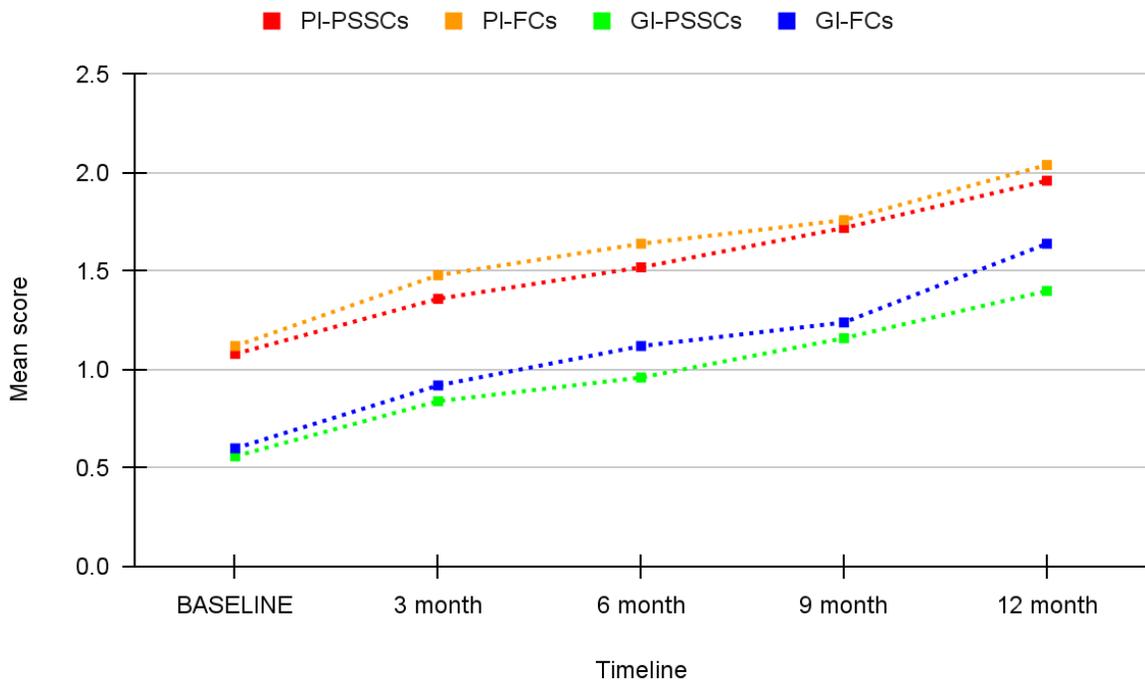
Table 2: Mean PI and GI with intergroup comparison between PSSCs and Figaro Crowns analyzed using student t-test

		Mean PI (SD)	p-value	Mean GI (SD)	p-value
3 months	PSSCs	1.36 (0.6)	0.12	0.84 (0.6)	0.6

	Figaro Crowns	1.48 (0.7)		0.92 (0.5)	
6 months	PSSCs	1.52 (0.5)	0.81	0.96 (0.5)	0.43
	Figaro Crowns	1.64 (0.6)		1.12 (0.4)	
9 months	PSSCs	1.72 (0.5)	0.58	1.16 (0.6)	0.57
	Figaro Crowns	1.76 (0.5)		1.24 (0.4)	
12 months	PSSCs	1.96 (0.2)	0.08	1.40 (0.6)	0.28
	Figaro Crowns	2.04 (0.6)		1.64 (0.9)	

p<0.05 - Significant

Figure 1: Mean scores of Plaque index and Gingival index of participants receiving PSSCs and Figaro crowns



DISCUSSION:

Early childhood caries has affected the majority of the children worldwide as well as in various parts in our country (17). Preservation of primary teeth until it exfoliates physiologically is the prime motto for pediatric dental practitioners (18). Despite the presence of minimally invasive management methods like silver diamine fluoride, the destruction of the tooth structure would have imposed pulpal management by the time the patient comes for dental care. Full coverage restorations play a vital role in preserving the strength of the primary teeth that had undergone pulp therapy (19). PSSCs had been the gold standard in performing this function for decades. Although the strength cannot be replaced by any other material, the esthetic requirements aren't met.

Parental esthetic demands for their children have been constantly increasing in the recent decades. This has driven the pediatric dental practitioners to shift from the vintage stainless steel crowns to the tooth colored crowns like pre-veneered crowns, zirconia crowns and recently the Figaro crowns (13,20). But the long term success is still an unresolved question which needs to be assessed. The measurement of success is not only the restoration but also the periodontal health. Our study compared the plaque and gingival scores of the periodontium around pulpectomised mandibular primary second molars restored with PSSCs and Figaro crowns.

The present study showed that pulpectomised mandibular primary second molars restored with PSSCs showed slightly lower PI and GI scores compared to those restored with Figaro crowns. This was in accordance with the studies conducted earlier (14,21) which showed PSSCs had better periodontal health compared to the test groups. Although there was an increase in the PI and GI scores during the 12 month follow up compared to baseline in both the groups, there was no significant difference noticed.

Gradual increase in the PI and GI scores in both the groups can be attributed to the change in the environment around the natural periodontium due to the subgingival adaptation of the crowns. Subgingival preparations are encouraged in primary molars as they yield higher retention of the crowns due to the presence of height of contour in the gingival third of the tooth. Trimming of the crowns for good adaptation can also lead to roughened surfaces which could increase the chances of biofilm formation leading to higher PI and GI scores. Minimal trimming of PSSCs were performed as the crowns were pre-trimmed and pre-cripped. This leads to minimal surface roughness of PSSCs thereby lesser chances for plaque accumulation rendering lower PI and GI scores (12).

One of the strengths of the present study was there were no drop-outs in the sample size. The participants were properly tracked and a regular follow-up was made possible with the parents' cooperative nature towards the study protocols. Crowns were placed by a single operator to avoid inter-operator variability, thus increasing the reliability and validity of the results of the present study. Limitation of the present study was, blinding was not possible due to the color of the crowns. The participants would have taken extra care on the oral hygiene measures when they received the more esthetically plausible restoration compared to metallic ones. This could also have an influence in the maintenance of oral hygiene. Further studies need to be done for long term evaluation of success of the crowns, radiographic evaluation of the periodontium, microscopic evaluation of crown margins which can cause an effect of plaque accumulation.

CONCLUSION:

Within the limitations of the present study, both PSSCs and Figaro crowns had reasonable amounts of plaque accumulation scores during the 12 month periodical follow ups. The results of PSSCs were comparable to Figaro crowns with no significant differences statistically and clinically.

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