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ORIGINAL RESEARCH

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Comparison of the clinical success of pediatric zirconia crowns applied with different luting cements: a clinical trial

Huseyin Karayilmaz[1], Ipek Sahin[2], Ayse Cengiz[1,*], Zulfikar Zahit Ciftci[1], Zuhal Kirzioglu[3]

[1]Department of Pediatric Dentistry, Akdeniz University, 07070 Antalya, Turkey
[2]Private Practice, 07070 Antalya, Turkey
[3]Department of Pediatric Dentistry, Suleyman Demirel University, 32260 Isparta, Turkey

***Correspondence**
aysecengiz@akdeniz.edu.tr
(Ayse Cengiz)

Abstract

Background: The effect of luting cement type on the clinical success of pediatric zirconia crowns (PZCs) is still not proven. This study aims to assess and compare the clinical effectiveness and effect on gingival health, of PZCs (NuSmile, ZR Zirconia Primary, TX, USA) cemented with different luting cements. **Methods**: A total of 60 PZCs were applied to the primary molars of 53 children. Four groups were formed based on the type of luting cement. (Group BC (n = 15): Resin modified glass-ionomer cement (RMGIC) with calcium and phosphate release (BioCem™, Nusmile, TX, USA), Group GC (n = 15): Dual-cure adhesive resin cement (G-CEM LinkForce™, GC, USA), Group F1 (n = 15): Glass-ionomer cement (GIC) (Fuji 1™, GC, USA), Group F2 (n = 15): RMGIC (FujiCEM™ 2, GC, USA). Groups were compared for retention durability, plaque index (PI), gingival index (GI), probing depth (PD), and periapical pathology. Assessments were conducted at 1st, 3rd, 6th and 12th months. **Results**: Retention loss was observed in seven PZCs, and there was no significant difference among the groups. Eight of the teeth showed periapical pathology. Group F2 showed the highest success in terms of pulpal survival. Across all groups, an observed increase in patients' PI, GI and PD scores was noted ($p > 0.05$). PI values obtained from the teeth treated with PZCs were significantly lower than the patients' total oral PI values ($p = 0.001$). **Conclusions**: The absence of a difference among the groups indicates that an ideal cement for luting the zirconia crowns cannot be conclusively recommended. The luting cement can be preferred according to the patient, considering the technical sensitivity of application steps and cooperation. **Clinical Trial Registration**: (Identifier: NCT06558747).

Keywords

Luting cements; Periodontal health; Primary molars; Preformed zirconia crowns

1. Introduction

The management of carious primary molars has perennially presented a complex clinical situation. Over the years, clinicians have employed different materials, including amalgam, composites, glass-ionomer cement (GIC), resin-modified GIC (RMGIC), compomers, and stainless-steel crowns (SSCs), to restore these teeth [1].

SSCs have established a longstanding presence as a fundamental element in the realm of full-coverage restorations of carious primary molars. These crowns have been widely employed by dental practitioners for decades to address various clinical scenarios, particularly in pediatric dentistry [2, 3]. However, the primary drawback associated with SSCs, their esthetic appearance, remains an issue [4, 5]. Within the context of achieving aesthetically pleasing full-coverage dental restorations, various alternatives to traditional SSCs have emerged, including veneered SSCs, open-faced SSCs, polycarbonate crowns, strip crowns, and prefabricated pediatric zirconia crowns (PZCs). Each of these options offers distinct advantages and disadvantages, catering to the unique needs and preferences of both pediatric patients and their parents [6].

With their smooth and polished surface texture, PZCs reduce plaque accumulation and minimize irritation to the gingival tissue. Furthermore, their commendable fracture resistance and strength properties contribute significantly to their overall longevity and clinical utility [7, 8]. PZCs require a passive fit on primary teeth due to their rigid and non-flexible nature. Additionally, compared to other ceramic materials, luting zirconia crowns can be challenging because of their non-adhesive characteristics [9]. Recent literature suggests that mechanochemical surface treatments combined with resin cements yield superior outcomes [10]. Although resin cements offer advantages for retention, they can pose difficulties during luting procedures. Studies have reported issues with the incomplete or partial removal of excess cement that overflows

beyond the restoration's margins [11, 12]. Excess cement at the tooth-restoration interface promotes bacterial adhesion and biofilm formation due to surface irregularities [13]. This can result in plaque accumulation, leading to soft tissue inflammation and dental demineralization.

Glass-ionomer cements are another preferred option among clinicians for luting PZCs. Researchers have also reported high success rates using conventional glass-ionomer luting cement for cementing PZCs [14–16]. Some studies propose that the amount of excess cement varies with the type of cement used [17], whereas others argue there is no difference between different cement types [18, 19]. While numerous studies have examined the impact of luting cement types on the clinical success of monolithic zirconia crowns, there is a scarcity of comprehensive clinical studies assessing the influence of luting cement on the clinical success of PZCs in pediatric patients [20, 21]. Moreover, the majority of existing studies in this context are *in-vitro* studies [8, 22–25]. In a recent study, Alrashdi *et al*. [26] suggested that self-adhesive resin cement is a viable option for cementing PZCs, demonstrating satisfactory clinical performance. They further highlighted the need for future studies comparing various types of cement to validate these findings.

Therefore, this study aims to evaluate and compare the clinical outcomes of PZCs for primary molars cemented with different luting cements ((1) RMGIC with calcium and phosphate release (BioCem™ NuSmile, TX, USA), (2) Adhesive Resin Cement (G-CEM LinkForce™, GC, USA), (3) GIC (Fuji I™ Capsule, GC, USA), (4) RMGIC (FujiCEM™ 2, GC, USA)).

Our hypotheses for this study are as follows:

H0-1: PZCs cemented with dual-cure resin cement will demonstrate superior retention compared to other groups.

H0-2: PZCs cemented with GIC will exhibit better periodontal and pulpal status.

2. Methods

This study was approved (06 November 2017; 70904504/400) by the Ethical Committee for the Clinical Research of the Medical Faculty of Akdeniz University and retrospectively registered to the https://clinicaltrials.gov (Identifier: NCT06558747).

Initially, 88 patients were screened, and 72 were found eligible for the study. Out of these 72 patients, 12 were excluded prior to the study for various reasons (6 due to non-cooperation, 4 due to poor oral hygiene habits, and 2 due to caries progression between the initial screening and intervention). This information is summarized in the flow chart along with the analyzed data and drop-outs (Fig. 1).

A total of 60 PZCs (NuSmile, ZR Zirconia Primary, Texas, USA) were applied to the primary molars of 53 children aged 5 to 11 years old (8.2 ± 1.27) using four different types of luting cement (bioactive cement, resin cement, GIC, RMGIC) by one researcher (IS) at Akdeniz University, Faculty of Dentistry, Department of Pediatric Dentistry between November 2017 and March 2019 (Fig. 2).

2.1 Sample size

The sample size for our study was determined using the results presented in the study by Walia *et al*. [22]. In the phase of establishing an adequate sample size in the study, the GPOWER 3.1.9.4 (Universität Düsseldorf, Düsseldorf, NRW, Germany) program was utilized. The power analysis indicated that a sample size of 14 for each group was anticipated for an effect size of 0.574, a sensitivity of 0.05, and a power of 0.90.

2.2 Eligibility criteria

2.2.1 Inclusion criteria

Patients who had the following criteria were included: (i) age between 5 and 11 years old, (ii) no systemic illnesses, (iii) no history of allergies, (iv) a Frankl scale score of 3 or 4, (v) had at least one carious primary molar. In addition to the criteria for patients, certain criteria were also assessed for the teeth:

Clinically:

- No percussion or palpation sensitivity,
- No abscess and/or fistula,
- No prior pulpal treatment,
- No mobility or signs of periodontal disease,
- Multi-surface carious lesion,
- Occlusal contact with the opposing teeth.

Radiographically:

- No pathological root resorption,
- No radiolucency at the furcation area,
- Normal position of permanent successor,
- Physiological root resorption no more than one-third of the root,
- Normal lamina dura and periodontal space,
- Multi-surface carious lesion reaching at least 1/2 dentin and not exceeding 2/3 dentin.

2.2.2 Exclusion criteria

Patients who did not meet the inclusion criteria, those with congenital developmental defects (such as amelogenesis imperfecta and dentinogenesis imperfecta), a history of bruxism, a history of trauma or infraocclusion in the teeth to be treated with PZCs and a skeletal or dental malocclusion were excluded. Also, it was determined that if pulp exposure occurred during the procedure, the affected teeth would receive the necessary pulpal treatment and be restored, but would be excluded from the study.

2.3 Randomization and blinding

Blinding was not feasible due to the differing procedural requirements for each cement type. Randomization was conducted using a paper-drawing method. Specifically, 15 papers for each group (total 60) were prepared, in a 3 × 5 cm format, folded twice with the written side inward, and placed into a glass container. A paper was randomly selected from the container, and the cement group indicated on the paper was used for the cementation process.

2.4 Preparation procedures

Prior to tooth preparation, crown sizes were determined using a Try-In crown (NuSmile, TX, USA) according to the manufac-

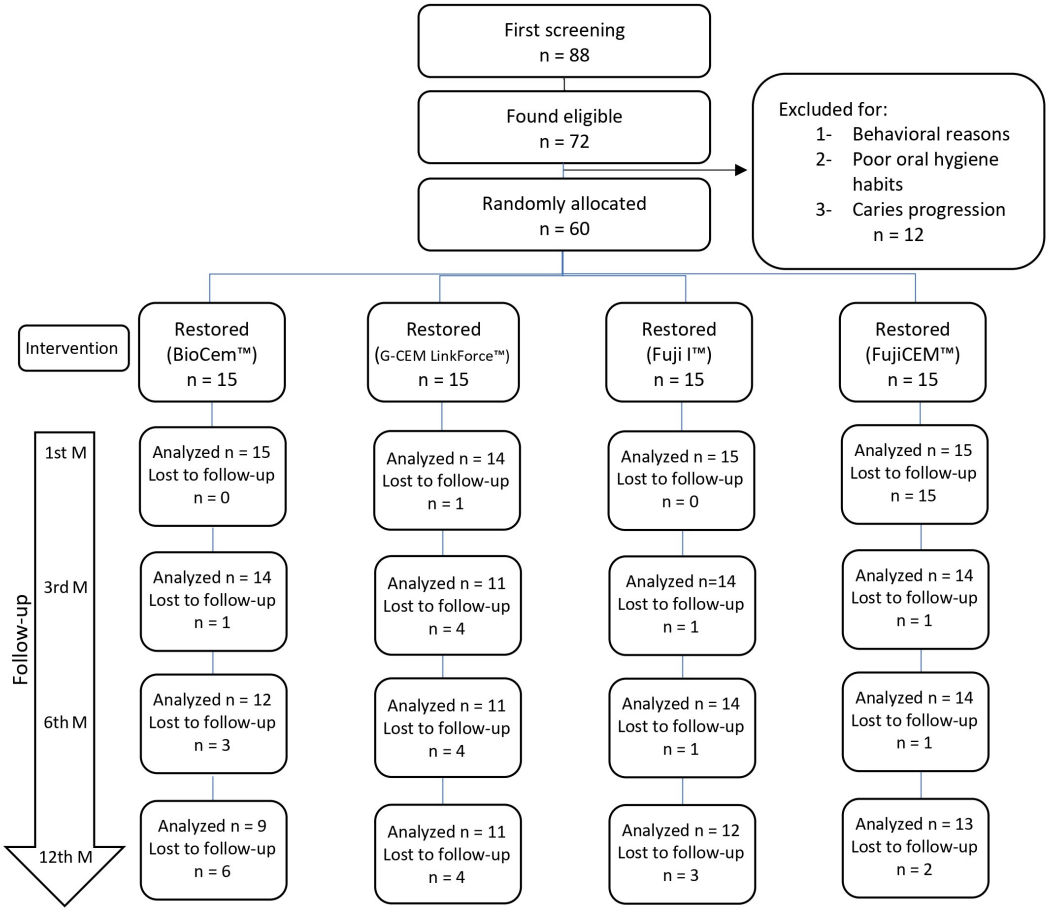

FIGURE 1. Flow-chart of the trial.

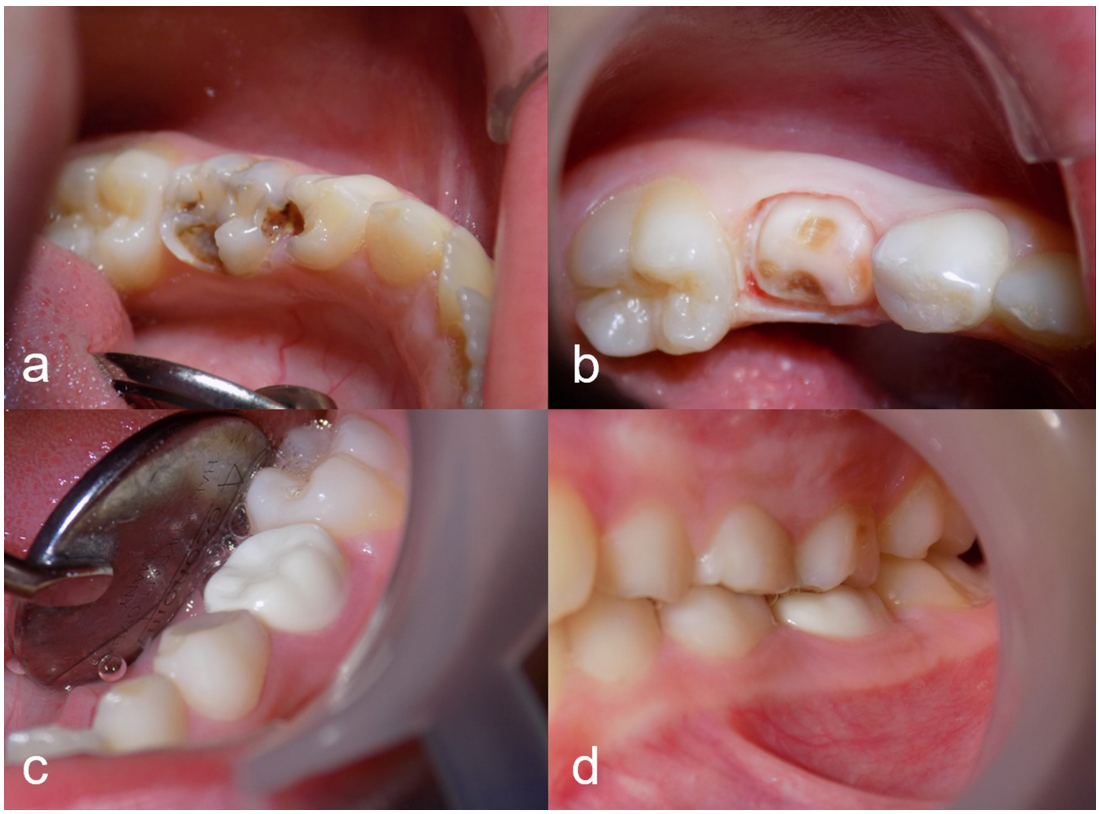

FIGURE 2. Intraoral views of the teeth treated with PZC: (a) before preparation, (b) after preparation (c) and (d) immediate after cementation.

turer's recommendations. Following the crown size selection, preparation began with a 2 mm reduction of the occlusal surface. Interproximal contacts with adjacent teeth were then eliminated. The buccal, lingual/palatal, and proximal surfaces were reduced by 1–1.5 mm. Preparation margins were designed with a feather-edge, approximately 1 mm subgingivally (Fig. 2b). An inspection was conducted to ensure that there were no undercuts, and Try-In crowns were tested for proper passive fit.

2.5 Study groups

Four groups were formed based on the type of luting cement used:

- Group BC (n = 15): BioCem™ (NuSmile, Texas, USA) (Bioactive Cement (RMGIC with Ca^{2+} and PO_4^{3-} release)),
- Group GC (n = 15): G-CEM LinkForce™ (GC, USA) (Dual-Cure Adhesive Resin Cement),
- Group F1 (n = 15): Fuji I™ Capsule (GC, USA) (GIC),
- Group F2 (n = 15): FujiCEM™ 2 (GC, USA) (RMGIC).

2.6 Cementation procedures

After the preparation, isolation of the tooth was achieved with cotton rolls and suction.

Group BC: According to the manufacturer's instructions, teeth were cleaned and then dried with air. The BioCem™ was evenly distributed within the crown and immediately placed onto the teeth. Crowns were stabilized for 20 seconds before applying halogen/LED (Light Emitting Diode) light (800–1200 mW/cm^2) (Valo Cordless, Ultradent, South Jordan, UT, USA) to the buccal and lingual/palatal surfaces for three seconds each. Any excess cement was removed using a probe, and dental floss was applied to the interproximal areas. Finally, all surfaces of the crown were light-cured for an additional 20 seconds.

Group GC: The inner surface of the all-ceramic crowns was treated with the "G-Multi Primer" using a brush and subsequently air-dried. The surfaces of the prepared teeth were treated with 37% orthophosphoric acid. The tooth surfaces were rinsed with an air-water spray to remove the acid from the surfaces. The tip of the air spray was held approximately 6 cm away from the prepared teeth to avoid excessive drying of the dentin surface while drying with air. After the etching process, the "G-Premio Bond" from the kit was applied to the teeth surfaces with a brush, rubbed for 10 seconds, and then air-dried for five seconds. Then the teeth were exposed to halogen/LED light (800–1200 mW/cm^2) (Valo Cordless, Ultradent) for 10 seconds. G-CEM Linkforce resin cement was gently applied to crowns, and then crowns were pressed onto the prepared teeth with finger pressure. After five seconds of light-cure, any excess cement was removed with a probe. Subsequently, to complete polymerization, an additional 20 seconds of halogen/LED light was applied to each surface.

Group F1: After activating the capsule piston, the capsule was attached to the mixer and mixed for 10 seconds. The cement was evenly distributed to the crowns paying attention that there were no air voids. Then crowns were placed by pressing them onto the prepared teeth with finger pressure. Subsequently, excess cement was removed using a probe within the working time of two minutes and 15 seconds from the start of mixing. Following the manufacturer's instructions, the cement was allowed to be set for at least four minutes and 30 seconds after mixing under isolation.

Group F2: The cement was placed into the crown, ensuring no air voids were created. The crowns were then seated onto the teeth with finger pressure. Excess cement was removed, paying attention to the specified working time of two minutes and 15 seconds at 23 °C from the start of mixing, and a shorter working time at higher temperatures. Following the manufacturer's instructions, the cement was allowed to be set for at least four minutes and 30 seconds after mixing under isolation.

2.7 Clinical parameters

The retention status, plaque index (PI), gingival index (GI), and probing depth (PD) scores, periapical/periodontal pathology of PZCs were assessed. PI, GI and PD were scored with the help of a periodontal probe by one investigator (IS). Clinical and radiographic assessments were conducted to evaluate the presence of periapical pathology. The clinical parameters included palpation sensitivity, percussion sensitivity, pain history, and the presence of abscess/fistula. The radiographic parameters included internal and external root resorption, lesions in the furcation area, and widening of the periodontal space. Periapical radiographs of the teeth, recorded through follow-ups by one investigator (IS), and were evaluated and analyzed by one investigator (AC) for criteria such as internal-external root resorption, lesions in the furcation area, and widening of the periodontal space. Periodontal health was evaluated by assessing the PI, GI and PD values of the patient recorded by one investigator (IS) during follow-ups. To assess intra-observer agreement for the plaque index and gingival index, the difference between the first and second measurements (taken 10 days later by the same researcher on a randomly selected group of 20 patients) was evaluated using the Intra-class Correlation Coefficient (ICC) statistic.

Assessments were conducted at 1st, 3rd, 6th and 12th months. If the teeth exhibited continuous and/or spontaneous pain, abscess/fistula, or palpation and/or percussion sensitivity at follow-up appointments, and if radiographically there was no evidence of root resorption, lesions, or widening of the periodontal ligament space, these teeth were considered successful in terms of pulpal survival.

At follow-up appointments, PZCs were considered successful in terms of retention if they remained in the mouth, and unsuccessful if they did not.

2.8 Statistical analyses

Statistical analysis of the data was performed using the SPSS package program (SPSS 17.00 for Windows, Chicago, IL, USA) with descriptive statistics, reliability analysis (ICC), correlation analysis, and comparison tests. After the homogeneity of variance and normal distribution had been verified by Levene's test, for the evaluation of the quantitative data, the "Student T" test and Pearson Correlation Analysis were used. For nonparametric qualitative data, Mann-Whitney U, Wilcoxon, Kruskal-Wallis and chi-square (χ^2) tests were used.

Survival times were evaluated with the Kaplan-Meier Test, and the difference was tested with the Log Rank (Mantel-Cox) analysis. The results were evaluated at the 95% confidence interval, at the $p < 0.05$ significance level.

3. Results

ICC values for the intra-observer agreements on GI and PI scores were found to be 0.946. There was no statistically significant difference between the first and second measurements.

In total, 53 children (30 female, 23 male), aged 5 to 11 years old (8.2 ± 1.27) met the inclusion criteria and were enrolled in the study. Sixty primary molars from these 53 patients were treated with PZCs. At the end of the study, 15 PZCs were lost to follow-up due to patient drop-outs for various reasons (such as moving out of the city, conflicting work hours, inability to contact patients, *etc*.). The number of teeth followed up and analyzed at each control appointment for each group is summarized in the flow-chart (Fig. 1). The distribution of primary molars included in the study is summarized in Table 1.

Out of the 60 PZCs applied to patients primary molars, retention loss was observed in seven (11.7%) of them and periapical pathology was observed in eight (13.3%) teeth. The seven (11.7%) PZCs were considered failed, and the remaining 53 (88.3%) were considered successful in terms of retention. The eight (13.3%) PZCs which showed pulpal pathology symptoms were considered failed and the remaining 52 (86.7%) were considered successful in terms of pulpal survival. Table 2 displays the mentioned PZCs distribution by the type of luting cement used. No significant differences were observed between the groups when inter-group comparisons were made based on the retention loss. Group F2 showed the highest success in terms of pulpal survival (Table 2). A Kaplan-Meier survival analysis graph is shown in Fig. 3.

Table 3 summarizes the patients' mean total PI, GI and PD values recorded during 12-month follow-up. Across all luting cement groups, there was an observed increase in patients' PI, GI and PD scores. Nevertheless, this increment did not reach statistical significance ($p > 0.05$).

The mean PI, GI and PD values for teeth with PZC at the 1st, 3rd, 6th and 12th months are also summarized in Table 3. When inter-group comparisons were made, no significant difference was observed in any parameter between the groups at any time interval.

A comparison was also conducted between the mean PI, GI and PD values of the teeth with PZCs, and the mean PI, GI and PD values of the patients' total mouth (Fig. 4a–c). Over the 12-month follow-up period, the PI values for the teeth treated with PZCs decreased. In contrast, there was a slight but not statistically significant ($p > 0.05$) increase in the total oral PI values recorded for the patients over the same period. At the 12-month follow-up, the PI values of the teeth with PZCs were significantly lower than the patients' total oral PI values ($p = 0.001$). A statistically significant difference was observed only in the 1st month when comparing the GI values of the teeth with PZC with the patients' total oral GI values ($p = 0.002$). No statistically significant difference was observed ($p > 0.05$) between the PD values obtained from teeth treated with PZCs and the patients' total oral PD values.

4. Discussion

In this study, we investigated the clinical success of PZCs cemented with four different luting cements in our clinic and assessed their impact on oral health.

While zirconia crowns have had a longstanding presence for dentistry in adult patients, the use of zirconia crowns, particularly for full-coverage restorations in pediatric dentistry, especially for primary teeth, is a relatively recent development that began about a decade ago. The first commercially available

TABLE 1. Distribution of the included primary molars.

Tooth	Group BC	Group GC	Group F1	Group F2	Total
#54	2, 3.3%	3, 5.0%	2, 3.3%	1, 1.7%	8, 13.3%
#55	3, 5.0%	2, 3.3%	2, 3.3%	2, 3.3%	9, 15.0%
#64	2, 3.3%	1, 1.7%	3, 5.0%	2, 3.3%	8, 13.3%
#65	1, 1.7%	2, 1.7%	1, 1.7%	2, 3.3%	6, 10.0%
#74	1, 1.7%	2, 3.3%	2, 3.3%	2, 3.3%	7, 11.7%
#75	2, 3.3%	2, 3.3%	2, 3.3%	2, 3.3%	8, 13.3%
#84	2, 3.3%	1, 1.7%	1, 1.7%	2, 3.3%	6, 10.0%
#85	2, 3.3%	2, 3.3%	2, 3.3%	2, 3.3%	8, 13.3%
Total	15, 25.0%	15, 25.0%	15, 25.0%	15, 25.0%	60, 100.0%

TABLE 2. Distribution of failed PZCs among the groups.

Status	Group				
	Group BC	Group GC	Group F1	Group F2	Total
PZC (Decementation) (n, %)	2, 13.3%	1, 6.6%	2, 13.3%	2, 13.3%	7, 11.7%
PZC (Periapical Pathology) (n, %)	4, 26.6%	3, 20.0%	1, 6.6%	0, 0.0%	8, 13.3%

PZC: Prefabricated Pediatric Zirconia Crowns.

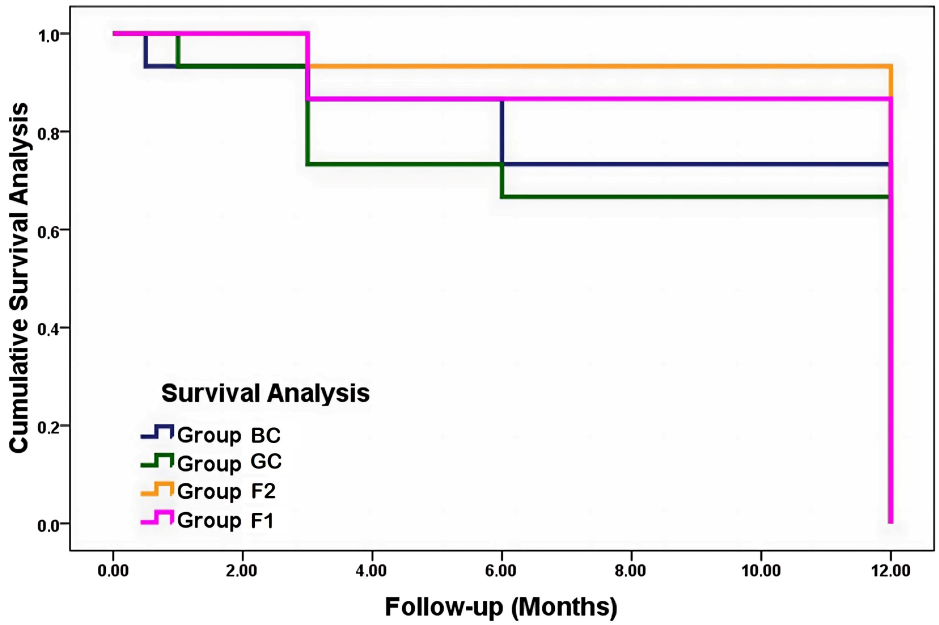

FIGURE 3. Kaplan-Meier survival analyses.

TABLE 3. Mean PI, GI and PD values of the patients and of the teeth with PZC.

	n	Group BC Mean ± SD	Group GC Mean ± SD	Group F1 Mean ± SD	Group F2 Mean ± SD	*p*
Mean PI, GI and PD values of the patients						
PI Baseline	60	1.46 ± 0.34 (n = 15)	1.47 ± 0.37 (n = 15)	1.50 ± 0.27 (n = 15)	1.43 ± 0.37 (n = 15)	0.95
PI 1st-Month	59	1.54 ± 0.40 (n = 15)	1.47 ± 0.27 (n = 14)	1.55 ± 0.25 (n = 15)	1.50 ± 0.24 (n = 15)	0.89
PI 3rd-Month	53	1.51 ± 0.38 (n = 14)	1.64 ± 0.27 (n = 11)	1.63 ± 0.39 (n = 14)	1.50 ± 0.31 (n = 14)	0.59
PI 6th-Month	51	1.59 ± 0.32 (n = 12)	1.70 ± 0.30 (n = 11)	1.77 ± 0.37 (n = 14)	1.59 ± 0.23 (n = 14)	0.37
PI 12th-Month	45	1.58 ± 0.30 (n = 9)	1.70 ± 0.29 (n = 11)	1.85 ± 0.37 (n = 12)	1.62 ± 0.32 (n = 13)	0.22
GI Baseline	60	1.28 ± 0.24 (n = 15)	1.19 ± 0.14 (n = 15)	1.20 ± 0.16 (n = 15)	1.27 ± 0.19 (n = 15)	0.42
GI 1st-Month	59	1.27 ± 0.20 (n = 15)	1.20 ± 0.15 (n = 14)	1.24 ± 0.17 (n = 15)	1.27 ± 0.20 (n = 15)	0.95
GI 3rd-Month	53	1.33 ± 0.26 (n = 14)	1.32 ± 0.21 (n = 11)	1.32 ± 0.29 (n = 14)	1.32 ± 0.14 (n = 14)	0.83
GI 6th-Month	51	1.25 ± 0.21 (n = 12)	1.32 ± 0.21 (n = 11)	1.39 ± 0.29 (n = 14)	1.31 ± 0.15 (n = 14)	0.45
GI 12th-Month	45	1.32 ± 0.27 (n = 9)	1.31 ± 0.14 (n = 11)	1.40 ± 0.22 (n = 12)	1.44 ± 0.27 (n = 13)	0.47
PD Baseline	60	1.63 ± 0.14 (n = 15)	1.72 ± 0.15 (n = 15)	1.65 ± 0.16 (n = 15)	1.66 ± 0.25 (n = 15)	0.60
PD 1st-Month	59	1.70 ± 0.21 (n = 15)	1.70 ± 0.16 (n = 14)	1.76 ± 0.11 (n = 15)	1.72 ± 0.11 (n = 15)	0.68
PD 3rd-Month	53	1.73 ± 0.12 (n = 14)	1.79 ± 0.06 (n = 11)	1.77 ± 0.08 (n = 14)	1.76 ± 0.10 (n = 14)	0.42
PD 6th-Month	51	1.72 ± 0.10 (n = 12)	1.76 ± 0.70 (n = 11)	1.75 ± 0.10 (n = 14)	1.74 ± 0.05 (n = 14)	0.75
PD 12th-Month	45	1.73 ± 0.10 (n = 9)	1.74 ± 0.03 (n = 11)	1.76 ± 0.07 (n =12)	1.76 ± 0.04 (n = 13)	0.68

TABLE 3. Continued.

	n	Group BC Mean ± SD	Group GC Mean ± SD	Group F1 Mean ± SD	Group F2 Mean ± SD	*p*
Mean PI, GI and PD values of the teeth with PZC						
PI 1st-Month	59	0.26 ± 0.39 (n =15)	0.35 ± 0.43 (n = 14)	0.18 ± 0.34 (n = 15)	0.30 ± 0.45 (n = 15)	0.71
PI 3rd-Month	53	0.16 ± 0.27 (n = 14)	0.29 ± 0.36 (n = 11)	0.19 ± 0.36 (n = 14)	0.05 ± 0.10 (n = 14)	0.24
PI 6th-Month	51	0.20 ± 0.33 (n = 12)	0.34 ± 0.52 (n = 11)	0.21 ± 0.35 (n = 14)	0.17 ± 0.28 (n = 14)	0.73
PI 12th-Month	45	0.02 ± 0.08 (n = 9)	0.27 ± 0.34 (n = 11)	0.30 ± 0.56 (n = 12)	0.14 ± 0.34 (n = 13)	0.36
GI 1st-Month	59	1.41 ± 0.63 (n = 15)	1.39 ± 0.33 (n = 14)	1.60 ± 0.44 (n = 15)	1.48 ± 0.43 (n = 15)	0.64
GI 3rd-Month	53	1.51 ± 0.39 (n = 14)	1.36 ± 0.30 (n = 11)	1.51 ± 0.50 (n = 14)	1.32 ± 0.31 (n = 14)	0.43
GI 6th-Month	51	1.41 ± 0.37 (n = 12)	1.20 ± 0.24 (n = 11)	1.16 ± 0.21 (n = 14)	1.39 ± 0.33 (n = 14)	0.07
GI 12th-Month	45	1.41 ± 0.39 (n = 9)	1.34 ± 0.37 (n = 11)	1.28 ± 0.30 (n = 12)	1.64 ± 0.43 (n = 13)	0.11
PD 1st-Month	59	1.76 ± 0.28 (n = 15)	1.67 ± 0.27 (n = 14)	1.80 ± 0.10 (n = 15)	1.80 ± 0.18 (n = 15)	0.35
PD 3rd-Month	53	1.80 ± 0.20 (n = 14)	1.76 ± 0.11 (n = 11)	1.75 ± 0.12 (n = 14)	1.75 ± 0.22 (n = 14)	0.87
PD 6th-Month	51	1.77 ± 0.13 (n = 12)	1.76 ± 0.13 (n = 11)	1.85 ± 0.34 (n = 14)	1.73 ± 0.29 (n = 14)	0.65
PD 12th-Month	45	1.77 ± 0.14 (n = 9)	1.78 ± 0.07 (n = 11)	1.76 ± 0.11 (n = 12)	1.78 ± 0.10 (n = 13)	0.93

PZC: Prefabricated Pediatric Zirconia Crowns; PI: Periodontal Index; GI: Gingival Index; PD: Probing Depth; SD: Standard deviation.

brand of PZCs, EZCrowns (Sprig Oral Health Technologies, USA), was introduced in the year 2008 [27]. PZCs were developed to harness the aesthetic, biocompatible, and color stability properties of dental zirconia for use in pediatric dental patients [9].

Studies have indicated favorable outcomes with the use of PZCs in both anterior and posterior teeth [14, 22, 28]. El Shahawy *et al*. [14] assessed the effectiveness of PZCs applied to the maxillary anterior deciduous teeth of 25 patients aged between 2 and 5 years, over a 2-year follow-up. All crowns were cemented using Fuji IX™ (GC, USA), and the results revealed a success rate of 95% in the 1st year and 80% in the 2nd year. They concluded that for the restoration of primary teeth with significant material loss, PZCs offer excellent aesthetic properties and integrate well with the gingival tissue. Geduk *et al*. [29] evaluated the SSCs and PZCs applied to permanent first molar teeth, comparing the success rates over an 18-month period. They reported that the cumulative survival rate for PZCs was 100%. In their systematic review, Alrashdi *et al*. [30] reported the mean survival for PZCs as 89%. Similarly, in the present study, we found the one-year success rate of PZCs to be 88.3%.

The number of clinical studies examining the effect of luting cement type on the retention success of PZCs is limited. Due to its inherent properties, bonding to zirconia presents significant challenges [9, 10, 31]. A recent retrospective clinical study suggested that self-adhesive resin cements demonstrate superior clinical success compared to GICs [26]. In an *in-vitro* study Stepp *et al*. [32] reported that PZCs luted with BioCem™ (Nusmile) offered enhanced resistance to microleakage when compared to PZCs luted with GIC (KetacCem™, 3M, USA) cement. Furthermore, a previous *in-vitro* study investigating the mechanical properties of PZCs luted with different types of cement (BioCem™, Nusmile; G-CEM LinkForce™, GC; Fuji One, GC; FujiCEM® 2, GC) indicated that PZCs bonded with resin cements exhibited higher performance [8]. However, limited clinical studies conducted with PZCs suggest more favorable results with GICs [15, 16]. In a split-mouth clinical trial, comparing the effect of two luting types of cement, BioCem™ (Nusmile) and Fuji IX™ (GC Corporation, Tokyo, Japan) on the retention of PZCs, Azab *et al*. [15] found that Fuji IX™ demonstrated better retention in the 36-month follow-up. They reported that at the end of the study, the PZCs cemented with Fuji IX™ showed 88% success while PZCs cemented with bioactive cement (BioCem™) showed only 40% success. In a similar vein, Srinivasan *et al*. [16]

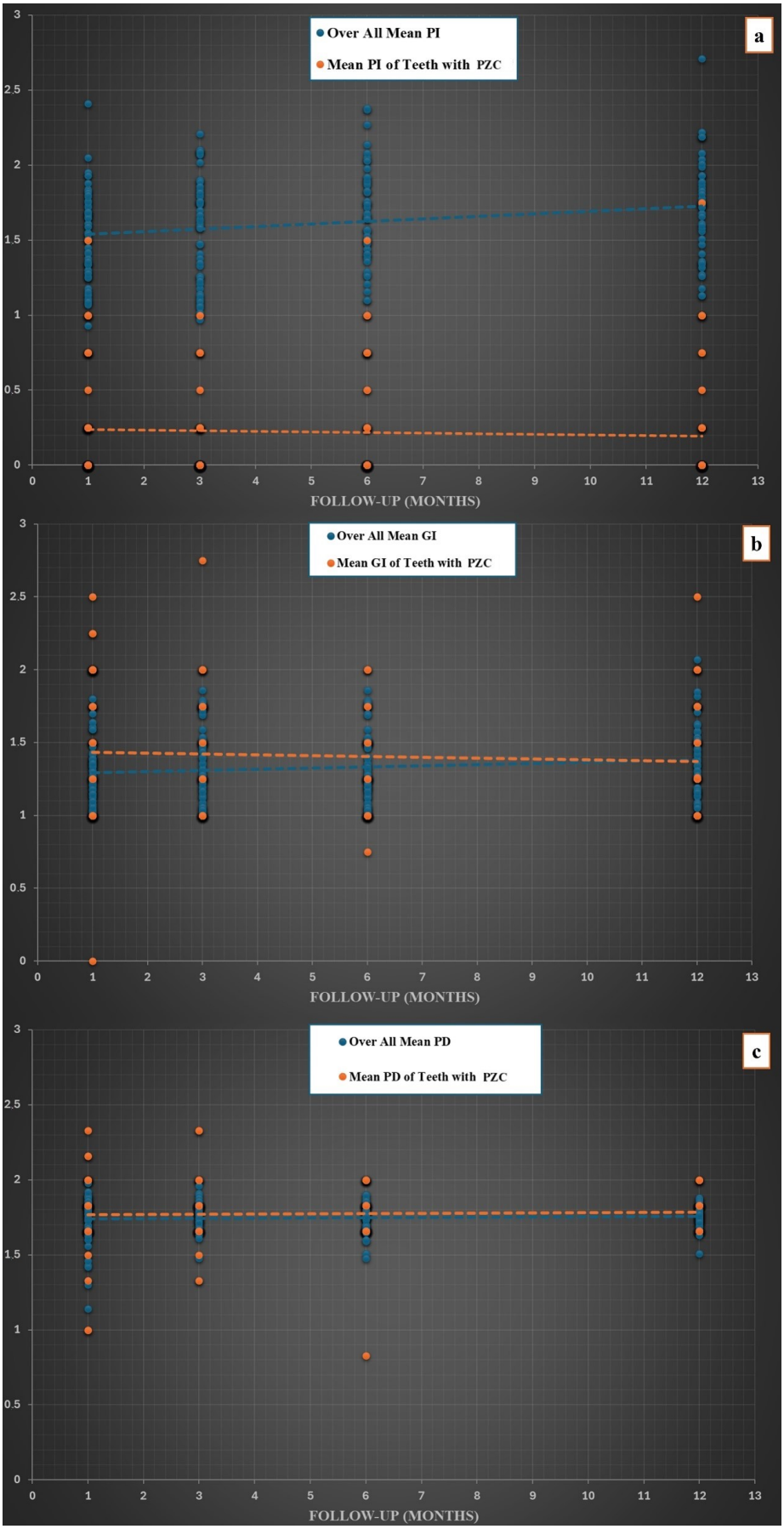

FIGURE 4. Comparative graph of the patients' total: (a) PI values and the mean PI values of teeth treated with PZCs, (b) GI values and the mean GI values of teeth treated with PZCs, (c) PD values and the mean PD values of teeth treated with PZCs. PZC: Prefabricated Pediatric Zirconia Crowns; PI: Periodontal Index; GI: Gingival Index; PD: Probing Depth.

compared the clinical success of PZCs applied using three different cement types: GIC (Fuji I®, GC Corporation, Tokyo, Japan), RMGIC (BioCem™, Nusmile), and adhesive resin cement (Clearfil™ SA Luting, Kuraray, Japan). After a 3-year follow-up, they reported survival rates for PZCs as follows: 77%, 70% and 50%, respectively, with the highest survival rate observed for GIC. In both studies investigators attributed this to the moisture sensitivity of BioCem™ due to its resin content. In our study, we did not find any difference among the groups in terms of retention (H0-1 hypothesis is rejected). Unlike the studies mentioned before, the primary reason for the lack of significant results among the groups in our study may be attributed to the limited follow-up period of only one year. A longer follow-up duration may be necessary to achieve a significant difference. More comprehensive clinical studies are needed to fully compare the effects of luting cements on the retention and longevity of PZCs. We suggest that the choice of cement types be guided by the patient's cooperation and the extent of remaining dental tissue. For teeth that are significantly compromised, resin-based cements may be employed to improve bond strength. Conversely, if adequate moisture control for resin cements cannot be ensured, traditional GICs should be considered as a viable alternative.

The cytotoxicity of dental cements can vary depending on the type of cement used, significantly impacting pulpal survival and periapical pathology. Research indicates that RMGICs exhibit greater cytotoxic effects compared to GICs [33, 34]. Additionally, non-polymerized residual monomers of resins have been shown to induce apoptosis and cell cycle arrest in pulp cells [35]. Furthermore, it has been shown that adhesive cements elicit a higher expression of substance P—a key neuropeptide involved in the generation of neurogenic inflammation—from human pulp compared to glass-ionomer cements [36]. The number of studies investigating the pulpal survival rates of teeth treated with PZCs is limited. Geduk *et al*. [29] reported that, over an 18-month follow-up period, none of the 24 first permanent molar teeth treated with PZCs exhibited any signs of periapical pathology. Ozdemir *et al*. [37] reported a 93.1% pulpal survival rate at 18 months for 43 maxillary primary anterior teeth treated with PZCs. In this study, where we examined 60 PZCs applied to the primary molar teeth, we found the pulpal survival rate to be 86.7%. Although no significant differences were observed among the groups, GIC and RMGIC groups demonstrated slightly better outcomes concerning pulpal survival (H0-2 hypothesis is rejected). None of these studies investigated the effect of different luting cements on the pulpal survival rates, but the discrepancy between reported survival rates in the studies could be due to differences in sample sizes or the variation in the teeth treated with PZCs across studies. Additionally, the pulpal survival rate of teeth treated with PZCs may be dependent on operator sensitivity.

Many studies have shown that PZCs reduce plaque accumulation and exhibit compatibility with periodontal tissues due to their smooth and polished surface structures. In most of the studies, the impact of PZCs on gingival health has mainly been compared to other full-coverage restorations [7, 14, 22, 37, 38]. It is known that excess cement residues remain in the subgingival area following the cementation of indirect restorations [11, 12]. These remnants have been shown to induce inflammation in the surrounding periodontal tissues [13]. While some studies suggest that different types of cements leave varying amounts of residue and exert different effects on adjacent tissues [17], other research indicates that the quantity of residual cement does not significantly differ among cement types [18, 19]. The number of studies comparing the impact of PZCs on gingival health applied using different luting cements is limited. Srinivasan *et al*. [16] found that PZCs luted with traditional GIC had lower plaque accumulation compared to those luted with BioCem™ and adhesive resin cement after three years. The results of our study showed no significant difference among groups (H0-2 hypothesis is rejected) and, did not coincide with the findings of Srinivasan *et al*. [16]. Although the PI values for teeth treated with PZCs significantly decreased regardless of the group, the patients' oral hygiene conditions declined over the course of 12 months. We believe this decline may be related to a decrease in motivation due to the extended time intervals between appointments.

Additionally, in our study, when comparing the patients' total oral PI values with the PI values obtained from the teeth treated with PZCs, it was observed that the mean PI values of the teeth restored with PZCs were significantly lower than the patients' total PI values. This suggests that even in cases where patients have inadequate oral hygiene habits, PZCs can substantially reduce plaque accumulation.

The one limitation of this study was the 12-month follow-up period. Longer follow-up durations would yield more comprehensive results regarding the luting cements used. Another limitation is that, although all crowns in the study were placed by a single researcher and patients were selected based on inclusion criteria, full standardization cannot be claimed due to the variability of factors associated with individual patients such as caries characteristics and different teeth size.

5. Conclusions

In conclusion, while longer follow-up periods and a greater number of studies are needed to investigate the impact of luting cement on the clinical success of PZCs, the absence of a difference among the groups in short-term success indicates that an ideal cement for luting the zirconia crowns cannot be conclusively recommended. The luting cement can be preferred according to the patient's cooperation and the remaining tooth tissue, considering the technical sensitivity of application steps.

AVAILABILITY OF DATA AND MATERIALS

The data supporting this study's findings are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

AUTHOR CONTRIBUTIONS

HK—conceptualization, data curation, formal analysis, investigation, methodology, validation, and writing-review and editing. IS—conceptualization, data curation, investigation, methodology, validation, writing-review and editing. AC—

data curation, validation, writing-original draft, and writing-review and editing. ZZC—conceptualization, data curation, formal analysis, validation, writing-review and editing. ZK—conceptualization, data curation, formal analysis, validation, writing-review and editing. All authors gave their final approval on the version that will be published. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted following the Declaration of Helsinki. The study protocol was reviewed and approved by the Ethical Committee for the Clinical Researches of the Medical Faculty of Akdeniz University (IRB no. 0904504/400). The eligibility for research was assessed, and informed consent was obtained from both the parents/guardians and patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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