

DIRECT RESIN COMPOSITE RESTORATION OF CARIOUS PRIMARY ANTERIOR TEETH USING CUSTOM 3D PRINTED TEMPLATES: A 12-MONTH PARALLEL RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Background: Esthetic restoration for primary anterior teeth constitutes one of the challenging situations in paediatric dental practice. **Aim of the study:** Assessment of the 12-month clinical performance of direct resin composite restorations of carious vital primary anterior teeth using custom 3D printed templates obtained from digitally waxed-up patients' dental models compared to conventional strip crowns.

Subjects and methods: A single-center, prospective parallel arms randomized controlled clinical trial was performed in which 98 carious vital primary anterior teeth in 32 children were directly restored with resin composite either with the help of custom 3D printed templates (Group A: study group) or celluloid crown forms (Group B: control group). Restorations were assessed for surface luster, anatomical form, material fracture, marginal adaptation, and periodontal response using the revised FDI criteria on three occasions; a week after placement (T0), at six months (T1), and at twelve months (T2) of follow-up and the tooth was the unit of analysis. Chi-square/Fisher exact tests were used for comparisons between groups. Cohen's kappa statistic was used to test the assessors' reliability. A significant level was set when the p-value < 0.05.

Results: Group A restorations showed better clinical performance for the tested criteria after 12 months, however, the results were not statistically significant except for the esthetic anatomical form (p= 0.03).

Conclusion: Custom 3D-printed templates could be a superior alternative to traditional celluloid crown forms in the direct composite restoration of carious primary anterior teeth.

KEYWORDS: Early childhood caries, Strip Crown, 3D Printing, Primary Anterior Teeth, Digital scan.

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INTRODUCTION

Esthetic restoration of primary anterior teeth constitutes one of the biggest challenges in paediatric dental practice due to several factors such as the small size of the teeth; the pulp proximity to the tooth surface; the reduced enamel thickness; the limited surface area for bonding; and the child behavior^[1].

The composite strip crown (CSC) technique is a popular esthetic treatment option for restoring primary anterior teeth. Despite being technique-sensitive, it has the benefits of colour match, fitting in crowded teeth, and simplicity of repair^[2]. Retrospective studies showed that eighty percent of these restorations were retained after more than two years^[3, 4]. Grewal et al. (2021)^[5] suggested considering CSCs for teeth with sufficient remaining healthy tooth structure for bonding for warranted retention.

Modern dental digital advancements such as digital intraoral scanning, computer-aided design, and three-dimensional (3D) printing have been included in various paediatric dental services aiming to deliver optimum oral health care to children. Scanning the dentition, analyzing occlusion, planning restorations, and directly fabricating models and templates has become possible^[6]. The current clinical trial aimed to assess the 12-month clinical outcomes of direct resin composite restorations of carious primary anterior teeth using custom 3D printed templates obtained from digitally waxed-up patients' dental models compared to conventional CSCs.

SUBJECTS AND METHODS

Study design

The present study is a single-center, prospective randomized controlled clinical trial with two parallel arms and an intended allocation ratio of 1:1. This trial entailed directly restoring carious primary anterior teeth with resin composite either with the help of custom 3D printed templates obtained from digitally waxed-up patients' dental models (Group: A) or conventional celluloid crown forms (Group: B). Restorations were assessed for clinical performance on three occasions; postoperatively (T0), after six months (T1), and after twelve months (T2).

Ethical compliance

The study was approved by the Ethics Committee of the local Dental School (reference #841/2023) and was registered on the ClinicalTrials.gov database (NCT06478004). Legal guardians of the recruited children were informed in an uncomplicated detailed manner about the purpose of the study and a written informed consent prepared in the local language was obtained. The study followed the guidelines published by the Consolidated Standards of Reporting Trials (CONSORT).

Setting, sampling, and eligibility criteria

A random convenient sample of patients with early childhood caries was selected from those attending the outpatient clinic of the Paediatric Dentistry Department at Minia University Dental Hospital. Eligibility criteria are summarized in table (1). Demographic and dental variables were collected and comprehensive examinations (including radiographs) were performed.

TABLE (1) The eligibility criteria.

Inclusion criteria	Exclusion criteria
<p>Patient-related criteria</p> <ul style="list-style-type: none"> - Age group: 3- 5 years. - Good general health (ASA class 1 or 2). - Cooperative children with Frankl's behavior rating 3 and 4. - Motivated parents willing to bring their children for follow-up. <p>Teeth related criteria</p> <ul style="list-style-type: none"> - Presence of at least two vital carious primary maxillary incisors. - Teeth had at least two carious surfaces requiring complete coronal restoration. - Carious teeth had at least half of the clinical crown remaining after caries removal. - Functioning opposing primary mandibular incisors. 	<p>Patient-related criteria</p> <ul style="list-style-type: none"> - Children with malocclusion and deep overbite. - Children with parafunctional oral habits such as bruxism and biting habits. - Children requiring pharmacologic management. - Legal guardians not signing the consent. <p>Teeth related criteria</p> <ul style="list-style-type: none"> - Teeth beyond restoration. - Teeth with extensive root resorption or internal resorption. - Grossly decayed teeth with irreversibly diseased pulp tissues requiring partial or complete pulp tissue excision. - Teeth with periodontal diseases.

The minimum sample size was calculated using the G*Power software 3.1.9.7 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). Based on prior analyses^[3,5,7] for the Chi-square (χ^2) test using a 1 degree of freedom with a medium effect size of 0.3, significance level of 0.05, and power of 0.80, the projected required sample size was calculated to be 88 teeth (44 crowns per group). Considering the dropout rate of 10%, an additional 5 teeth per group were included, providing 49 teeth for each group.

Randomization and allocation

Eligible children were enrolled and a computer-generated list of random numbers was used to allocate the participants. Random allocation was performed by an independent researcher using block randomization with a block size of 4 (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). The allocation sequence was concealed using tightly sealed opaque envelopes, including each participant's restoration type, and opened at the time of treatment. All teeth in the same patient

were randomly allocated to the same intervention (figure: 1).

Treatment procedures

For both groups, a single paediatric dentist, with ten years of professional competency and previously calibrated in the procedure, performed the restorations with either the help of the 3D printed templates or celluloid crown forms. Also, the same dental materials were used following the manufacturer's instructions; N-Etch, Tetric N-Bond, and Tetric N-Ceram with appropriate shade (Ivoclar Vivadent dental product, Liechtenstein).

For the study group (A); a digital scan was performed using an intraoral scanner (Omnicam AC; Dentsply-Sirona, Germany) following the manufacturer's scanning protocol. The scan included a pre-preparation scan of the maxillary arch, an antagonist arch scan, and an occlusal scan for the inter-occlusal relationship. The case files were saved as STL (standard tessellation language) files. Another scan was performed after tooth preparation and caries removal.

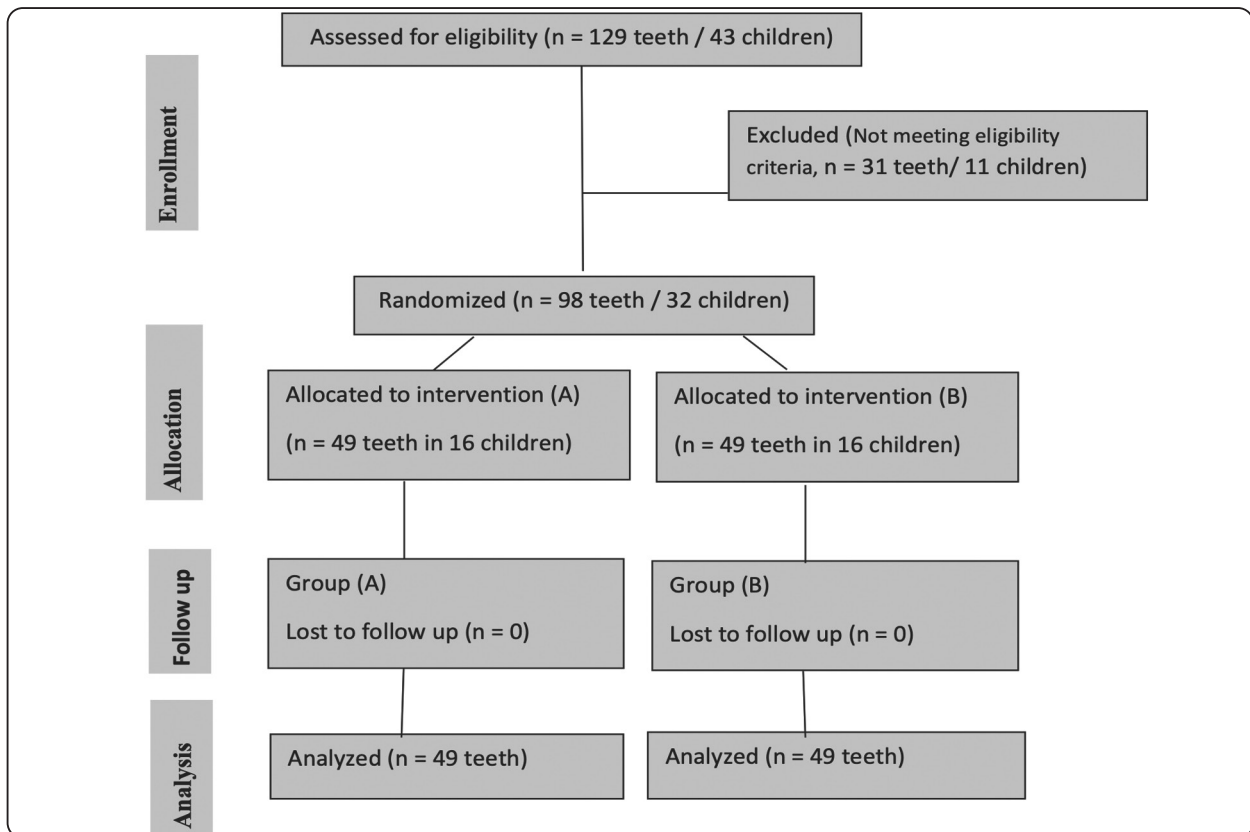


Fig. 1: Consort Flowchart of the trial design.

STL files were exported to Exocad dental software (Exocad Dental Cad 3.0 Galway) for digital waxing-up. The diagnostic tools of the CAD software were used for addition on the surfaces of the virtual primary maxillary anterior teeth. The pre-preparation scan and that obtained from the digital wax-up were overlapped. Then, occlusion was checked as well as tooth shape, alignment, and contours.

The final STL file was exported to the 3D printer (Shining accuFab D1 3D printer, Kowloon Bay, Kowloon, Hong Kong, China) to produce a digitally designed clear template using Chitubox software (figure: 2). The template was fabricated by digital light processing additive manufacturing with clear flexible photopolymer resin (Norton standard Resin Clear 8k, 3D smart). For group (A) patients, direct composite resin restorations were performed

with the help of these custom 3D printed templates while for group (B), CSCs were performed using paediatric strip crown forms (3M™ ESPE™, St. Paul, Mn, USA) following the technique described by Kupietzky et al. (2005) [3].

Composite restorations were cured using the LED curing light unit (Bluephase N; Ivoclar Vivadent AG, Schaan, Liechtenstein) with standardized intensity and time in both groups. Following the removal of the crown form; the occlusion was checked. Standard postoperative instructions, including oral hygiene instructions, were given to the patients. Supplemental documentation was performed via photographing the restoration, the surrounding structures, and part of the adjacent teeth at baseline and, if feasible, again during recall visits to facilitate clinical assessments.

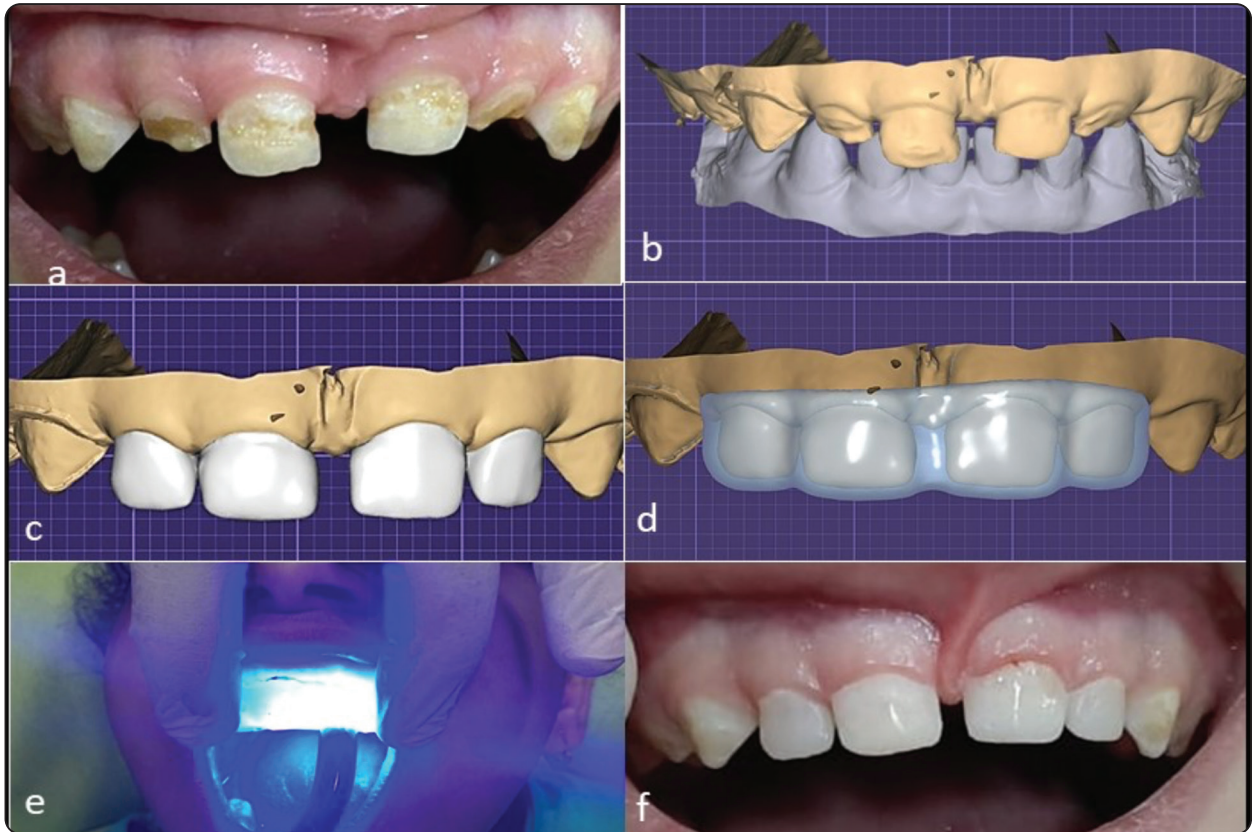


Fig. 2: The treatment procedures of the group (A): (a) preoperative photo, (b) digital acquisition, (c) digital waxing-up, (d) designing the template, (e) direct composite restoration using the custom 3D printed template, (f) immediate postoperative photo.

Assessment

Children were re-evaluated concerning the inclusion and exclusion criteria at each recall visit. In particular, bruxism and changes to the medical history. Other carious teeth were restored, but these restorations were not part of the study.

Based on the revised clinical criteria for the evaluation of direct and indirect restorations of the World Dental Federation (FDI) ^[8], the restorations in both groups were evaluated for their clinical performance in terms of surface luster compared to adjacent teeth, esthetic anatomical form, fracture of resin composite, adaptation at margins, and periodontal response compared to a reference tooth. These parameters were evaluated in both groups, via inspection and magnification, short air drying,

and probing, on three occasions; T0; at baseline (a week after crown placement), T1; at six months, and T2; at twelve months of follow-up.

Scoring of criteria was executed according to a five-step grading of the restoration that was then dichotomized into “acceptable” (for scores 1, 2&3) and “not acceptable” (for scores 4&5) (Table: 2).

Clinical assessment was performed by two experienced, calibrated paediatric dentists not involved in the restoration procedures. They recorded the results separately at the same appointment. Inter-observer reliability using the Kappa coefficient (κ) was high at each examination time ($\kappa = > 0.85$). Both assessors and statisticians were blinded to the type of intervention.

TABLE (2) Description and details of the revised FDI criteria.

FDI criteria	FDI score				
	1 Clinically excellent	2 Clinically good	3 Clinically satisfactory Refurbishment is possible	4 Clinically unsatisfactory (Reparable)	5 Clinically poor (Replacement necessary)
	Acceptable			Not acceptable	
Surface luster	Comparable Surface luster	Slightly dull surface not noticeable from a speaking distance.	Slightly dull surface but is acceptable if wet	Displeasing dull or rough surfaces requires intervention	Generalized, displeasing dull, and/or rough plaque retentive surface
Esthetic anatomical form	Outline, contour, convexity, embrasure, and/or marginal ridge are restored ideally. No marginal step	Minor deviations in anatomical form and/or minor marginal steps, and overhangs.	Distinctly misshaped anatomical form but clinically acceptable and/or distinct negative/positive steps, overhangs.	The anatomical form is in parts severely undersized, and/or prominently negative marginal steps.	The anatomical form is generally and severely under or oversized.
Material fracture / retention	Restoration is completely present without deficiencies detectable after air drying. No crack, or chipping.	Restoration is completely present with minor deficiencies detectable after air drying, e.g., insignificant chipping or a hairline crack	Restoration is present with deficiencies detectable without air drying, e.g., hairline cracks or distinct material loss (chipping).	Localized but severe deficiencies e.g., chipping which cannot be refurbished, bulk fracture, or partially loose/lost restoration.	Generalized severe deficiencies, e.g., multiple bulk fractures, or (nearly) completely lost restoration.
Marginal adaptation	Ideal marginal adaptation of restoration at dental hard tissue after air drying. No marginal gaps.	Slight deficiencies after air drying. Minor, marginal gap(s) or ditching	Distinct deficiencies without air drying: gap(s) or ditching (width < 250 µm and/or depth < 2 mm)	Localized but severe deficiencies: width ≥ 250 µm and/or depth ≥ 2 mm marginal gap(s). Partially lost restoration.	Generalized and severely compromised marginal adaptation: width ≥ 250 µm and/or depth ≥ 2 mm. Complete lost restoration.
Periodontal response	No plaque, no inflammation, no pockets	little plaque, no inflammation, no pockets	Acceptable plaque, bleeding & pocket formation	Not acceptable plaque or bleeding. Pocket depth increase > 1mm	Severe acute gingivitis or periodontitis

Statistical Analysis

Statistical analysis was performed with IBM® SPSS® (ver. 26. SPSS Inc., IBM Corporation, Armonk, NY, USA). Quantitative data were presented by mean and standard deviation. Qualitative data were presented as numbers and percentages. Comparisons between groups were

evaluated by chi-square/Fisher exact test. Cohen's kappa statistics were used to test the inter-rater reliability. A statistically significant level was considered when the p-value < 0.05. The tooth was the unit of analysis; since restoration failure was the outcome of interest, all analysis was done at the tooth level even though the study was randomized at the patient level.

RESULTS

In the current study, 43 patients with 129 carious primary anterior teeth were examined, of them, 11 patients with 31 teeth were excluded as they did not fulfill the eligibility criteria and 32 children with 98 eligible teeth were enrolled; 18 females (56.25%) and 14 males (43.75%). At baseline, the children were, on average, 4.18±0.51 years old, with a mean dmft score of 4.73±1.68. In both groups, no statistically significant difference regarding the characteristics of patients and the location of restored teeth (central or lateral incisor) was detected.

All the planned treatments and the three-time

points of recall evaluations were completed without patient dropout resulting in a 100 % attendance rate (**Table: 3**). There were no adverse effects that necessitated other interventions.

Group (A) restorations showed better clinical performance regarding surface luster, material fracture, marginal adaptation, and periodontal response after 12 months, however, the results were not statistically significant (p>0.05). Meanwhile, group (A) restorations exhibited superior esthetic anatomical form than group (B) throughout the follow-up period and the results were statistically significant (p= 0.03).

Table (3): Results of clinical evaluation of restorations according to revised FDI criteria.

FDI criteria	The time point of recall evaluation	Group (A)					Group (B)					p-Value
		FDI score					FDI score					
		1	2	3	4	5	1	2	3	4	5	
Surface luster	T0	47	1	1	0	0	47	2	0	0	0	
		49			0		49			0		-
	T1	46	1	2	0	0	45	1	3	0	0	
		49			0		49			0		-
	T2	45	2	1	1	0	41	2	1	2	3	
		48			1		44			5		0.2
Esthetic anatomical form	T0	48	1	0	0	0	39	2	2	3	3	
		49			0		43			6		0.03*
	T1	48	1	0	0	0	39	2	2	3	3	
		49			0		43			6		0.03*
	T2	48	1	0	0	0	39	2	2	3	3	
		49			0		43			6		0.03*
Material fracture/retention	T0	48	1	0	0	0	47	1	1	-	-	
		49			0		49			0		-
	T1	45	3	1	0	0	40	5	4	-	-	
		49			0		49			0		-
	T2	44	3	1	1	0	36	4	5	3	1	
		48			1		45			4		0.3
Marginal adaptation	T0	48	1	0	0	0	46	1	2	-	-	
		49			0		49			0		-
	T1	48	1	0	0	0	40	3	6	-	-	
		49			0		49			0		-
	T2	47	1	0	1	0	38	3	4	2	2	
		48			1		45			4		0.3
Periodontal response	T0	49	0	0	0	0	47	2	-	-	-	
		49			0		49			0		-
	T1	48	0	1	0	0	44	1	2	2	-	
		49			0		47			2		0.4
	T2	48	0	0	1	0	41	3	2	3	-	
		48			1		46			3		0.6

(*): p>0.05 is statistically significant

DISCUSSION

Early childhood caries continues to be a global health problem, affecting almost half of preschool children^[9]. Preformed paediatric zircon crowns and CSCs are the most commonly used aesthetic restorations for carious primary anterior teeth where zircon crowns are usually indicated in cases with excessive tooth structure loss while CSCs are indicated for teeth providing adequate remaining healthy tooth structure at least half to two-thirds^[5, 10, 11].

Literature comprises several trials that aimed at promoting CSC procedures and outcomes. Jeong et al. (2013)^[12] suggested using strip crowns with self-adhesive resin cement after chemo-mechanical caries removal to reduce chair time in children with difficult behavior management.

Gugnani et al., (2017)^[13] clinically tried a bis-acrylate temporization material instead of composite aiming to overcome its technique sensitivity. They stated that using temporization material resulted in a cost-effective good immediate esthetics. Souza et al., 2018^[14] reported the use of acetate custom-made crown forms made by vacuum plasticizer from an analogue mock-up mold produced from a waxed-up plaster model. They suggested that this technique decreased the clinical time and enhanced the esthetics.

Digital advancements could help paediatric dentists to revolutionize treatment methods and improve patient outcomes^[15]. Thus, the current clinical study was conducted to assess direct resin composite restorations performed using custom-made crown forms produced using 3D scanning, computer-aided design, and 3D printing compared to conventional CSCs for the management of carious primary anterior teeth. A parallel arms randomized controlled trial was designed to improve the quality of evidence for treatment recommendations^[16].

Selected children were cooperative as CSCs are more suitable for cooperative children due to the

high technical sensitivity^[17]. Their age ranged from three to five years; younger children were excluded due to limited compliance that can affect restoration success, and older children were also excluded due to the limited life expectancy of the treated teeth and the functioning opposing ones^[18].

Regarding the teeth-related eligibility criteria, grossly decayed primary teeth were excluded as less than half of the available sound tooth structure was detrimental to the retention rate of these crowns^[5]. Mutilated primary anterior teeth could be better restored using zirconia crowns^[19]. To prevent imbalances between groups, teeth requiring pulp therapy were also excluded as they could have higher failure rates due to decreased remaining healthy tooth structure^[20]. In the current study, the risk of selection bias was avoided through the randomization process and allocation sequence concealment^[21, 22].

Given the preparations to be made, depth of the carious lesions, and the patient's cooperation, it was better to manage children non-pharmacologically. When considering dental interventions, general anesthesia should be regarded as a last resort after alternative methods have been deemed unsuitable, especially in cases of experimental treatment where restoration failure could result in a problem for replacement^[23].

Both conventional CSCs and the clinical part of the tested new treatment approach were performed by the same experienced paediatric dentist using the same dental materials since these can influence the restorations^[24]. It was impossible to blind participants and operators due to implementing different treatment procedures, however, this could result in performance bias^[23].

Direct intraoral scanning was performed to produce a virtual model rather than scanning a plaster model since children prefer and become more comfortable with the digital impression method compared to conventional impressions^[25, 26]. It is

noteworthy that virtual diagnostic waxing and template designs; and 3D printing were executed by the same experienced prosthodontist.

The revised FDI criteria for the evaluation of direct and indirect restorations were used to evaluate the clinical performance of the restorations since they are considered “Standard Criteria” in clinical trials assessing restorative materials or operative technique. A significant increase in the use of this sensitive and discriminative scale recently over the modified United States Public Health Service (USPHS) criteria has been observed. This would allow for standardized evaluation of restorations, making comparisons between studies easier and even enable meta-analysis^[8].

In the current study, some criteria were not applicable, and only certain relevant criteria were selected. Hickel et al., (2023)^[8] stated that it is not necessary to use the full set of criteria, however, certain categories can be selected according to the purpose and design of the study.

Restorations were evaluated according to pre-stated regular time intervals; at baseline, after 6, and after 12 months. The baseline evaluation was not executed during the placement appointment but after 1 week later to allow for restoration rehydration^[8]. Assessment was performed by experienced calibrated independent outcome assessors blinded to intervention to avoid bias in outcome measurement and guarantee a reproducible result. Moreover, bias due to missing outcome data was not encountered since there was no drop-out^[21, 22, 27].

The study revealed that both types of restorations served very well during the follow-up period regarding all the tested criteria. This may be due to the selected eligibility criteria, operator skill, and material properties^[28]. Restoration retention rates after twelve months were 97.9% and 91.8 for the test and control groups respectively. These results goes in accordance with Kupietzky et al. (2003)^[29] who reported 88% retention rate of CSC after

one year, and, Grewal et al., (2021)^[5] who observed that retention rate ranged from 88-95% for CSCs the were performed on teeth with half to two-thirds of remaining healthy tooth structure at the end of 15 months.

Ram & Fuks (2006)^[4], Gill et al. (2020)^[2], and Vaghela et al. (2021)^[7] had a lower CSC retention rate of 80%. This can be attributed to the difference in the methodology followed as the first study had a three-year follow-up, while the latter studies included high caries-risk children and pulp-treated teeth.

In both groups, restorations exhibited good surface luster, marginal adaptation, and periodontal response after twelve months with overall successful restorations of 93.8%, 94.9%, and 95.9% respectively. Similar results were reported by Ram & Fuks (2006)^[4] who stated that 97% of teeth restored with CSCs showed good surface luster and marginal adaptation. Also, Vaghela (2021)^[7] had similar results regarding marginal adaptation however only 82% of teeth had healthy periodontium and 18% with mild gingivitis.

Restorations of the test group showed better clinical performance than the control group regarding tested criteria after 12 months, however, a statistically significant difference was only observed for esthetic anatomical form. The higher success rates of the test group can be rendered to using digital mock-up that can accurately analyze and evaluate occlusions, and propose a customized treatment plan that improves the efficiency and aesthetics of restorations^[30, 31].

Although, Souza et al., (2018)^[14] produced custom crowns forms using conventional mock-up, the digital workflow is more precise and consumes less clinical and laboratory time. It allows for visual representation of the treatment plan and for modifications without special artistic abilities^[30- 33]. Moreover, data acquisition via intra-oral scanning and virtual modeling can motivate children and enhance their compliance^[6].

Although many trials have been conducted on permanent teeth to benefit from customized 3D-printed templates^[34,35], to the best of our knowledge, no studies have described their use for the restoration of carious primary anterior teeth. However, techniques involving digital dentistry will inevitably replace several traditional techniques.

The current study limitations included the higher cost of the 3D printed templates compared to the strip crown kit and the need for trained clinicians, however, the restoration achieved the anticipated esthetic, functional, and biological aspects. It is recommended to test this new approach over a longer follow-up period as different clinical outcomes might be encountered^[36].

CONCLUSION:

Custom 3D-printed templates could be a superior alternative to traditional celluloid crown forms in the direct composite restoration of carious primary anterior teeth.

List of abbreviations:

- Three Dimensional: 3D.
- Composite strip crown: CSC.
- World Dental Federation: FDI.
- United States Public Health Service: USPHS.

DECLARATIONS

- Ethics approval and consent to participate: The study was approved by the Ethical Committee of the Faculty of Dentistry, Minia University (reference #841/2023). An informed consent was obtained from participants.
- Consent for publication: A consent for publication was obtained from the study participants.
- Availability of data and material: All data generated during this study are included in this article.

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