

Clinical Performance of Indirect Composite Onlays as Esthetic Alternative to Stainless Steel Crowns for Rehabilitation of a Large Carious Primary Molar

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Objective: The aim of the present study was to evaluate the clinical performance of indirect resin composite onlays (IRC onlay) compared to stainless steel crowns (SSCs), as an esthetic alternative for rehabilitation of extensively carious primary molars. **Study design:** Fifty pediatric patients each received either IRC onlay or SSC randomly on extensively carious endodontically treated primary molars. All the restorations were evaluated at baseline and then every 6 months till 36 months using 'modified FDI criteria' for retention, marginal integrity, occlusion, proximal contact, secondary caries and gingival health. The dental chair side treatment time and post-operative acceptability were also evaluated for both the groups. **Results:** The cumulative survival rate of IRC onlays was 82.9% compared to 90.7% for SSCs over a time period of 36 months. The difference between the two study groups at various time intervals in terms of retention, marginal integrity, secondary caries, proximal contact, occlusion and gingival health was not statistically significant ($p > 0.05$). The IRC onlays required significantly less mean chair side treatment time and were preferred the most by parents and children as per VAS scores compared to SSCs. **Conclusion:** IRC onlays are an acceptable esthetic alternative to SSCs and may be considered for use in aesthetically conscious children/parents as per their preference.

Key words: Indirect resin composite onlays; Stainless steel crowns; Extensively Carious primary molars; Aesthetic Restorations

INTRODUCTION

Presently, the gold standard treatment for extensively carious primary molars is stainless steel crowns (SSCs) due to their excellent clinical performance, low cost, protection of tooth from further decay, maintenance of morphologic form, ability to regain vertical dimension and retain occlusion.¹⁻³ However, the most obvious limitation of SSCs is their unsightly appearance. Few citations have directly or indirectly reported parent's and children's dislike towards the appearance of SSCs.⁴⁻⁷ In today's trendy world, the preference for aesthetic restoration has grown significantly for children and parents.⁸⁻¹⁰ It assumed a greater importance where children participate in various stage programs, television shows and modeling.

Aesthetic treatment of extensively carious primary molars presents a clinical challenge to pediatric dentists due to few available alternatives. *Open faced stainless steel crowns* procedure is tedious, with an unfavorably long clinical time and metal is usually always still visible¹¹ at the margin. *Pre-veneered crowns* too, present several inconveniences like poor gingival health, very expensive, bulky, poor occlusal anatomy and lacking a natural pleasing appearance.^{2,12} *Zirconia crowns* require extensive tooth preparation for passive fit, tedious crown adjustments, antagonist tooth wear, bearing high cost and lack of available evidence for primary dentition. Thus, need

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for an aesthetic alternative to SSCs is evident; in view of technical, functional or esthetic compromises with these available restorative techniques, especially for aesthetic conscious parents and children.

Developments in adhesive technology have expanded the scope to deliver highly pleasing restorations with indirect resin composite (IRC) onlays in a conservative manner.¹³⁻¹⁹ The IRC onlays procedure aims at coverage of lost tooth structure with minimal further tooth preparation.^{13,15} It offers better control over polymerization shrinkage, proximal contact and anatomical form; requires less clinical time with optimal aesthetics.¹³ The other advantages include a) ease to adjust/repair/replacement of restoration; b) avoid gingival manipulation/trauma and thus need for local anesthesia.²⁰ The other limitations of SSCs like nickel allergy^{21,22}, marginal seal²³, availability in only specific sizes and chances of marginal defects, crimping error with operators of variable skills²⁴ may also be overcome by these IRC onlays. To accept the IRC onlays as a definitive treatment option for extensively carious endodontically treated primary molars, the present study was planned to evaluate the long term clinical efficacy of IRC onlays compared to SSCs.

MATERIALS AND METHOD

A hospital based convenient sample of 50 children (Age range 4-7 years) was recruited in the present study in between Dec 2010 to May 2011 and allocated to one of the two study groups (25 in each group) viz. IRC onlays study group and SSCs study group by block randomization using sealed envelope (one per group/material per subject). The selection criterion was extensively carious primary second molar (more than two carious surfaces) requiring endodontic treatment and SSCs restoration. Children with known systemic disease, mental disability or abnormal para-functional habits were not included in the study. The primary molars with missing antagonist, mobility, sinus or abscess were also not included. The present investigation was approved by Ethics Committee, PGIMER, Chandigarh, India. Informed consent was signed by the patients' parents.

All the children entered an individualized preventive program being part of routine clinical practice for high caries risk children. The clinical and lab procedure was carried out by single, trained operator (HCM) following a strict protocol. The selected extensively carious primary molar was endodontically treated and approximately 1mm thick glass-ionomer cement (Fuji IX, GC, Tokyo, Japan) was used as orifice barrier. The assessment for remaining tooth structure was done clinically and on dental casts followed by tooth preparation for the two types of restorations. The treatment in IRC onlay study group was completed in two short treatment visits- visit I included tooth preparation and impressions; and Visit II included try in and cementation procedure. In the SSCs study group, procedure got completed in either single visit or two treatment visits- visit I included composite build up; and visit II crown preparation followed by cementation of SSCs.

A minimum tooth preparation dictated by carious involvement of tooth was carried out. The preparation included placement of shoulder or butt type of margin, shoeing type of cuspal coverage and providing withdrawal form following the basic principles of tooth preparation. Poly vinyl siloxane elastomeric impressions (AFFINIS, Coltene/ Whaledent AG, Switzerland) were made, washed and autoclaved. Eugenol free temporary restorations were used for temporization. IRC onlays were fabricated incrementally with chair side

direct restorative composite material Z350 XT A1 (3M ESPE, St. Paul, USA) on removable dies after application of die hardener, die spacer (15 µm) and die separator sequentially. Each increment of composite was cured for 20 seconds, initial anatomical shape given to the cusps and occlusal grooves; and then each surface was additionally cured for 40 seconds. Final anatomical shape was made with carbide burs. The restoration thus made was finished with sequential use of silicone polishing points at slow speed followed by polishing with diamond impregnated brush. Occlusion was checked using 40 µm thick blue articulating paper (Coltene/ Whaledent GmbH & Co. KG, Germany) by occluding the casts and then tried clinically on prepared tooth for marginal fit, proximal contacts and occlusion, followed by adjustment if required. The prepared tooth was isolated, etched, washed and air dried followed by cementation of onlay with dual cure resin cement (Rely X U100, 3M ESPE) and light cured for 5 seconds to allow removal of excess material and then each surface was light cured for 40 seconds. Occlusal adjustments were accomplished if required and finishing of the margins was done with silicone points and diamond brush.

Clinical technique for SSC

Standardized procedure for SSCs placement was used which included incremental build up of tooth with direct restorative composite Z350 XT A1 (3M ESPE, St. Paul, USA); occlusal preparation to provide uniform occlusal clearance of 1.0-1.5mm while maintaining the original occlusal contour, proximal reduction to break the contact point, buccal and lingual reduction ending in feather edge. Rounding of all line angles and sharp corners was done. The preparation was finally checked by sliding an explorer through the proximal surface gently to ensure that contacts were cleared and smooth, rounded preparation. The preselected crown was trimmed, adjusted, contoured and crimped to place the crown margins 1mm below the gingival margin. The knife edge finish was made at the margins of SSCs with a large green stone. The crown margins were polished with rubber wheel, retrieved and margins were checked with an explorer for adaptation. The tooth was isolated and cemented with luting glass ionomer cement (Fuji I, GC, Tokyo, Japan) followed by checking of occlusion and removal of excess cement.

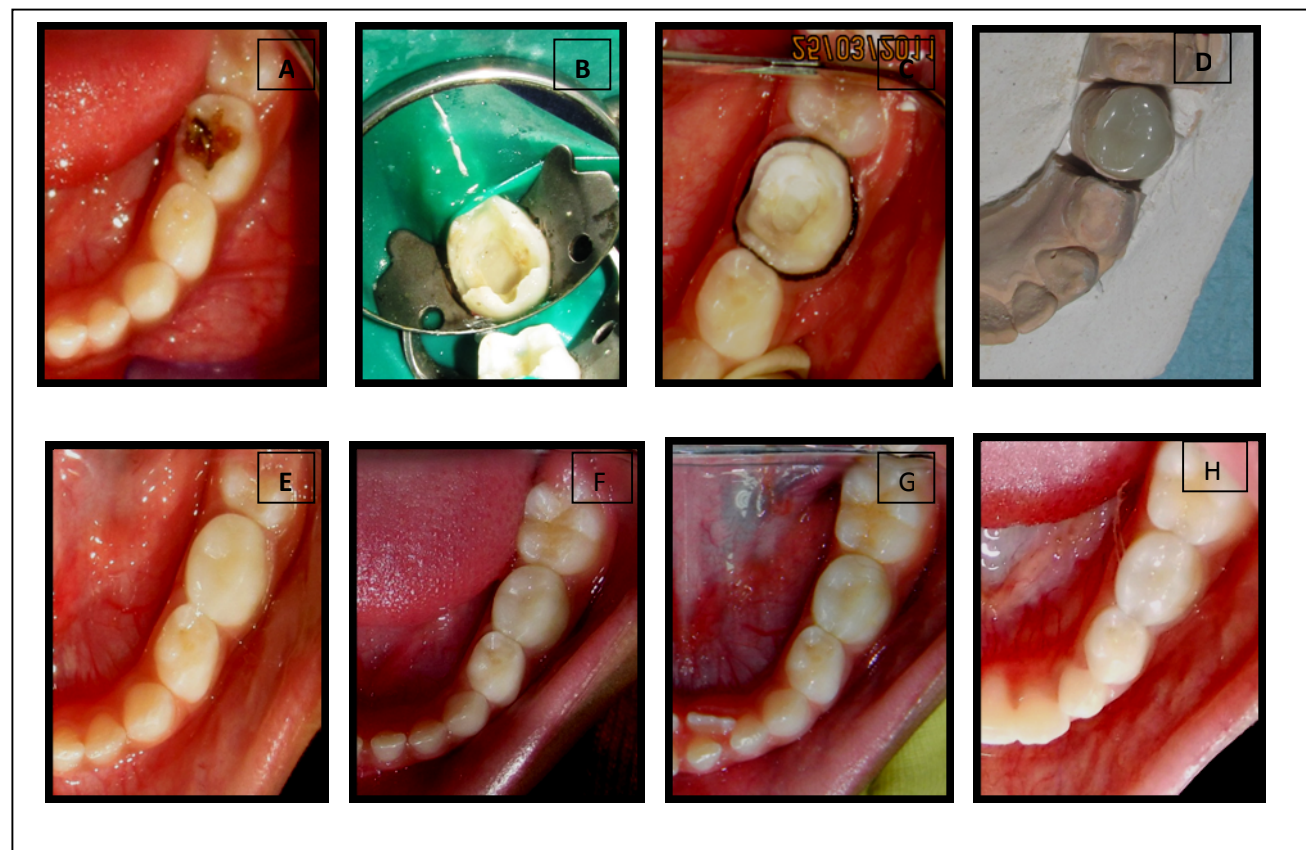
Evaluation

All the restorations were evaluated at baseline and then every 6 months using 'modified FDI criteria'¹⁹ (Table 1) by two independent & calibrated investigators (AG & AK) for clinical success and quality of the restorations. For statistical analysis, range of excellence (success) was considered by combining excellent and acceptable scores; and range of failures (requiring intervention) by combining unacceptable and poor scores. The differences in the two methods of rehabilitation were also evaluated in terms of dental chair side treatment time (excluding lab fabrication time for IRC onlays) and post-operative acceptability using Visual analogue scale. The cumulative survival of the two types of restorations was calculated using Gehan-Wilcoxon statistics.²⁵

The statistical analysis was performed using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). Kolmogorov Smirnov tests were used to determine normality of data. Student's t-test for normally distributed data and Mann-Whitney test for skewed data were applied for comparing

Fig.1 Clinical procedure for placement of indirect composite onlay

- A) Pre-operative extensive carious lesion
 B) Remaining tooth structure after caries removal and endodontic treatment with GIC lining
 C) After preparation and placement of retraction cord
 D) IRC onlay on the fabricated die
 E) One week Post-cementation of indirect composite onlay
 F) Six months Post-cementation of indirect composite onlay
 G) 18 months Post-Cementation of indirect composite onlay
 H) 36 months Post-Cementation of indirect composite



two groups. Categorical variables were compared using Chi square or Fisher's exact test whichever was applicable. Wilcoxon Signed Ranks Test was used for intra-group comparison between scores at different time intervals. All statistical tests were two-sided and performed at a significance level of $\alpha=0.05$.

RESULTS

The mean age of children enrolled in the study was 5.98 ± 1.34 years. Data from one evaluator was used for statistical analysis as no significant difference was found on method error determination between the two evaluators. The baseline parameters in the two study groups viz. age wise distribution, sex wise distribution, tooth wise distribution, tooth structure loss (i.e. 3-4 full cusp missing & 2-3 missing walls) and mean DMFT+deft score of children were similar statistically ($p>0.05$).

The table 2 shows the absolute frequency of clinical success in terms of parameters evaluated during the study for the two study groups. There difference between the two study groups at various time intervals in terms of retention, marginal integrity, secondary

caries, occlusion and gingival health was not statistically significant ($p>0.05$). The cumulative survival rate was calculated based on above parameters for IRC onlays and SSCs was 82.9% and 90.7% respectively (Table 2). A total of six and two failures were recorded for IRC onlays and SSCs respectively over a period of 36 months. The failure reasons for IRC onlays include loss of retention ($n=3$), deterioration of marginal integrity requiring intervention ($n=3$); and for SSCs was loss of retention only ($n=2$).

Also, there was no statistically significant difference in gingival health of test and control tooth in both the study groups at various time intervals ($p>0.5$). The two study groups were not statistically different ($p>0.5$) in terms of established proximal contacts with the two types of restorations (Figure 2). None of the case showed any secondary caries.

The deterioration of marginal integrity occurred in nine IRC onlays over 36 months (six cases showed no significant clinical deterioration but change in degree only and other three cases showed significant clinical deterioration requiring intervention).

Table 1. Criteria for clinical evaluation of indirect composite onlays and stainless steel crowns

Retention	1	<i>Excellent</i> – Restoration in place, no mobility	
	2	<i>Poor</i> – Restoration missing or mobile	
		IRC onlays group	SSC study group
Marginal Integrity	1	<i>Clinically excellent margin</i> - Restoration is contiguous with existing anatomical form, explorer does not catch	Excellent margin- Sealed, smooth margin, well flushing with tooth
	2A	<i>Clinically Acceptable margin</i> - Explorer catches but no crevice visible, Small marginal fracture removable by polishing, slight ditching/step/minor irregularities.	
	2B	<i>Sufficient satisfactory</i> - Several marginal chips which damage marginal quality or approximal contact but repairable.	
	3	<i>Poor margin</i> – Bulk fracture, partial loss which cannot be repaired, mobile restoration	Poor margin- Explorer detected open margin, crevice detected)
Secondary caries	1	<i>Excellent</i> - No evidence of caries contiguous with margin of restoration	
	2	Small and localized demineralization	
	3	Poor – repairable cavitated lesion or inaccessible deep caries for repair	
Proximal contact	1	Resistance met when passing floss	
	2	Floss passed without resistance but contact present	
	3	No contact with adjacent tooth	
Occlusion	1	Normal occlusion	
	2	Slightly tilted occlusion or rotated crown	
	3	Faulty occlusion	
Marginal discoloration	1	Absent	
	2	Present	
Gingival health	1	No gingival bleeding	
	2	Bleeding with probe	
	3	Spontaneous bleeding	

Figure 2 Proximal contact established with two types of restoration.

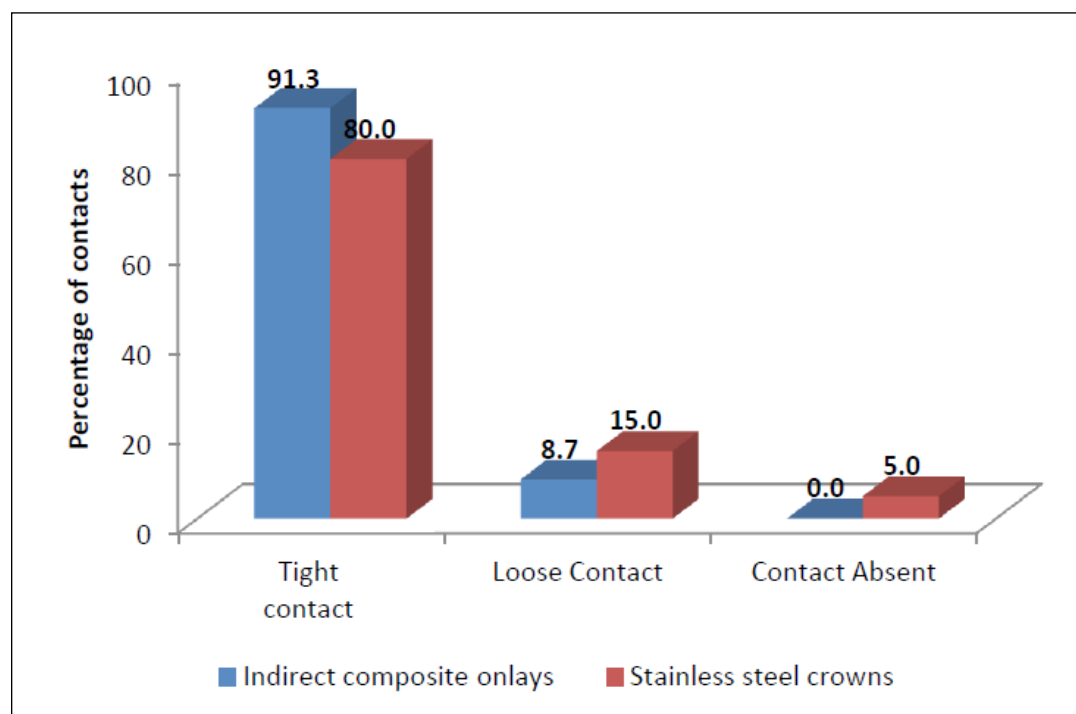


Table 2 Absolute Frequency of clinical success in terms of various parameters evaluated for the two types of restorations

Groups	Post-cementation Time Intervals	Retention (score 1)		Marginal integrity		Occlusion	Gingival health Score 2		Cumulative Survival rate using Gehan-Wilcoxon Statistics (S) ²⁵
		Success	Failure	Success Score 1+2A	Failure Score 2B+3	Satisfactory	Test tooth B+L	Control tooth B+L	
Group-I Indirect composite onlays	One week	25/25 (100%)	0/25 (0%)	25+0/25 (100%)	0/25 (0%)	25/25 (100%)	0+3/50 (6%)	0+4/50 (8%)	82.9%
	6 months	22/25 (88%)	3/25 (12%)	20+2/22 (100%)	0/22 (0)	22/22 (100%)	0+1/44 (2.3%)	0+3/44 (6.8%)	
	18 months	22/22 (100%)	0/22 (0%)	16+4/22 (90.9%)	2/22 (9.1%)	20/22 (90.9%)	1+4/44 (11.4%)	0+2/44 (4.5%)	
	36 months	17+3*/20 (100%)	0/20 (0%)	16+0/17 (94.1%)	1+0/17 (5.9%)	17/17 (100%)	0+2/34 (5.9%)	0+0/34 (0%)	
Group II Stainless steel crowns	One week	25/25 (100%)	0/25 (0%)	25/25 (100%)	0 (0%)	25/25 (100%)	2+2/50 (8%)	1+4/50 (10%)	90.7%
	6 months	25/25 (100%)	0/25 (0%)	25/25 (100%)	0 (0%)	25/25 (100%)	0+1/50 (2%)	0+3/50 (6%)	
	18 months	20/21** (95.2%)	1/21 (4.8%)	20/20 (100%)	0 (0%)	20/20 (100%)	3+8/40 (27.5%)	2+3/40 (12.5%)	
	36 months	16+3*/20 (95%)	1/20 (5%)	16/16 (100%)	0 (0%)	16/16 (100%)	0+2/32 (6.3%)	0+1/32 (3.1%)	

*3 primary molars with restoration in place in each group were exfoliating ; ** 4 cases were lost to follow up;

B= buccal surface, L=lingual surface, test tooth= tooth restored with either IRC or SSC, Control tooth=healthy contra-lateral tooth

d=no. of failed restorations in the period; n=baseline nonfailed restorations; w=no. of restorations not evaluated due to loss of follow up + successful restorations in exfoliated teeth.

The deterioration of marginal integrity with time was not found to be statistically significant ($p>0.05$). The marginal discoloration appeared in total of six IRC onlays over 36 months duration which was not found to be statistically significant with time ($p>0.05$). The marginal discoloration in IRC onlays was not found to be correlated with marginal integrity ($p>0.05$).

Table 3 shows the statistically significant difference ($p=0.000$) between the two study groups for acceptability of parents and children favoring IRC onlays at one week post-cementation.

Significantly less total chair side time (Figure 3) was taken in IRC group compared to one visit SSCs group ($p=0.007$) and two visit SSCs group ($p=0.000$).

DISCUSSION

Recently, esthetic dentistry has developed considerably showing promising results with tooth colored bonded restorations as alternative to SSCs in endodontically treated primary molars with minimal to moderate tooth structure loss.^{6,26-28} However, in case of *severely damaged* primary molars, SSCs have continued to remain the gold standard¹⁻³ due to lack of acceptable esthetic alternative methods. In recent years, *indirect* composite restorations have been tried as conservative and esthetic alternative treatment modality for rehabilitation of grossly decayed permanent^{14,15,29-32} as well as primary¹⁶⁻¹⁹ molars.

The indirect composite restorations can be fabricated with i) Direct restorative composite resin cured on model with light

curing unit, ii) Second generation laboratory composite resins with improved physical properties; cured with different combination of light, heat, pressure, vacuum, nitrogen, xenon and water, according to manufacturers recommendations.¹³ In the present study, direct composite restorative material was chosen for fabrication of indirect composite onlays because of less sophisticated equipment requirement, more economical approach, easy availability and opportunity for chair side fabrication. Indirect composite restorative technique employed was derived from the published reports.^{14,15,17,18} The minimal preparation design was dictated by carious involvement. The retention was primarily based on adhesion to remaining tooth structure and augmented by pulp chamber walls of the primary molars. As a general guide, the thickness of the enamel-dentin complex on the cusps dictated the need for cusp coverage. When the perimeter of the intracoronal cavity was in proximity to or coincided with the tip of the cusp, shoeing type of cuspal coverage was made. Minimal amount of divergence was provided to the preparation because of reduced height of the vertical walls. Vertical walls were created wherever possible to resist the displacement of restoration under oblique or horizontal forces.

The 'Cumulative survival of IRC onlays' in the present study was calculated using Gehan- Wilcoxon Statistics (S)²⁵ as 82.9% for IRC onlays compared to 90.7% for SSCs over a time period of 36 months (Table 2). The survival rate in the present study for IRC onlays is satisfactory but comparatively low which may be due to strict criteria followed. The IRC onlay in primary molars has not been

investigated previously except for few case reports/series¹⁵⁻¹⁸ with excellent results. A recent randomized controlled study in children found 100% success rate for IRC onlays and direct composite restorations placed in first permanent molars with extensive tooth structure loss over a period of two years.³³ The IRC onlays outperformed the direct composite restorations in terms of marginal integrity and staining with basic fuchsin.³³ These indirect composite restorations with or without fiber reinforcement have been used on both vital and non-vital permanent teeth with satisfactory results.^{13-15,29,31-33} The success rates of IRC onlays in permanent dentition varies widely between the studies due to different methodology, subjective evaluation and difficult to quantify the assessment for analysis.

The 'retention failure' of IRC onlays occur in three cases (12%) which was found to be adhesive failure at dentin and resin cement interface during first 3 months of placement. On analysis of available tooth structure for adhesion (Figure 4) in these three cases compared with rest of the cases was found to be statistically significantly ($p < 0.05$). The retention failure for SSCs occur in two cases over a period of 36 months ($n=1$; 4.8% at 24 months & $n=1$; 5% at 36 months) which is similar to the other studies.¹ In a recent study, Atieh reported 5% failure for SSCs due to retention.

'Marginal integrity' in the present study deteriorated from baseline in a total of nine IRC onlays over a period of 36 months. In six of these cases, the marginal integrity score fell from excellent (score 1) to acceptable (score 2) which differed only in degree and did not require any intervention. In the other three IRC onlays the scores fell from excellent to unacceptable or poor which necessitated intervention and were thus rated as failure. Two of these were repaired with flowable composite and one required replacement due to bulk fracture of restoration. On the other hand, SSCs showed excellent margins over the duration of present study as margins once placed with due care didn't deteriorate with time. The poorly adapted SSCs, however, can affect periodontal tissues and can also hinder eruption of permanent teeth resulting in serious malocclusion and caries.³⁴

The occurrence of 'marginal discoloration' in six IRC onlays observed over 36 months duration might have resulted due to microleakage. The other possible reason could be the exposed resin cement at margins which acquired stains with time due to inferior conversion compared to onlay.³⁵

Incipient 'secondary carious' lesion can develop in a minimum time period of 3 weeks in a high caries risk patient.³⁶ None of the child in any of the two study groups developed secondary caries

Table 3. Acceptability of Onlays/Crowns at One Week Post Cementation

Visual Analogue Scale		Strongly dislikes	Does not like much	Just OK	Likes	Strong liking
Study Groups		%	%	%	%	%
Indirect composite onlays (Group 1)	Parents* N=25	0	0	8	12	80
	Children** N=25	0	0	4	4	92
Stainless steel crowns (Group 2)	Parents* N=25	16	40	40	4	0
	Children** N=25	52	16	4	16	12

Group I vs Group II

* $\chi^2=40.333$, $p=0.000$ Significant ; ** $\chi^2=34.185$, $p=0.000$ Significant

Figure 3 Treatment time in the two study groups

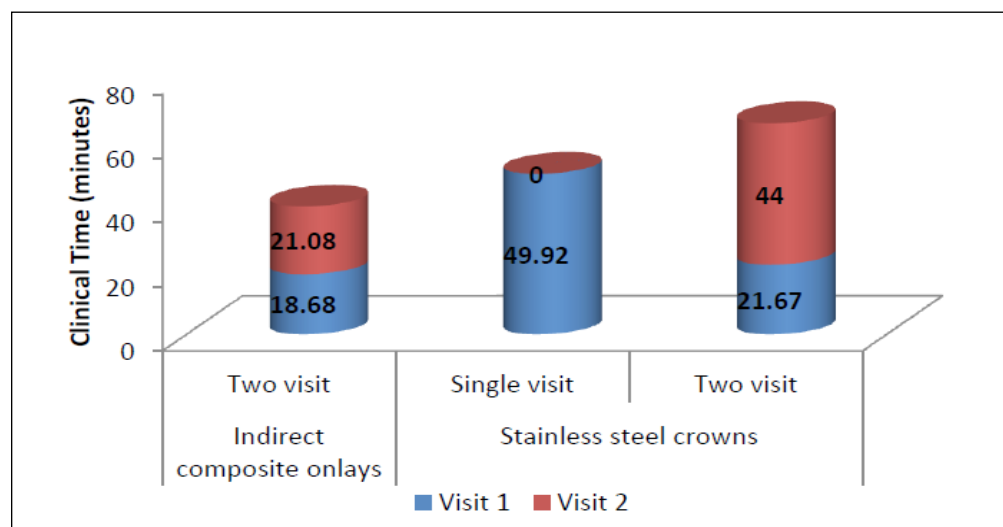
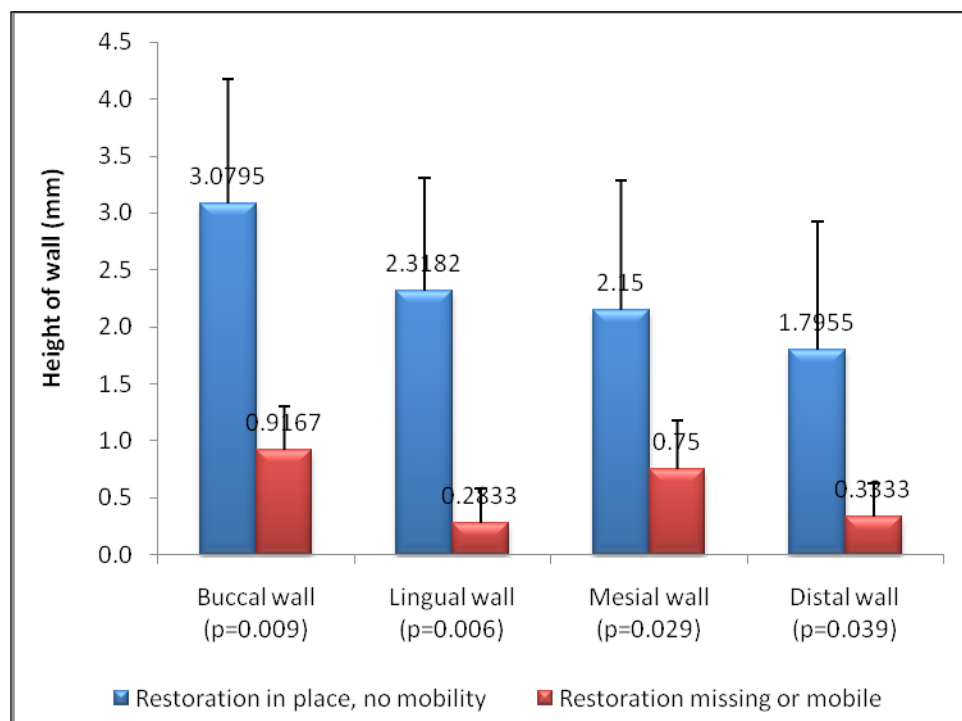


Figure 4 Retention of IRC Onlays versus Tooth Structure Available for Adhesion

which might be due to individualized preventive program, regular follow up and motivation.

The 'chair side treatment time' to place IRC onlays was significantly less compared to stainless steel crowns. Moreover, the less total chair side time divided in two short visits is an added advantage of IRC onlays over SSCs in younger children.

Also, the IRC onlays established good 'proximal contact points' comparable to stainless steel crown as IRC onlays were precisely and custom fabricated on the model.

'Gingival health' status of restored vs. control teeth in both the study groups was not found to be significantly different at any of the time intervals. However, marginal gingival thickening close to SSC was observed in one case. Atieh⁶ reported higher percentage of SSCs causing spontaneous gingival bleeding compared to the modified sandwich restorations. Henderson³⁷ also noticed that some gingival inflammation is always observed due to the differences in form/contour of the tooth and the SSC. While other studies^{1,24,28} reported no direct effect of SSCs on gingival health if properly placed and good oral hygiene levels were maintained. In the present study, the acceptable gingival health of primary molars with SSCs compared to contralateral control teeth might be due to a) carefully placed SSC margins which were found to be excellent on evaluation with no crimping defect, no rough margins and no gingival blanching; b) continuous motivation to follow preventive instructions.

The 'acceptability of two type of restorations' was accessed using VAS scale at one week follow up examination as this allowed to judge the clinical and psychosocial outcomes of the treatment. Most of the parents rated IRC onlays as 'Strong liking' and SSCs as 'Does not like much' or 'Just OK'. Also, some of the parents left the treatment decision with dentist and opted neutral score for restorations. Parental rating might be influenced by various factors like aesthetic expectations, longevity of the restorations and number

of visits for the two types of restorations. Threlfall and colleagues³⁹ published that parents hate SSCs because of metal silver appearance and long procedure. Zimmerman et al⁸ found that parents' greatest concern was about aesthetics (57%) and 70% of the inquired pediatric dentists felt some parental pressure to use tooth colored materials. Atieh⁶ also provided anecdotal evidence that parents requested the more aesthetic restoration in preference to metal crowns.

Most of the children (92%) strongly liked restorations in IRC onlays group compared to 12% in the SSCs study group. Fifty two percent of children strongly disliked the SSCs and some of these needed to be counseled to render the treatment being a part of SSCs study group as routinely done in the clinics. The age and sex was not found to influence the VAS score in the present study. It has been seen that children had different opinions for SSCs which may have been influenced by factors like personality of child, influence of peer group and socioeconomic status. Children are conscious about the dental aesthetic appearance of themselves and others.⁴⁰ Some case reports^{4,7} are also available where strong objections were encountered for SSCs and aesthetic alternative restorations had to be placed.

The operator's opinion about the two techniques was that placement of SSCs is more demanding in terms of child cooperation but comparatively comfortable and easy for the operator in most cases. However, IRC onlays allowed short and comfortable treatment for most children but clinical precision and tedious lab procedure was demanding for the operator.

Therefore, from the above discussion it can be inferred that the IRC onlays fabricated using direct composite material technique are comparable in their clinical efficacy to SSCs when evaluated over a period of 36 months. The IRC onlays used in the present study have some inherent limitations a) a highly technique sensitive procedure b) requirement of a number of materials and sequential steps c)

cumbersome laboratory procedure. Parent's willingness to spend comparatively higher cost for tooth colored restorations, however, was not studied in the present study which may affect the final decision for type of restoration. Nevertheless, the final outcome and the wide acceptance by children and parents do not undermine the need of these pleasing tooth colored aesthetic restorations.

CONCLUSIONS

Indirect composite onlays are an acceptable aesthetic alternative to stainless-steel crowns and may be considered for use in aesthetically conscious children/parents as per their preference. This study provided the validity of indirect composite onlays technique for further study of the technique with different preparation design and materials with simplification and improvement of technique in a wider sample.

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