DOİ:10.34108/eujhs.1040023

SAĞLIK BİLİMLERİ DERGİSİ
JOURNAL OF HEALTH SCIENCES
Erciyes Üniversitesi Sağlık Bilimleri Enstitüsü Yayın Organıdır

Araştırma Yazısı 2021; 30: 238-244

CLINICAL AND RADIOLOGICAL EVALUATION OF A PREFORMED COMPOSITE CROWN IN SEVERELY DECAYED PRIMARY MOLARS
AŞIRI MADDE KAYIPLI SÜT AZI DİŞLERİNDE BİR PREFABRİK KOMPOZİT KRONUN BAŞARISININ KLİNİK VE RADYOLOJİK DEĞERLENDİRİLMESİ

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ABSTRACT

The aim of this study was to evaluate the clinical and radiographic success and parental acceptance of a preformed composite crown (PTC) for primary molars and compare with that of conventional stainless steel crowns (SSC).A total of 38 children (Girls:12, Boys:26) infivenine age range, selected from among patients attending the pediatric dentistry clinic. Seventy-sixth crowns were applied in a split-mouth design with a random allocation for mandibular primary 1st and 2nd molars. Assessment of the clinical and radiographic performance of the restorations was performed by two calibrated examiners during 12-month follow-up period and parental satisfaction was determined for both crowns.Total clinical success rates were 100% and 63% for SSCs and PTCs, respectively, at the end of 12-month follow-up, and the difference was statistically significant ($p<0.05$). Despite the high rates of cementation and endodontic failures, parents were much more satisfied with PTCs ($p<0.05$). It has been determined that SSCs is more successful than PTCs, but PTCs were preferred by parents due to their aesthetic features.Despite the high rate of aesthetic satisfaction in the PTC group, studies are needed to evaluate the coronal leakage factor in terms of its potential to cause the problems of "falling out of crowns" and "endodontic problems", observed as clinical failure.

Keywords: Composite resins, primary tooth, stainless steel, tooth crown.

ÖZ

Bu araştırmada aşırı madde kaybı olan süt azı dişlerinin tedavisinde prefabrik kompozit kuronlar (PK) ile paslanmaz çelik kuronların (PÇK) başarısının klinik ve radyografik olarak karşılaştırılması ve ebeveynlerin memnuniyetinin ölçülmesi amaçlanmıştır. Çalışma Pedodonti Anabilim Dalı'na başvuran, yaşları beş-dokuz arasında değişen 38 çocuk (12 kız, 26 erkek) hasta üzerinde yürütülmüştür. Kuronlar, aşırı madde kayıplı birinci ve ikinci alt süt azı (n=76) dişine split-mouth tekniği ile uygulanmıştır. 12 aylık takip süresi sonunda iki adet kalibre olmuş değerlendirici tarafından klinik ve radyolojik başarı değerlendirilmiş ve ebeveyn memnuniyeti ölçümü yapılmıştır. Genel klinik başarı oranları 12 aylık takip süresi sonunda PÇK grubu için %100 iken PK grubu için %63 olarak tespit edilmiştir ve aradaki farkın istatistiksel olarak anlamlı olduğu belirlenmiştir. PKkuronlarda "Endodontik sorunlar" ve "kuronların düşmesi" gibi başarısızlıklara rağmen ebeveynlerin memnuniyet derecesinin PÇK'lara kıyasla daha yüksek olduğu bulunmuştur ($p<0.05$). Tüm klinik ve radyografik değerlendirme kriterlerinde PÇK'nın PK'ya oranla daha başarılı olduğu ancak estetik özellikleri nedeniyle PK'ların daha çok tercih edildiği saptanmıştır. PK grubunda estetik açıdan memnuniyet oranının yüksek olmasına karşılık klinik başarısızlık olarak gözlenen "kuronların düşmesi" ve "endodontik sorunlar" problemlerine neden olma potansiyeli açısından etken olabilecek faktörlerin değerlendirileceği çalışmalara ihtiyaç olduğu düşünülmektedir.

Anahtar kelimeler: Dental taç, kompozitrezin, paslanmaz çelik, süt dişi.

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Makale Geliş Tarihi : 19.04.2021
Makale Kabul Tarihi: 23.08.2021

INTRODUCTION

Despite the development of preventive dentistry, dental decay is still one of the diseases of great prevalence, mainly in children. Primary molars with large carious lesions are frequently encountered in the clinical practice of pediatric dentistry. They must be properly restored to reestablish their anatomy, and thus their phonetic, aesthetic and space-maintaining functions in the dental arches (1,2).

Restoration of these teeth poses a challenge, and important issues such as durability, biocompatibility, ease of application, compatibility with natural tooth tissue and the need for minimum number of appointment should be considered in order to achieve satisfactory results. For many years, the stainless steel crown (SSC) has been shown to be the choice of restoration for teeth having more than Class II restorations because it protects the tooth from fracture and minimizes the possibility for leakage (1-3). However, these materials do not offer aesthetically satisfactory results. Several attempts have been made to improve upon the esthetics of stainless steel crowns, but to date none of these approaches has been very successful (4-7). Although there have been some indirect methods of crown applications, their being time consuming, costly and unable to be made in a single appointment have restricted their use (8-11). Finally, pre-formed zirconia crowns are aesthetic, retentive, biocompatible and rapid to place, but they cannot be crimped, require an invasive preparation, cause a slight abrasion of the opposing teeth and can fracture during placement (11-12). As a result, pediatric dentists have emphasized the identification of a more acceptable, easily applicable and cost effective esthetic solution (2,13-15).

Self-supporting, malleable and curable material materials are a new class of dental materials. Being wax like and therefore malleable, they are easily adapted to the shape of the tooth to be restored, and following light curing, they take on properties similar to resin composite materials. Protemp Crowns (3M ESPE, St Paul, USA) (PTC) are an example of this novel class of material; and these crowns are available in a variety of sizes for maxillary and mandibular permanent teeth.

The wear of the PTCs were found to be similar to permanent composite restorative materials (15-16). In addition; the durability of PTC has been tested by researchers (17) with the results indicating that fracture resistance, marginal adaptation and wear after artificial aging, which is expected to withstand the loading in posterior areas. These properties have prompted a number of clinicians to explore the use of PTCs as a long-term provisional restoration (2,13,18). These results have demonstrated that the potential for the use of PTCs as a long-provisional restoration for permanent teeth is promising. Thus, it could be hypothesized that the physical properties of PTCs are appropriate for restoring severely decayed primary molars (15-18). Therefore, the present study aimed to clinically evaluate and compare the use of PTCs and SSCs in primary molars.

MATERIALS AND METHODS

PS Power and Sample Size Calculation Program, version 2.1.3 were used for the sample size calculation. A sample size of 30 was planned for each study group to detect a significant difference with a power of 80 and a sensitivity of 75%. The minimum sample size increased to 76 in total, assuming a 20% loss in each group.

Inclusion criteria were given in Table I. Ethical approval was received from the Institutional Review Board (No:149/1). Before giving informed consent for their children to participate in the study, the parents were informed about the risks and possible consequences of the treatment and alternative treatment options. The study followed the principles of the Declaration of Helsinki. A matched-pair study design was used, as both the PTC and the SSC would be subjected to a similar oral environment and comparable hygiene habits. 38 children who needed at least 2 crown restorations of mandibular molars were included in the study. Randomization was achieved with a die where each subject had an equal possibilityof being assigned to either one or another group. The crowns were applied with split mouth design to mandibular left and right primary molars. Adjacent and antagonist teeth were sound or previously restored.

Treatment Procedure

All treatments were applied by the same pediatric dentist under local anesthesia and rubber dam isolation. The pulp status was assessed following caries removal

Table I: Specified inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Patient	• Fit and healthy (ASA I or II) • Patient 5-9 ys old • Behavioral rating score of 3 or 4 on the Frankl scale • Had at least two restorable severely decayed mandibular first or second primary molars These should be in proximal contact with an adjacent tooth and with an antagonist.	• ASA ≥III • Informed consent not achieved
Tooth	• Multi-surface caries • Postendodontic treatment • Caries free or treated opposing and proximal contact teeth • Normal lamina dura and periodontium	• Acute infection • Abscess or fistula • Mobility • Pre-operative radiographic pathology • Exfoliation imminent

prior to completing crown preparation, and appropriate pulp therapy was performed according to current best practice guidelines (19). After that, teeth were restored with reinforced glass ionomer cement (Ketac Molar, 3M ESPE, USA). For the PTC (3M ESPE) and SSC (3M ESPE,USA) preparation, the instructions of manufacturer were used to develop a step-by-step customized tooth preparation and crown fit.

In the PTC group; or primary first molars, PTC crowns manufactured for premolar teeth with a mesiodistal width of six-nine mm and for primary second molars PTC crowns manufactured for permanent molars with a width of 19 mm were used. The occlusal surface was prepared 2 mm with a dia diamond bur (Meisinger, Hager&Meisinger GmbH, Germany). The mesial and distal contact points were removed with flame (Meisinger, Hager&Meisinger GmbH, Germany) burs and one and a half-two mm steps were prepared for all over the tooth supragingivally. The selected crown was trimmed according to the gingival contour and placed onto the prepared tooth. Margins were adapted, occlusion adjusted and cured for two-three seconds with LED light (Elipar S10 LED Curing Light, 3M ESPE, St. Paul, USA) while it was on the tooth. The crown was gently removed from the tooth and cured for 60 seconds at each surface for final curing. Sof-Lex discs (3M ESPE, St. Paul, USA) were used to finish the surfaces and then the crown was cemented using resin modified glass ionomer cement RMCIS (RelyX Luting, 3M ESPE, St. Paul, USA).

For the SSC group; the appropriate sized crown was selected with the appropriate mesiodistal width. The occlusal surface was prepared 2 mm with a dia diamond bur. The mesial and distal contact points were removed with flame burs. An unstepped preparation was done subgingivally for all over the tooth. The crown was placed from lingual and rolled towards buccal surface. Gingival tissue was examined in order to determine if the crown produced blanching of the marginal gingival tissue. Occlusion was checked. If necessary, the long sides were shortened. The margins of the crown were contoured for better gingival adaptation. The crown was polished with a rubber to remove scratches anda bitewing radiograph was taken to verify proximal integrity. If appropriate, the crown was cemented using resin modified glass ionomer cement RMCIS (RelyX Luting).

At the end of the first visit, the parents were given oral hygiene instructions and included in the appointment schedule for follow-up visits.

Follow-up Examinations

Clinical and radiographic follow-up examinations were performed at third, sixth, and 12th months by two experienced and calibrated pediatric dentists (SA, TB). At each follow-up visit, pairs of bitewing radiographs were taken and children were clinically examined with a dental mirror and a probe in a dental chair. In case of disagreement, the teeth and radiographs were reevaluated and the case was discussed to reach consensus.

The clinical and radiographic outcome variables were given in Table II. These variables were modified from previous studies (5,20,21). PTC crown was considered clinically successful if the surface was smooth, there was no chipping, or the color remained good or acceptable.In minor cracks, PTCs were restored with composite resin restoration. Radiographically, if the margins were properly adapted and there was no pulpal or periapical pathosis, the teeth were stated as successful.

Clinical and radiographic failure parameters for the total survival rate evaluation were acute infection, soft tissue swelling, abscess or fistula, sensitivity to percussion and/or palpation, pathological tooth mobility, postoperative radiographic pathology, crown loss following cement failure.

In addition, parental satisfaction rating was evaluated at the end of 12-months according to Roberts et al. (22). Parents scored both crowns for their look, color, shape, size and reliability from one to five and the satisfaction rates for both groups were calculated.

Statistical Analysis

All data collected was recorded on registration forms and analyzed by the software Statistical Programme for Social Sciences (SPSS) (version 15.0). After descriptiveanalysis, chi-square test was used to study differences between the materials. Significance was set at $p< 0{\cdot}05$.

Table II: Cinical and radiographical outcome variables

Category	Scores	Criteria
Clinical assessment for anatomical integrity	0	Crown appears normal; no cracks, chips or fractures
	1	Small but noticeable areas of material loss
	2	Large or complete loss of crown
Clinical assessment of marginal adaptation	0	Good with sealed margins
	1	Poor, the explorer detected an open margin
Clinical assessment for color match of PTC	0	No noticeable difference from adjacent teeth
	1	Slight shade mismatch
	2	Obvious shade mismatch
Radiographic assessment for interproximal bone level	0	The distance between the crest of interproximal bone and the cement enamel junction was 2 mm or less
	1	Bone was resorbed when the distance more than 2 mm
Radiographic assessment of marginal adaptation	0	Adequate
	1	Inadequate when away from tooth surface more than 1 mm
Radiographic assessment of pulpal/periapical tissues	0	Healthy, no pathosis noted
	1	Pathosis apparent, requiring immediate treatment

RESULTS

A total of 38 children (Girls:12, Boys:26) between ages of five and nine (Mean:7.1; Standard deviation: 1.189) were included in the study. 76 teeth requiring endodontic treatment (31 first primary molars, 45 second primary molars) were restored either using SSCs (n:38) or PTCs (n:38). 39 indirect pulp capping (SSC:20, PTC:19) and 37 pulpotomies (SSC:18, PTC:19) were performed.

Of 38 patients, 36 were evaluated in the third evaluation period, 32 in the sixth month, and, 29 patients in the 12th month 29. Clinical and radiographic outcomes have been presented in Table III.

Table III: Findings concerning clinical and radiographical variables

		3 months n (%) (36 patients were evaluated)		6 months n (%) (32 patients were evaluated)		12 months n (%) (29 patients were evaluated)	
Category		**SSC**	**PTC**	**SSC**	**PTC**	**SSC**	**PTC**
Anatomical integrity	0	36 (100)	35 (97.2)	32 (100)	30 (96.8)	29 (100)	21 (84)*
	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8)
	2	0 (0.0)	1 (2.8)	0 (0.0)	1 (3.2)	0 (0.0)	2(8)
Clinical assessment of Marginal adaptation	0	36 (100)	34 (97.1)	32 (100)	27 (90)	29 (100)	20 (87)
	1	0 (0.0)	1 (2.9)	0 (0.0)	3 (10)	0 (0.0)	3 (13)
Clinical assessment for Color match of PTC	0	_	29 (8.9)	_	17 (56.7)	_	9 (39.1)
	1		6 (17.1)		12 (40.0)		13(56.5)
	2		0 (0.0)		1 (3.3)		1 (4.4)
Radiographic assessment for Interproximal bone level	0	36 (100)	34 (97.1)	31(96.9)	27 (90)	29 (100)	21(91.3)
	1	0 (0.0)	1 (2.9)	1 (3.1)	3 (10)	0 (0.0)	2 (8.7)
Radiographic assessment of Marginal adaptation	0	36 (100)	33 (94.3)	31(96.9)	27 (90)	29 (100)	20 (87)
	1	0 (0.0)	2 (5.7)	1 (3.1)	3 (10)	0 (0.0)	3 (13)
Radiographic assessment of pulpal/periapical tissues	0	36 (100)	36 (100)	32 (100)	28 (90,3)	29 (100)	23 (92)
	1	0 (0.0)	0 (0.0)	0 (0.0)	3 (9.7)	0 (0.0)	2 (8)

*p<0.05

Results of Clinical Variables

Anatomical integrity: SSC exhibited 100% anatomical integrity during 12-month follow-up; while PTC exhibited two teeth with Score 1 at the 12th month follow-up and restored with composite resin; and one tooth in the 3th month, one tooth in the sixth month and two teeth in the 12th month exhibited Score 2. At the end of 12-month follow-up, SSC showed 100% successful anatomical integrity (Score 0) while PTC showed 84% and the difference in success between the materials at the 12-month follow-up was statistically significant (p<0.05).

Marginal adaptation: SSC showed excellent marginal adaptation (Score 0) during the 12-month follow-up while one tooth in the sixth month, three teeth in the sixth month and three teeth in the 12th month showed Score 1 adaptation in the PTC group. However, the difference between the groups was not statistically significant (p>0.05).

Color stability (PTC group): During the 12-month follow-up, five teeth in the PTC group exhibited slight mismatch in color (Score 1) (Figure Ia), and two teeth showed obvious mismatch in color (Score 2) (Figure Ib).

Results of Radiographic Variables

Interproximal bone level assessment: During the follow-ups, only one tooth in the SSC group showed interproximal bone resorption more than two mm at the sixth month follow-up; while six teeth in the PTC group (one in the third month, three in the sixth month and two in the 12th month) showed more than two mm bone resorption (Score 1). However, the difference between the groups was not statistically significant (p>0.05).

Marginal adaptation: SSC showed 100% good marginal adaptation during one-year follow-up (Score 0); while one tooth in the third month, three teeth in the sixth month and three teeth in the 12th month in the PTC group showed inadequate adaptation (Score 1). Nevertheless, the difference between the groups for radiographic marginal adaptation was not statistically significant (p>0.05).

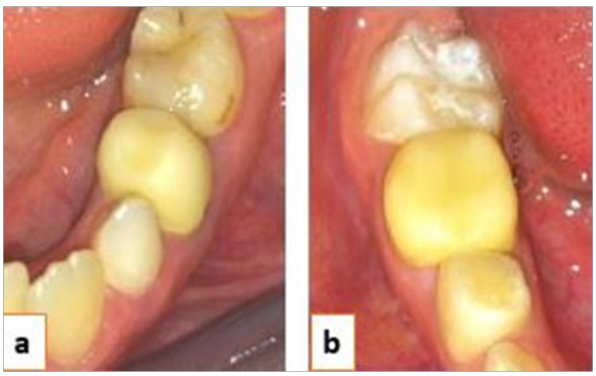

Figure Ia: Slight shade mismatch (Score 1) **Ib:** Obvious shade mismatch (Score 2)

Total Success Rates

Teeth with any of the symptoms identified as acute infection, soft tissue swelling, abscess or fistula, pathological tooth mobility, sensitivity to percussion and/or palpation, post-operative radiographic pathology (periapical and/or furcal radiolucency, external or in-

ternal root resorption, loss of lamina dura), crown loss following cement failure at the end of 12-month follow-up were scored as unsuccessful. During 12-month follow-up, there was no cementation failure in the SSCs, while four teeth in PTC were lost as a result of cement failure. It was observed that four of the teeth that were evaluated as clinically and radiographically unsuccessful in the PTC group were treated with indirect pulp capping, and the other two were treated with pulpotomy. SSCs showed no endodontic failures. Total success rates were given in Table IV. SSCs were found to be statistically more successful in the sixth and 12th month follow-ups ($p<0.05$).

Table IV: Total success rates for the PTC and SSC groups

	PTC		SSC		Chi-Square
	n	%	n	%	p
3-month	35	97.22	36	100	0.500
6-month	27	84.38	32	100	**0.026**
12-month	21	72.41	29	100	**0.002**

Parental Satisfaction

The mean parental satisfaction rate for PTCs was 19.9 while it was 16.38 for SSCs. This difference was statistically significant ($p<0.05$).

DISCUSSION AND CONCLUSION

The superiority and durability of SSCs over other restorations such as tooth-colored resin restorations or amalgams in the primary dentition have been documented and is considered as a 'golden standard' (2,19,22-28). However, these materials are not considered esthetically acceptable. Increased expectations of pediatric patients and parents towards esthetics have prompted pediatric dentists to search for new alternative esthetic and functional materials (28). Over the years, several available options such as resin crowns, polycarbonate crowns, composite strip crowns, glastech crowns, biologic crowns, pedo jacket crowns, prefabricated resin crowns, zirconia crowns etc. have been tried for providing full coverage restoration for primary molars each having itsown advantages and limitations (11,18,29-34).

SSCs preveneered with composite resin have been used for primary molars as an alternative; however, increased tooth preparation is required and retention does not rely on the natural contour of the tooth, as crimping is not possible on the composite facing. Additionally, success rates are lower than those in conventional SSCs and veneer facing loss or fracture were usually seen (4,5,33,34). For these reasons, resin bonded composite band crowns have been used by many clinicians, mainly due to their superior aesthetics and the possibility of repair in the event of subsequent fracture of the crown (35). However, it is technique sensitive. Moisture contamination may interfere with the bond. In addition, sufficient tooth structure must remain after caries removal to ensure sufficient surface area for adhesion (6). Zirconia crowns have also been introduced as an alternative for restorations of primary molars (11). However, zirconia crowns have some disadvantages. These crowns are expensive, thicker than SSCs, cannot be modified in any way, and a more aggressive preparation is required, cause a slight abrasion of the opposing teeth, can fracture during placement and are incapable of withstanding flexure (11,12).

Protemp Crowns are designed for use as a temporary restoration for permanent teeth. It is reported to be a self-supporting, formable, visible light activated composite crown that allows for a personalized fit. This crown was reported to have a wax-like consistency which maintains its shape and easily malleable allowing for easy shaping. Although this material was instructed for temporary use, researchers have found that margin quality, proximal contacts, surface roughness and occlusal wear remained acceptable after six months and one year (11,16,18). The observed mean wear of PTC materials was found to be similar to composite restorative materials used for permanent restorations and its long term use was recommended (2,17,18).

In this study, PTC crowns were tested clinically as full coverage restorations of extensive or multi-surface carious lesions in the primary molars. A split-mouth model was used to test PTCs with the control group was conventional SSCs in the same patient. Treatments were performed only mandibular primary molars.

In the present study, the anatomical integrity of crowns was evaluated in the clinical follow-ups performed in the third, sixth and 12th months in order to evaluate the success of SSC and PTC. After 12-month follow-up, although the anatomical success of SSC in all months is 100%, PTC crowns showed 84% full anatomical integrity (Score 0) while 2 teeth needed repair with composite restoration (Score 1). It was determined that the difference between the groups was statistically significance at the 12th month ($p<0.05$).

In the present study, as well as none of the SSCs were lost in all follow-up periods, structural defects such as holes, crushes and cracks were not observed in crowns. Stainless steel crowns are considered the gold standard for coronal restorations in primary teeth, thanks to their superior sealing properties (1,2). In the literature, it is observed that the success level is very high in studies in which the retention of SSCs is evaluated retrospectively. In a prospective study in which SSCs were followed for 24 months, it was found that 95% of them were functional (36). It has been reported that only 2.4% of SSC crowns failed in 12-month follow-up of teeth (37). The higher number of cases with clinical loss observed in much longer-term follow-ups compared to other studies was attributed to the fact that the restorations were made by less experienced physicians (38).

In addition to the loss of 4 PTC crowns as a result of desimantation, minor defects in the form of a fracture in

one crown and a small crack in a crown (two in total) were observed on the occlusal surfaces at the 12th month. It has been reported in the studies evaluating the clinical success of PTCs in permanent teeth that cementation failure or heavy occlusal loads may be the reasons for failures observed as fracture or loss at different follow-up periods in crowns (18). In the present study, it was thought that crown losses observed in different periods in PTCs may be related to cementation failure or parafunctional movements. Minor defects could be repaired with composite resin since the structure of PTCs is similar to composite resins and in subsequent controls, these teeth were found to maintain their functions in the mouth. It is considered as an important superiority of these crowns that the minor losses observed in the structure of the PTCs can be restored with composite and regaining their function (39).

For success of crowns applied to primary teeth, cementation is a very important factor (7,27,40-43). In this study, both crowns were cemented using resin modified glass ionomer cement. This kind of luting cement has many advantages over glass ionomer cements such as reduced early sensitivity to moisture, and low solubility in the oral fluids and successfully used for SSC cementation over years (44,45). However, the supragingival preparation method used for PTC crowns may have caused cement loss at the marginal area and loss of the crowns due to microleakage in this study. It would be noteworthy to see if resin cement altered the results.

When total success rates were examined using crown retention and endodontic treatment success rates, SSCs were statistically more successful than the PTC crowns. As described above, the cementation failure and may have caused more endodontic failures for the PTC crowns.

Although cementation failures were highly observed and slight mismatches in color for PTC crowns, parental satisfaction was much higher than SSCs for these crowns. There are studies reporting dissatisfaction with stainless steel crowns when patients and their parents have high aesthetic expectations (36;46,47). While the metal appearance and color are cited as the justification for dissatisfaction, the physician's inability to make an adequate explanation is also presented as a reason. Our findings were similar to these studies.

This result shows the high demand of patients and parents for more esthetic restorative materials.

While parental satisfaction with preformed composite crowns was high, the high failure of cementation was problematic. More clinical studies are needed for this material with different cementation agents to able to be used in primary molars.

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