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Stainless steel crown versus modified open-sandwich restorations for primary molars: a 2-year randomized clinical trial

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Objective. The aim of this study was to investigate the clinical performance and survival of stainless steel crown (SSC) restoration and modified open-sandwich technique using resin-modified glass ionomer cement.

Design. Randomized clinical trial.

Setting. General dental practice.

Materials and methods. A total of 87 children aged 4–7 years at baseline with one or more primary molars that have undergone pulp therapy were randomly assigned to receive either SSC or modified open-sandwich restoration. One hundred and sixty restorations were placed and evaluated after 6, 12, 18, and 24 months using the Ryge criteria.

Results. Comparable survival rates were observed for both SSC and modified open-sandwich restoration. With only four SSCs and six modified open-sandwich restorations failing over 24 months, the survival rates were high for both materials (2-year survival rate: 95.0% for SSCs and 92.5% for modified open-sandwich restorations). Significantly better gingival health ($P < 0.05$) was observed for the modified open-sandwich restorations compared with SSCs, as only one modified open-sandwich restoration was rated Charlie compared to 13 SSCs. No significant differences were observed between the two materials for marginal integrity, proximal contact, occlusion, or recurrent caries.

Conclusion. The 2-year results indicated that the modified open-sandwich restoration is an appropriate alternative to SSC in extensive restorations, particularly where aesthetic considerations are important.

Introduction

The literature reported high levels of caries in Saudi children[1,2]. Despite every effort to promote and implement preventive oral health measures, Saudi children are often presented in practice with cariously exposed pulp, and pulp therapy with multisurface restoration became an integral part of oral care for paediatric patients in everyday practice.

In recent years, many developments have taken place in restorative dentistry, and the choice of the best final restorative material for pulpotomized primary molars became very difficult. Several reports showed that preformed crowns achieved a better success rate than multisurface amalgam restorations[3–6], and had been recommended by the British Society of Paediatric Dentistry for the management of teeth affected by advanced tooth decay and following pulpotomy or pulpectomy procedures[7]. Although it is clear that the stainless steel crown (SSC) is the most reliable and durable, and a relatively inexpensive restorative material for restoring badly broken down primary molar tooth, there is little evidence within the literature to support this[8], and few dental practitioners adopt its use in clinical practice[9,10].

Dental amalgam has been the preferred choice of material for restoration of primary dentition for many decades, mainly for its durability[11]. In recent years, however, there has been increasing demand for aesthetic coupled with concerns about potential mercury toxicity and its effect on the environment. These concerns, although not supported by the major healthcare organizations[12–14], had led to the development and use of alternative restorative materials. These include composites, glass ionomer cements (GICs),

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resin-modified glass ionomer cements (RMGICs), and compomers.

The use of directly placed resin composite fillings is increasing, and good durability has been reported when they are placed in smaller cavities and under ideal conditions[15,16]. Some of the clinical problems associated with resin composite are related to the polymerization shrinkage, which can result in lack of adaptation to the cavity wall and increased susceptibility to caries[17].

The RMGIC contains the same component of traditional GICs, but have resin materials added to provide strengthening as well as the possibility of 'command cure' with a light-initiated curing of the resin composite component. RMGICs offer several advantages over the traditional GICs as they have substantially increased wear resistance and physical strength[18]. The GIC component offers fluoride release, whereas the resin component offers strength and better aesthetics than with the traditional GICs. However, because RMGICs contain resins, these restorative materials can potentially shrink during polymerization[19].

Among the other alternatives is the placement of a substantial part of resin composite with a GIC base in the so-called composite laminate GIC or 'sandwich' restoration. The original sandwich concept, with the GIC cement element open to the oral environment, has been recommended in high-caries-risk patients[20]. Several studies in adult population showed clinical failure rates between 13% and 35% after 2 years, and 75% after 6 years[21–23]. To increase the quality and longevity of the open-sandwich restoration, a modified open-sandwich restoration was suggested[24]. The modified version utilizes RMGIC, which showed equal fluoride release and improved mechanical and physical properties compared with the conventional GIC[25].

The aim of this study was to examine the survival time of SSC and RMGIC/composite resin restoration (CRR) when placed as final restoration in pulpotomized primary molars, and to compare the quality and performance of the two restorations.

The hypothesis was that no difference exists between the two restorations in terms of survival rate and the characteristics evaluated during a defined 2-year period.

Materials and methods

Study design

The study was carried out at Dammam Medical Center (DMC) in the Eastern Province in Saudi Arabia.

Children aged 4–7 years at last birthday were selected into this randomized clinical trial between January 2003 and January 2004, and met the following inclusion criteria: children were healthy and free of systemic disease or any developmental disturbances of the teeth or jaws, showed an acceptable oral hygiene with a plaque index score of 20% or less, had a behavioural rating score of 3 or 4 on the Frankl scale[26], and had at least one restorable primary molar with cariously exposed vital pulp. Symptomatic teeth with spontaneous pain, swelling, tenderness to percussion, pathological mobility, and pre-operative radiographic pathology were excluded from the study.

A total of 535 children were screened for eligibility by the author, and 126 were invited to participate in this study, which was approved by the Health Services at the Saudi Electricity Company, 39 of which refused to participate. At the baseline visit, the objectives of the study and its methodology were clarified to the parents, and an informed consent was obtained. All necessary baseline data were collected and recorded by the computer, and each child in the study had pairs of bitewing radiographs taken at baseline. Further radiographs were only taken if there was a clinical indication and not for the purposes of the study.

Interventions and follow-up

All pulpotomies were performed by the same dentist (author) under local anaesthesia, and following a standard clinical practice. After rubber dam isolation and caries removal, the pulp chamber was opened with a sterile high-speed #56 fissure bur, and the coronal pulp tissue was completely removed by a sterile slow-speed round bur (#6 or #8). Bleeding was controlled by placing sterile, saline-wetted cotton wool pellets on the pulp stump under

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Table 1. Modified United States Public Health Service criteria[27].

Category	Scores	Criteria
Marginal integrity*	A	Close marginal adaptation
	B	No detectable margin
	C	Detectable margin
Proximal contact	A	Resistance met when passing floss
	B	Floss passed without resistance but contact present
	C	No contact with adjacent tooth
Secondary caries	A	No caries present
	C	Caries present
Occlusion	A	Normal occlusion
	C	Faulty occlusion
Gingival health	A	No gingival bleeding
	B	Bleeding with probe
	C	Spontaneous bleeding

*Marginal integrity for stainless steel crown was assessed as: A, 0.5 mm marginal extension; B, 1.0 mm marginal extension; C, more than 1.0 mm marginal extension.

slight pressure. At this stage, failure to achieve complete haemostasis was an exclusion criterion. A cotton pellet soaked with diluted formocresol (1 : 5 Buckley's solution) was placed on the radicular pulp stumps for 5 min, after which the coronal pulp space was filled with a reinforced zinc oxide eugenol base (IRM, Dentsply DeTrey, Konstanz, Germany). Following the manufacturer's instructions, an RMGIC/CRR (Vitremer + Filtek Z250, 3M ESPE, St Paul, MN, USA), or an SSC (3M ESPE) cemented with a GIC (Ketac Bond, 3M ESPE) was used in the same visit.

The parents received oral hygiene instructions at the end of the visit, and were instructed to have follow-up visits every 6 months after the treatment. At each follow-up visit, the children were examined by the same dentist in a dental chair with a dental mirror and a probe. All data were collected and recorded onto recording forms and then entered on a spreadsheet run by the software Statistical Programme for Social Sciences (SPSS).

Hypothesis and outcome measures

The quality of the resin-based composite restoration and the SSC was assessed at 6, 12, 18, and 24 months ± 2 weeks, or until tooth exfoliation or patient dropout. The primary end points were a satisfactory retention of the modified RMGIC/resin composite open-sandwich restorations and SSCs in pathologically free teeth 2 years after baseline.

Clinical failure parameters were spontaneous pain, fistula, soft tissue swelling, pathological tooth mobility, partial fracture or total loss of RMGIC/CRRs, crown loss following cement failure, or perforation of occlusal surface as a result of wear.

The performance of the two restorations was evaluated using the modified United States Public Health Service (USPHS) criteria[27], in terms of marginal integrity, gingival health, secondary caries, proximal contact, and occlusion, which were determined as secondary outcomes. The gingival health was assessed by whether a site bled on gentle probing (Table 1).

Randomization

Randomization was generated through a computer program where each primary molar had an equal chance to be assigned to either SSC or RMGIC/CRR. Both the participants and the dentist could not be blinded to the intervention because of the different appearance of the two types of restoration.

Sample size determination

The sample size calculation was performed with the PS Power and Sample Size Calculation Program, version 2.1.3[28]. A sample size of 61 in each intervention group was planned for the detection of a significant difference using a power of 80%, a two-sided significance level of 5%, and based on previously experienced

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Table 2. The clinical findings and number of modified open-sandwich restorations.

Category	6 months *N* (%)	12 months *N* (%)	18 months *N* (%)	24 months *N* (%)
Marginal integrity				
A	68 (90.7)	58 (79.5)	54 (78.3)	46 (70.8)
B	7 (9.3)	15 (20.5)	13 (18.8)	17 (26.2)
C	0 (0.0)	0 (0.0)	2 (2.9)	2 (3.1)
Proximal contact				
A	71 (94.7)	63 (86.3)	58 (84.1)	53 (81.5)
B	4 (5.3)	10 (13.7)	10 (14.5)	10 (15.4)
C	0 (0.0)	0 (0.0)	1 (1.4)	2 (3.1)
Secondary caries				
A	75 (100)	73 (100)	68 (98.6)	63 (96.9)
C	0 (0.0)	0 (0.0)	1 (1.4)	2 (3.1)
Occlusion				
A	75 (100)	73 (100)	69 (100)	64 (98.5)
C	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)
Gingival health				
A	70 (93.3)	62 (84.9)	56 (81.2)	54 (83.1)
B	5 (6.7)	11 (15.1)	12 (17.4)	10 (15.4)
C	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)

median survival times for preformed crowns and composite resin[29]. Assuming a dropout of 15% in each group, the total minimal sample size increased to 144.

Statistical analysis

We used statistical software SPSS (version 12.0) to perform statistical analysis. Descriptive statistics were used to describe the frequency distributions of the evaluated criteria. Chi-squared test was used to study differences between the two materials at 6-, 12-, 18-, and 24-month follow-up periods. Values of $P < 0.05$ were accepted as statistically significant.

Survival analysis was carried out using the Kaplan–Meier[30] and the log rank test; the fillings that had dropped out, natural exfoliation, and other reasons for replacement of the restorations (e.g. new proximal lesion independent of evaluated filling) were estimated as censored. The date at which data were censored was taken to be the last time at which the tooth was seen.

Results

Following the assessment for eligibility, 41 boys and 46 girls ($N = 87$), with a mean age of 5.5 ± 1.1 years (range, 4–7) participated in this study, and had 160 primary molars, allocated to receive either SSC, or modified open-sandwich restoration (RMGIC/CRR). Out of 87 children, 47 had more than one restoration. Two teeth from the SSC group and four teeth from the RMGIC/CRR group were excluded from follow-up, because of uncontrollable bleeding. After 24 months, three teeth had exfoliated physiologically, and four teeth from each group were lost to follow-up, because most patients felt that the clinic is far from them.

Over the 2 years, a total of ten restorations failed; four SSCs were lost, and six RMGIC/CRRs were unacceptable (one total retention loss, two partial fractures, and three with secondary caries). No pulpotomy failure was reported during the evaluation period. The results of the parameters evaluated for the two groups at different follow-up times are presented in Tables 2 and 3. The majority of the restorations examined clinically up to 24 months rated Alpha according to the modified USPHS criteria[27].

There were small differences, although not significant after 24 months with 88.2%, and 81.5% of SSCs and open-sandwich restorations, respectively, showing resistance when passing floss. Also, at 18 months and 24 months, a slightly higher prevalence of recurrent caries was seen in teeth restored with the modified open-sandwich technique compared with SSC. Regarding the marginal integrity, 70.8% of RMGIC/CRRs showed close adaptation to the

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Table 3. The clinical findings and number of stainless steel crown restorations.

Category	6 months	12 months	18 months	24 months
Marginal integrity				
A	65 (84.4)	57 (77.0)	54 (76.1)	52 (76.5)
B	12 (15.6)	17 (23.0)	16 (22.5)	14 (20.6)
C	0 (0.0)	0 (0.0)	1 (1.4)	2 (2.9)
Proximal contact				
A	71 (92.2)	65 (87.8)	62 (87.3)	60 (88.2)
B	6 (7.8)	9 (12.2)	9 (12.7)	8 (11.8)
C	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Secondary caries				
A	77 (100)	74 (100)	71 (100)	67 (98.5)
C	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)
Occlusion				
A	77 (100)	73 (98.6)	69 (97.2)	66 (97.1)
C	0 (0.0)	1 (1.4)	2 (2.8)	2 (2.9)
Gingival health				
A	70 (90.9)	61 (82.4)	53 (74.6)	47 (69.1)
B	7 (9.1)	8 (10.8)	11 (15.5)	13 (19.1)
C	0 (0.0)	5 (6.8)	7 (9.9)	8 (11.8)

tooth structure, and 76.5% of SSCs had 0.5 mm marginal extension after the 24-month recall period. In addition, most of the restorations in both groups occluded in a proper position (score A). There were no statistically significant differences between the two groups for all the parameters assessed at any of the follow-up periods, except for a considerable difference concerning the gingival bleeding at the 24-month recall visit. Thirteen SSC restorations were rated B and eight C, whereas ten RMGIC/CRR scored B and one C for this parameter; the difference was statistically significant (chi-squared $P = 0.014$).

Figure 1 shows the cumulative survival curves for SSCs and modified open-sandwich restorations. After 2 years, the survival rate for SSCs was 95.0%, and for RMGIC/CRRs a survival rate of 92.5% was computed. Over the whole clinically observed period of 24 months, the Kaplan–Meier algorithm shows a mean survival time for SSCs of 23.8 months with 95% confidence interval between 23.4 months and 24.2 months. For the modified open-sandwich restorations, the mean survival time was 23.7 months with 95% confidence interval between 23.3 months and 24.1 months (Table 4).

Relative to the success rate, the test statistic for equality of the survival distribution resulted in no statistical difference between the two groups within the observation time (log rank test, $P = 0.50$).

Discussion

The restoration of severely broken-down primary molars is often a clinical challenge. Requirements for an acceptable restoration include: durability, efficacy, natural colour, and easy and rapid placement. SSCs have been recommended to restore badly broken teeth and are considered to be superior to large multisurface amalgam restorations[3–6]. Furthermore, SSCs are easily utilized, require no impression or laboratory procedures, can be completed in one appointment, and may require a rubber dam to provide a dry field in many of the patients especially when GICs are used. However, when a rubber dam cannot be applied, alternative systems that involve a conventional cementation should be used. SSCs may also be considered unaesthetic and require a significant amount of tooth preparation and invariably local anaesthesia, because of soft tissue manipulation.

On the other hand, the sandwich-style aesthetic restoration is highly technique sensitive and requires patient compliance and adequate moisture isolation. Nevertheless, RMGICs and CRRs have an increasingly important role to play in the management of carious lesions in primary molars, because of their adhesive and fluoride-leaching properties[31–34]. Increasingly, the multiple advantages of modified open-sandwich restorations are outweighing the increased

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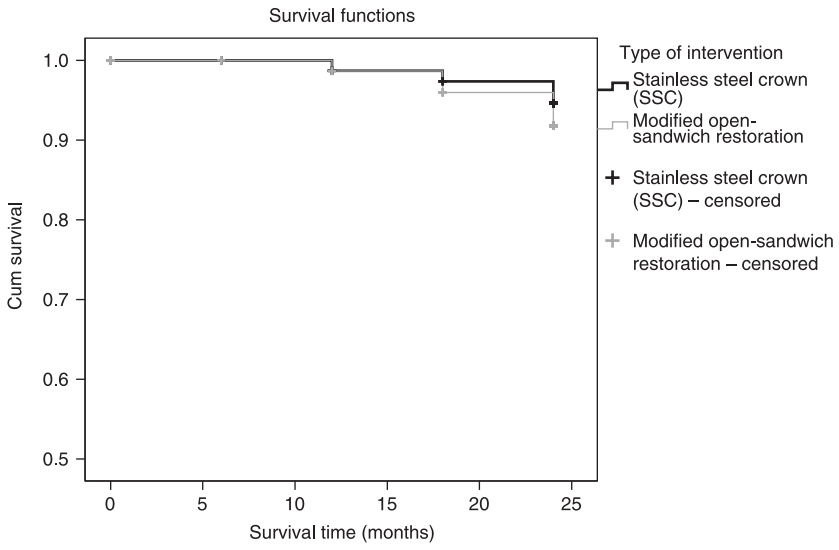

Fig. 1. Kaplan–Meier chart.

Table 4. Survival characteristics.

Group	Number of cases	Number of events	Number censored	Mean survival time in months (95% confidence interval)
SSC	80	4	76 (95.0%)	23.8 (23.4, 24.2)
RMGIC/CRR	80	6	74 (92.5%)	23.7 (23.3, 24.1)

CRR, composite resin restoration; RMGIC, resin-modified glass ionomer cement; SSC, stainless steel crown.

expense in time and material, and parents are requesting this form of restoration. A previous study investigating the durability and cariostatic effect of a modified open-sandwich restoration using RMGIC concluded that it had acceptable durability for the extensive restorations evaluated[35]. Furthermore, the open-sandwich technique allows the least amount of microleakage of the various direct restorative options currently available[36].

When comparing data on longevity of restorations from different clinical trials, caution has to be exercised. Settings for such trials can vary from academic to specialist private practices, with very few being run in general dental practice. In addition, the outcome measures for ascribing restoration success or failure can vary between different studies.

This study examined the longevity and clinical performance of SSC and modified open-sandwich technique in the restoration of primary molars that have undergone pulp therapy in general dental practice, where the majority of child dental care is provided in Saudi Arabia. One limitation of this study was the lack of identification of specific radiographic parameters, as the evaluation of pulpal treatment was solely based on clinical symptoms, and the fact that none of the pulpotomies failed during the 2-year period remained questionable and had to be confirmed radiographically. Nevertheless, it showed an excellent survival rate for SSC and RMGIC/CRR after 24 months, with 95.0% and 92.5%, respectively. It must be remembered, however, that teeth were carefully chosen for inclusion in this study. Only patients who had a behavioural rating score of 3 or 4 on the Frankl scale[26] were selected, to allow the use of rubber dam for maintaining a dry field of operation, which contributed to the high success rate of the restorations.

Failures such as bulk fracture, secondary caries, and total loss were uncommon in this study, and only four cases of SSCs and six cases of RMGIC/CRR were classified as failed restorations in this study. The high success

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rates of SSCs and RMGIC/CRRs were consistent with previously published studies[4,31], although these authors were specialists in paediatric dentistry and didn't compare the sandwich technique with other restorative materials. It can be argued that they used the same restorative materials.

The assessment of restorations is often subjective and difficult to quantify for analysis. The use of modified USPHS criteria[27] seeks to address this issue, but it is a fairly blunt tool when used to assess restorations. Despite this, it remains popular and has been used in several studies. Our study showed that the clinical outcomes for both SSCs and RMGIC/CRRs were comparable when used for primary molars, and there were no statistically significant differences between the two groups for marginal integrity, proximal contact, occlusion, and secondary caries at different recall visits.

The only criteria that showed a significant difference was the assessment of the gingival health as evidenced by the higher percentage of SSCs causing spontaneous bleeding at the 24-month recall visit compared to the modified sandwich technique. It is probable that bulky SSC with poorly finished margins would act as a secondary plaque-retaining factor. In addition to the difficulty in obtaining a good gingival fit in these cases, the problem was also aggravated by the pre-existing gingivitis presented by many of these patients. The results, however, do not imply that SSC causes gingivitis. Similarly, other studies showed that a higher degree of gingivitis was only associated with poorly adapted SSC and poorly maintained oral hygiene, and still considered SSC as having no harmful effect on the gingiva if properly placed[37,38]. Moreover, less recurrent caries was associated with SSC than with RMGIC/CRR; this difference was not statistically significant, and the very few number of the modified open-sandwich restorations which had recurrent caries compares well with the number in van Dijken and colleagues' study[24].

The need for further investigation of alternative techniques for managing grossly broken-down primary molars might be questioned in view of the fact that SSC is recommended for use for its proven efficacy and cost effectiveness. However, the need for exploration of equal or higher quality preventive and restorative alternative restorations, which are more acceptable to children, their parents, and clinicians, remains.

What this paper adds

- This study suggests that the modified open-sandwich restoration seems to be a suitable alternative to SSC in the restoration of primary molars of young children, not only for providing fluoride release locally, but also for its aesthetic advantages. It can help the dentist in clinical treatment decision.
- The two types of restorations evaluated, presented excellent clinical performance during the time evaluated (24 months), with little difference in the survival rate.

Why this paper is important to paediatric dentists

- This study showed that clinicians had other restorative alternatives for grossly decayed primary molars that would meet the patients and parents' aesthetic demands.
- This paper highlights the need for further research in the paediatric restorative field in general dental practice, where the majority of the child dental care takes place.

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