



Research article

Evaluation and comparison two types of prefabricated zirconia crowns in mixed and primary dentition: A randomized clinical trial

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ABSTRACT

Introduction: Prefabricated zirconia crowns are available to treat anterior and posterior primary teeth, which possess high resistance, long durability, and short working time. They are also esthetic and available in various sizes for all primary teeth. However, their high costs can present a clear disadvantage in many communities around the world.

Materials and methods: This random clinical trial study sample included 63 crowns (31 CCZC, 32 NZC) applied to 44 children aged five to nine years with zirconia crowns placed on anterior or posterior primary teeth. Group (1): Locally manufactured crowns were created with different measurements by using CAD/CAM (CCZC) and Group (2): NuSmile® zirconia crowns (NZC). Glass ionomer cement was used to cement all crowns. The children were followed-up at one, three, and six months, using oral hygiene index-simplified (OHI-S), gingival index (GI), plaque index (PI), bleeding on probing (BOP), and crown margin extension. Statistical analyses used: Mann-Whitney U test, Friedman test, and Wilcoxon test.

Results: This study showed that CCZC did not cause gingival changes after crown application in clinical tissue appearance, bleeding, and gingival recession. Reduced plaque accumulation was observed during follow-up periods. Finally, there was no statistically significant difference between CCZC and NZC, according to this study.

Conclusions: CCZCs are a convenient and economical option to achieve esthetic, healthy, and functional aspects during restoring primary teeth.

1. Introduction

There has been rapid development in the field of dentistry in the area of esthetic dentistry. Researchers and clinicians have directed their interest towards the esthetic solutions in the restorative process to provide naturally colored, durable, long-lasting restorations that society currently demands. This esthetic direction seems to afford the child a sense of health, safety, self-esteem [1].

Crowns are the preferred final restoration for primary teeth restoration as they outperform the direct restorations and increase the success rate of endodontic treatments due to their better sealing abilities [2]. Pediatric dentistry has used stainless-steel crowns (SSC) to repair severely damaged primary teeth as a treatment option since their introduction in 1950 due to its ease of use and mechanical properties [3]. Although stainless steel crowns are functional and long-lasting, and

economical to use, they are the least attractive due to their silver metal color, which is not desirable for the child or their parents [4].

Both stainless steel and the prefabricated commercially available zirconia crowns are considered an optimal choice for posterior teeth full coverage restorations. However, zirconia crowns have been shown to perform better in gingival response, reduced plaque retention, and of course, esthetic [5].

These ready-made commercially available zirconia crowns are available for the treatment of anterior and posterior primary teeth. They are functional, feature high resistance, long durability, and can be used in a short working time. Ready-made zirconia crowns provide satisfaction to the child's parents as a restoration in the primary maxillary anterior dentition since they improve their children's appearance and oral health [6]. The various sizes available for all primary teeth additionally provides a real convenience to the dental clinician. However, in parts of the world,

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the high cost associated with these using these prefabricated commercial zirconia crown use can be a significant drawback [7, 8].

Therefore, there is a need for a satisfactory cost effective esthetic therapeutic restorative solution for parents and children, which like similar stainless-steel crowns and commercially available zirconia crowns, can provide a long-lasting and high resistance to failure treatment.

This random clinical trial aims to demonstrate the effectiveness of locally manufactured zirconia crowns created via Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) system [9] and compare these locally milled zirconia crowns to commercially available zirconia crowns, assess the integrity of the gingiva around them after application to restore primary teeth. The null hypothesis is that there will be no difference between the two types of zirconia crown types tested in this clinical trial.

2. Materials and methods

2.1. Study design

This study is a randomized progressive double-blind prospective controlled clinical trial composed of four phases T0 = before the preparation of the primary tooth, T1 = one month after the application of the crown, T2 = after three months, T3 = after six months. Ethical approval was attained from the IRB committee of Damascus University - Faculty of Dentistry, Damascus Syria. The trial was conducted in accordance with the principles for medical research involving human subjects, as described by the Declaration of Helsinki, and registered at clinical trials database www.clinicaltrials.gov (trial id: NCT03740308), Damascus University - Faculty of Dentistry. See the Consort checklist (Figure 1). Informed consent was obtained before enrolling all patients into the study.

The study's sample size included 63 ready-made zircon crowns, 31 ready-made crowns made locally via CAD/CAM system, and 32 ready-made crowns from the NuSmile® company. These crowns were applied to 44 children aged between 5-9 years who visited the Department of Pediatric Dentistry (Table 1). Random distribution of the crowns studied was carried out to allocate them into either second mandibular primary molars or maxillary primary central incisors. Sixty-four percent of the sample provided only one crown per child to provide a larger sample and greater accuracy in the results.

2.2. Inclusion criteria [5]

- 1 Children between 5-9 years old.
- 2 Definitely positive or positive behavior according to Frankl behavior rating scale.
- 3 A primary tooth with one or more indications for crown restoration.
- 4 Primary teeth were not submerged.
- 5 Opposite teeth were not lost or destroyed.
- 6 The child does not have occlusal problems or periodontal diseases and does not take medications that lead to symptoms of them.
- 7 Angle's Class 1 first permanent molar occlusion in case of mixed dentition.
- 8 The crowned molar is in contact with at least one adjacent molar (standard for posterior teeth).

2.3. Laboratory work

CAD-CAM crowns were designed in a dental technical lab locally. These crowns were milled in different sizes in a CAD-CAM milling machine (Roland DWX-510, Japan) to produce a prefabricated primary crowns kit.

Stainless steel crowns (3M ESPE) for posterior teeth were used to design the locally milled zirconia crowns and individually prepared for each size crown (E3, E4, E5, E6, etc.). Two faces of the crown (inner and

outer) were sprayed with the digital scanner's spray marker and scanned in an Open Technologies Optical 3D Scanner. The scanned crown's inner surface is virtually waxed-up by computer design (CAD) using exocad software 2015 to achieve the crown's thickness of 0.6 mm for all crown walls to maintain the outer dimensions surface (distal mesial distance). Some modifications were made for these crowns (height, lingual-buccal distance) before sending the STL file to the CAM device for fabrication. This procedure was then repeated with Temporary polycarbonate crowns (3M ESPE) for anterior crown fabrication (Figure 2). Each milled zirconia crowns were then separated from the zirconia blocks, and a final polishing procedure was carried out (Figure 3).

This process is repeated for each size of anterior and posterior crowns. The resulting zirconia crowns are collected in a special separated box and encoded in different sizes to produce a full kit of prefabricated locally created CAD-CAM zirconia crowns.

2.4. Clinical work

Clinical and radiographic examination of the primary teeth (second mandibular molar and maxillary central incisors) were conducted to ensure compliance with the study criteria. Oral health instructions to the child and parents were given in a separate appointment. Child data were collected and distributed by type of crowns (CAD/CAM or NuSmile®) randomly selected using Excel 2015 software. Signed informed consent was obtained from one parent of each child before the study. Enrolled children were divided randomly into two groups:

Group A: primary teeth restored with CAD-CAM Zirconia crowns (CCZC) [16 posterior and 15 anterior] (Figure 4) (Figure 6).

Composition of Zr Blocks used to produce CCZC: ZrO₂ >94.10%, Y₂O₃ 5.20%, Al₂O₃ 0.25%, HfO₂ <0.30%, SiO₂ < 0.02%, Fe₂O₃ < 0.01%, Na₂O < 0.04%.

Group B: primary teeth restored with NuSmile crowns (NZC) [16 posterior and 16 anterior] (Figure 5) (Figure 7).

Composition of NZC: ZrO₂ 88–96%, Y₂O₃ 4–6%, HfO₂ 5%, an organic binder, pigment.

In this study, posterior teeth were second mandibular primary molars, and anterior teeth were primary maxillary incisors, and both children and examiner were blinded. The examiner was a pediatric dentist who recorded parameters for clinical evaluation.

The local anesthesia procedures were then applied using 2% lidocaine and 1: 80.000 adrenaline. The primary tooth intended for receiving the ready-made zirconia crown was prepared according to a standardized preparation method consistent with the recommendations for preparation by NuSmile® [10]:

The appropriate size of the zirconia crown was selected for the tooth chosen for treatment. The occlusal relationships were evaluated; then, the occlusal surface was reduced by 1–2 mm by using a flame bur. The interproximal areas were opened, and the crown dimensions were reduced by 20–30% (or 0.5–1.25 mm) using a tapered diamond bur, making the contour of the prepared tooth consistent with the natural contour. The prepared tooth walls were finished with a 1–2 mm subgingival feather-edge preparation using a thinner pointed tapered diamond bur.

The selected crown was tested for appropriate fit before the final cementation, including having appropriate occlusal contact with the opposing teeth without any high occlusal contacts. Finally, the prepared tooth was cleaned from saliva, blood, and the remnants of preparation and ready for cementation.

The selected zirconia crown was cleaned and then filled with Fuji I glass ionomer cement. The crown was then applied with no resistance to the fully seated position on the tooth (Passive Fit) since forcing the crown to place can produce micro-fractures in the zirconia structure. Excess cement was removed using a dental probe and dental floss. Finally, occlusion was examined using articulating paper, and high points were reduced on the opposing tooth.

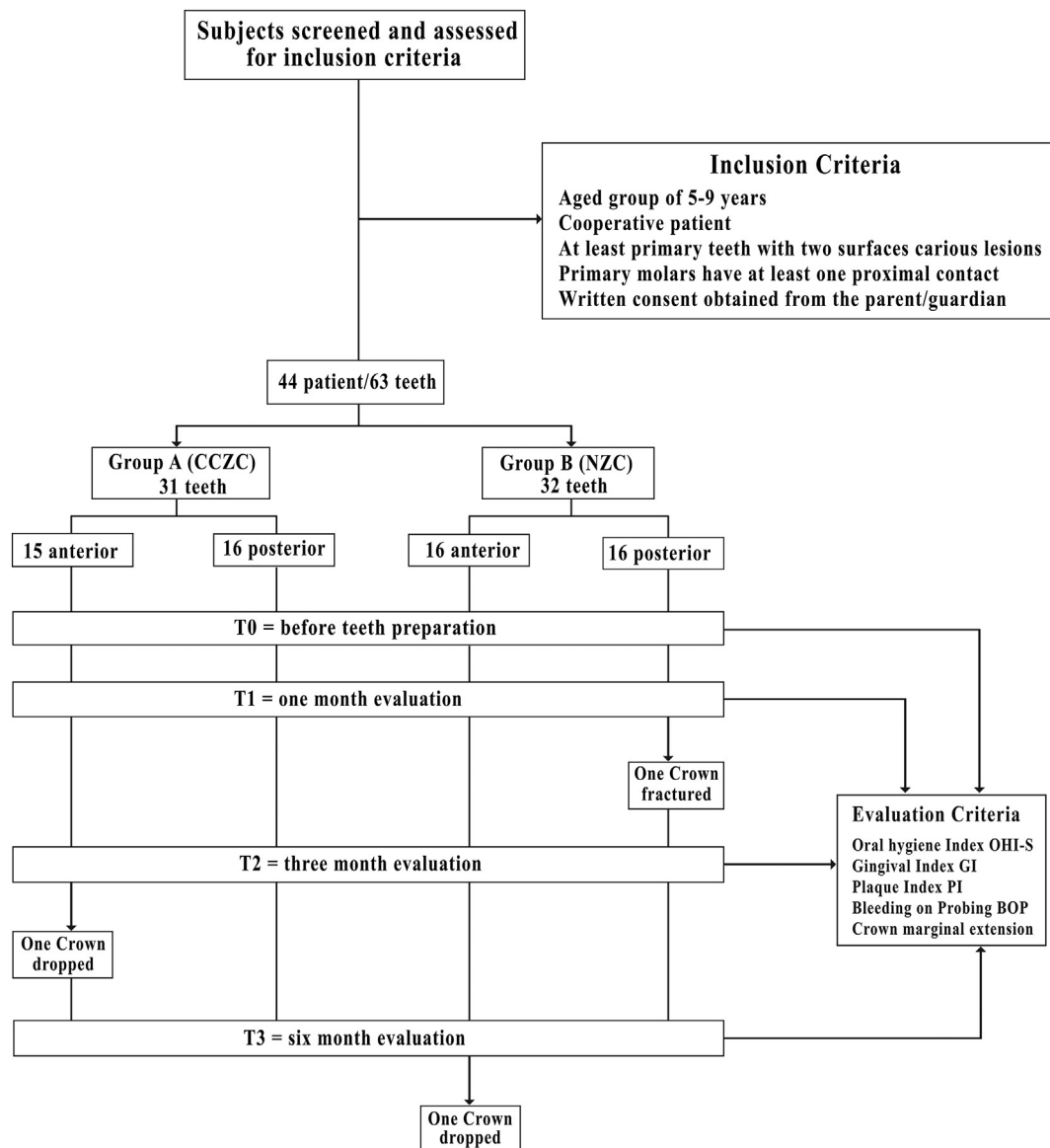


Figure 1. Research process flowchart.

2.5. Clinical evaluation

During the study, three crowns were lost in the follow-up phase: one NuSmile® posterior crown, broken after one month of follow-up; one child withdrew with one anterior crown after one month of follow-up, and; another child withdrew with one anterior crown after three months of follow-up (Figure 1).

Clinical evaluation for all zirconia crowns was recorded with the following parameters:

Oral hygiene indicators (OHI-S) were measured for the following teeth (75, 82, 61, 54) for primary occlusion. As for the mixed occlusion, the following teeth (46, 82, 75, 26, 61, 54) were examined, passing the edge of the probe on the selected surface of the examined teeth. The following are the recorded results [11]:

0 = no debris, 1 = soft debris less than one-third of the tooth surface, 2 = soft debris between one third and two-thirds of the tooth surface, 3 = soft debris more than two-thirds of the tooth surface.

Oral health is rated good if values range from 0 to 1, acceptable for values between 1 to 2, bad for values between 2-3 [12].

The Gingival Index (GI) was measured by the William Gingival Probe with a blunt-ended instrument gently placed within the gingival gutter around each tooth to be crowned/previously crowned, and the values were as follows [13]:

0 = normal gingiva, 1 = mild inflammation: a slight change in color, slight edema, no bleeding on probing, 2 = moderate inflammation: redness, edema, and glazing, or bleeding on probing, 3 = severe inflammation: marked redness and edema, a tendency toward spontaneous bleeding, ulceration.

Table 1. Sample distribution.

Gender	N= Patients	Percentage	CCZC	NZC
Male	28	63.60%	20	19
Female	16	36.40%	11	13
Total	44	100%	31	32

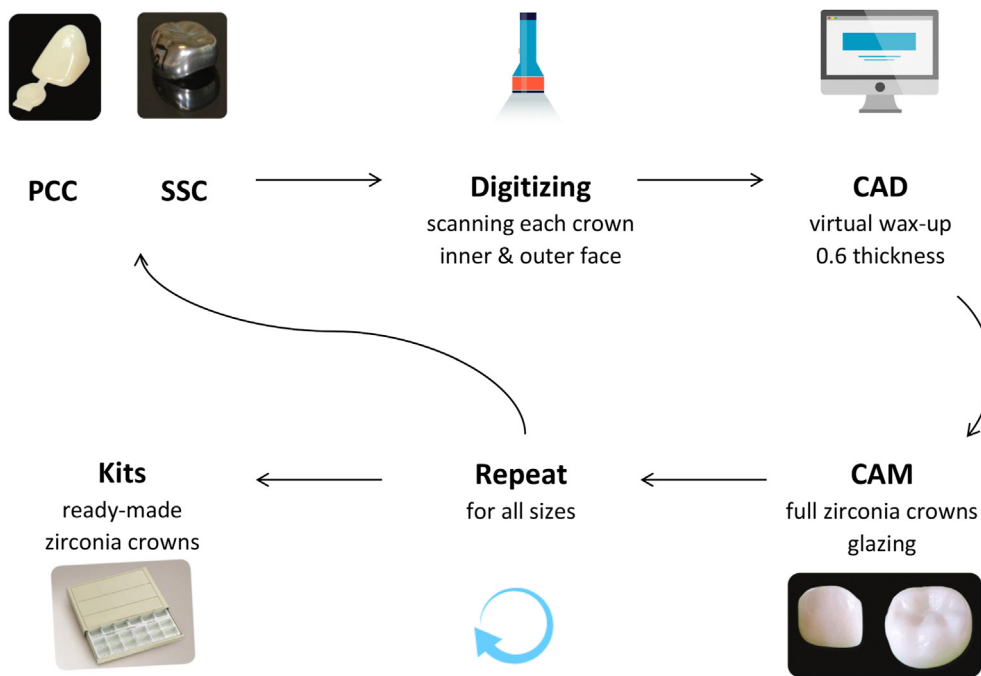


Figure 2. Summary of laboratory procedure to create prefabricated CAD-CAM crowns.

Plaque Index (PI) was measured by passing the gingival probe around each tooth to be crowned/previously crowned., and the values were as follows [13]:

0 = no plaque, 1 = film at the gingival margin and adjacent tooth, 2 = moderate accumulation of plaque, 3 = abundance of plaque. The plaque is measured on the four surfaces of the tooth and then divided by four.

BOP was also measured by William Gingival Probe with a blunt end and gently within the gingival collar circumferentially around each tooth to be crowned/crowned. The values were as follows: (0) no bleeding, (1) bleeding, by probing four points (mesial, lateral, buccal, lingual). Bleeding or not bleeding is examined after 10 s of probing [14]. The bleeding points for each of the four surfaces were noted and recorded with a maximum number possible of 4 and a minimum score of zero for each tooth.

Crown marginal extension was either (0) = at gingival margin, (1) = below the gingival line (apical to gingival margin), or (2) = above the gingival line (occlusal to gingival margin) [15].

The placed crowns were followed up after one month, three months, and six months. Clinical examination and taking intraoral photos were made at each follow-up were performed similarly to the first phase T0 (before the preparation of the primary tooth). Gingival status around the crowned teeth was recorded using OHI-S, GI, PI, BOP, and Crown marginal extension (Figures 4, 5, 6, 7).

2.6. Statistical analysis

All clinical measurements were collected and statistically analyzed using SPSS software with Mann-Whitney U, Friedman test, and Wilcoxon tests for comparing index scores between CCZC and NCZ at the same stage and between five stages of treatment follow-ups.



Figure 3. CCZC after milling and polishing as a ready-made crown.



Figure 4. Anterior NZC at six-months Follow-up. (a) Buccal view (b) Lingual view.

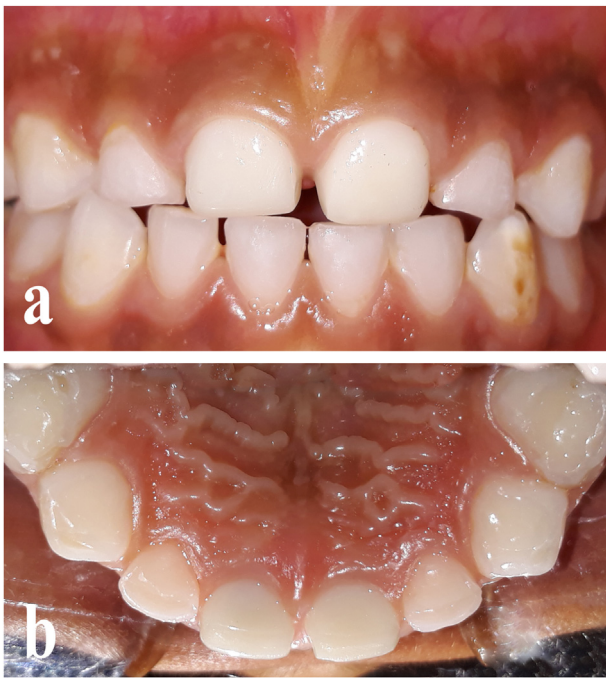


Figure 5. Anterior CCZC at six-months Follow-up. (a) Buccal view (b) Lingual view.

3. Results

GI showed that 33% of the study sample had a 0 = healthy Gingiva score, and 77% of them had a grade 1 = mild inflammation in phase T0. GI also showed no difference between posterior teeth in all follow-up

phases, whether the crown type was used, whether the CCZC or NZC (Table 2). In terms of the anterior teeth, CCZC achieved values smaller than GI values after the first month of follow-up T1 compared to NuSmile crowns ($P < 0.05$), and there was no difference between the two types of crowns in the anterior teeth in other phases T0, T2, T3 (Table 3).

PI showed that 3% of the study sample had a score of 0 = no plaque, 30% had a score of 1 = slight accumulation, and 66% with a score of 2 = moderate accumulation in phase T0. However, PI value had a statistically significant decrease in all follow-up phases compared to phase T0 (pre-treatment) in all crowns of the study sample ($P < 0.05$), and there was no difference between the two types of crowns at any of the study phases (Tables 2 and 3).

BOP showed that 47% of all the examined points bled during probing in phase T0. There was no statistically significant difference in the number of bleeding points when examining the crowned posterior teeth at follow-up phases. In addition, there was no difference between the two types of posterior crowns at any of the study phases (Table 2). Anterior teeth, restored with CCZC, showed fewer bleeding points compared to NuSmile® crowns after one month of follow-up (T1) compared to pre-treatment phase T0 ($P < 0.05$). There was no difference in the number of bleeding points in the remaining phases T2, T3, whatever type of crown used (Table 3).

Crown marginal extension showed that all the study samples had a score of 0 = at the gingival margin and 1 = below the gingival line. However, no crown had a score of 2 = above the gingival line. The results recorded no statistically significant difference in all anterior and posterior crowns between follow-up phases (T1, T2, T3); none of the crowns (NZC or CCZC) indicated gingival recession.

According to the OHI-S, oral health in the study sample was 73% acceptable and 27% good in phase T0. There was no difference in oral health level in the posterior crowns between all follow-up phases, while the oral health of the anterior crown samples improved at follow-up

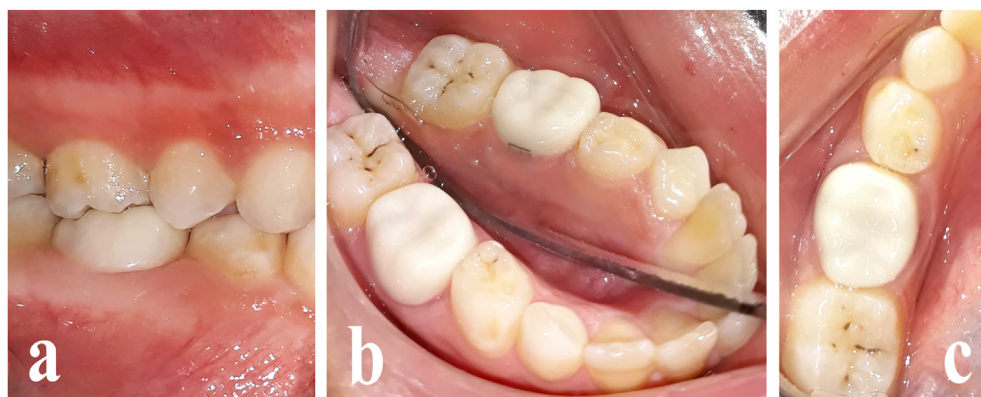


Figure 6. Posterior NZC at six-months Follow-up. (a) Buccal view (b) Lingual view (c) Occlusal view.

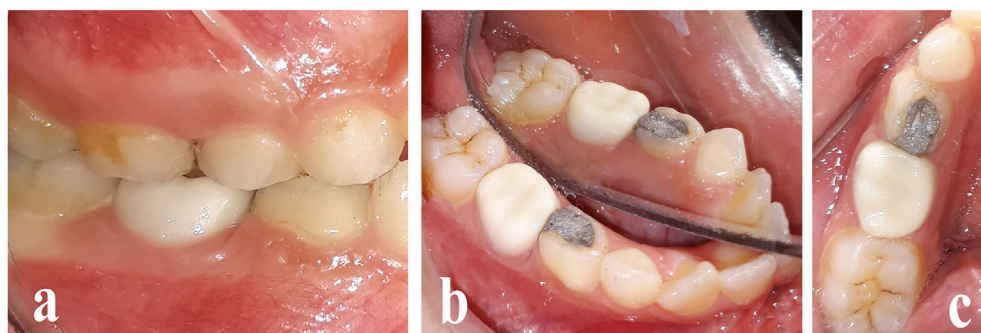


Figure 7. Posterior CCZC at six-months Follow-up. (a) Buccal view (b) Lingual view (c) Occlusal view.

Table 2. Time-dependent relationship between plaque index (PI), gingival index (GI) and bleeding on probing index (BOP) scores for posterior zirconia crowns (NuSmile AND CAD/CAM).

Characteristic	Restoration type	T0 N (i)	T1 N (i)	T2 N (i)	T3 N (i)	P-value
GI	CAD/CAM	15 (1)	12 (1)	14 (1)	15 (1)	>0.05
			3 (2)	1 (2)		
	NuSmile	16 (1)	16 (1)	15 (1)	15 (1)	>0.05
P -value		1	0.06	0.3	1	
PI	CAD/CAM	1 (1)	13 (0)	15 (0)	15 (0)	<0.05
		14 (2)	2 (2)			
	NuSmile	1 (1)	16 (0)	15 (0)	15 (0)	<0.05
		15 (2)				
P -value		0.963	0.137	1	1	
BOP	CAD/CAM	44/60 (1)	48/60 (1)	37/60 (1)	40/60 (1)	>0.05
	NuSmile	46/64 (1)	49/64 (1)	37/60 (1)	41/60 (1)	>0.05
P -value		0.96	0.32	0.81	0.91	

*T = study phases.

*N = number of crowns.

*i = index scores.

phases T1, T2, T3. However, there was no statistically significant difference between the two types of crowns used at any phase of the study.

4. Discussion

A CAD-CAM system was used with zirconia blocks to produce primary zirconia crowns in many sizes (kits) as a ready-made crown according to specific computer designs. CAD-CAM systems in any laboratory or clinic can help dentists use local zirconia crowns to restore primary teeth instead of commercial brands, which may be overly expensive or even unavailable in some countries. The creation of STL files as described in this paper and the milling of many crowns by CAD/CAM can significantly reduce the total cost (by approximately 50%) to clinicians in the world where commercial zirconia crowns may be overly expensive or even unavailable.

OHI-S index was used in this study basically to ensure that all samples are conforming with inclusion criteria (good or acceptable oral health) before treatment with no statistical differences between two groups NZC and CCZC.

Most previous studies have focused on the posterior zirconia crowns comparing ready-made zirconia crowns to the SSCs. All these studies showed better gingival index results (GI) around the zirconia crowns compared to SSCs. When a comparison was conducted between GI results for the ready-made zirconia crowns of these studies during the pre-treatment and post-treatment periods (follow-up phases) and the results of this current study, the results were consistent. These results show no difference between NuSmile ZR crowns before treatment and after one, three, six, and 12 months of follow-up [5, 16].

Other studies have used MGI (Modified Gingival Index), which differs from GI (Gingival Index) used in this study. With the elimination of probing of these young children, soft tissue trauma was avoided. The current study was consistent with the results of Walia 2014, which found no difference in gingival health (MGI) in the anterior NuSmile® crowns between pre-treatment and post-treatment periods within the follow-up period of 6 months. However, the difference between the current study and the Walia 2014 study is that there was an improvement in gingival health (MGI) in the anterior ready-made CAD/CAM zirconia crowns pre-treatment and after six months of follow-up [17].

Table 3. Time-dependent relationship between plaque index (PI), gingival index (GI) and bleeding on probing index (BOP) scores for anterior zirconia crowns (NuSmile® and CAD/CAM).

Characteristic	Restoration type	T0 N (i)	T1 N (i)	T2 N (i)	T3 N (i)	P-value
GI	CAD/CAM	8 (0)	6 (0)	6 (0)	3 (0)	>0.05
		8 (1)	10 (1)	9 (1)	12 (1)	
	NuSmile®	6 (0)		2 (0)	2 (0)	<0.05
		10 (1)	16 (1)	14 (1)	13 (1)	
P -value		0.483	0.007	0.085	0.63	
PI	CAD/CAM	0 (0)	16 (0)	15 (0)	15 (0)	<0.05
		8 (1)				
		8 (2)				
	NuSmile®	2 (0)	13 (0)	16 (0)	15 (0)	<0.05
		9 (1)	2 (1)			
		5 (2)	1 (2)			
P -value		0.173	0.074	1	1	
BOP	CAD/CAM	12//64	19/64	15/60	22/60	>0.05
	NuSmile®	17/64	33/64	24/64	25/60	<0.05
P -value		0.46	0.02	0.09	0.47	

*T = study phases.

*N = number of crowns.

*i = index scores.

The current study also differed from Dimitrova 2018, which showed an improvement in the gingival health (MGI) of pre-made CAD/CAM crowns and NuSmile® crowns between the pre-treatment and follow-up phases of 2 weeks, two months, six months, and one year [18].

The last two studies' difference is the modified gingivitis Index (MGI), which depends on the clinical appearance. The author's opinion is that MGI produced an incomplete evaluation and that GI, which depends on the use of a gingival probe and the clinical appearance, is a better index. In the current study, the gingiva appeared to be healthy no matter which type of crown was used and no matter if the crown was anterior or posterior (Figures 4, 5, 6, 7). The use of the gingival probe and the occurrence of bleeding are likely the reasons for an accurate evaluation.

Zirconia crowns of both types also contributed to improving the gingival condition as the value of PI of the restored primary teeth decreased compared to that in the pre-treatment phase. This result is consistent with Taran 2018 and Abdulhadi 2017 studies, which examined the PI of posterior teeth when applying the NuSmile ready-made zirconia crowns compared to the SSCs crowns. The two studies showed improvement in the Gingival condition after applying the zirconia crowns during the follow-up period compared to the Gingival condition before applying the crowns. These crowns also proved to be better regarding the PI than the SSCs crowns after one month, three months, six months, and 12 months [5, 16].

Comparing the BOP index for both types of crowns demonstrates no difference in the average number of bleeding points between teeth restored with CCZC and NZC, in anterior or posterior regions, pre-treatment, and during the follow-up. The comparison also showed that CCZC were better after one-month T1 compared to NZC in anterior teeth samples.

In the study of Abdulhadi 2017, which examined the gingival condition around 60 NuSmile® posterior crowns, there was no bleeding on gingival probing around 80% of the crowns after three months and no bleeding at 100% after six months and 12 months. However, the gingival condition was not mentioned before the application of crowns (pre-treatment), which means there is no comparison between Gingival health before and after treatment. In addition, the probing method in the follow-up phases does not identify whether it was applied to one point or several points. The current study addresses these points; the number of probing points was four points, and their results were clarified before and after treatment [5].

Regarding margin extension, this study presented similar results with Taran 2018 study, as none of the crowns created any type of gingival recession [16] (Figures 4, 5, 6, 7).

Some limitations of this study are:

The need for radiographic data to improve clinical status expression, i.e., the alveolar bone around crowned teeth.

The need for larger sample sizes (crowns and children) and more extended follow-ups periods.

5. Conclusions

Within the limits of this study, the application of CCZC on the anterior and posterior primary teeth showed the following:

CCZC and NZC preserve the Gingival health (clinical appearance, bleeding) of primary teeth compared to its health before applying crowns.

CCZC and NZC reduced microbial plaque accumulation on the primary teeth after crowning compared to how they were before crowning.

There was no difference between CCZC and NZC after a six-month follow-up. The null hypothesis was accepted.

Ready-made zirconia crowns created via a CAD/CAM system can offer a convenient, economical option to achieve cosmetic, healthy, and functional aspects when restoring primary teeth.

Declarations

Author contribution statement

Louay Hanafi: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Mohamed Altinawi and John C Comisi: Analyzed and interpreted the data; Wrote the paper.

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Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

The clinical trial described in this paper was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under the registration number NCT03740308.

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