Success and Acceptability of Stainless Steel Crowns placed using Hall Technique with Modifications: A Randomised Clinical Trial

DHIGVIJAY AREPOGU¹, SVSG NIRMALA², INTHIHAS SHAIK³, SIVAKUMAR NUVVULA⁴

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ABSTRACT

Dentistry Section

Introduction: High frequency of caries in primary teeth and its inadequate treatment is major public health problem, that significantly affecting children's lives. The Hall Technique (HT) is a novel method of caries management for treating primary molars compared to conventional treatment techniques used in primary health care settings. It is one of the methods used for biological sealing in carious primary molars, in which bacteria will be sealed from the oral environment thereby inactivating the carious lesion. This technique also increases the child's compliance and operator comfort as the local anaesthetic administration is eliminated.

Aim: To prospectively evaluate the clinical success and failure rate, and acceptability of Stainless Steel Crowns (SSC) placed using Hall Technique (HT) and with Modified Hall Technique (MHT) in rural school children aged 6-9 years.

Materials and Methods: In a school-based setting, a randomised clinical trial was done with a total of 60 children

(60 teeth) aged 6-9 years, who were randomly divided into two groups, 30 in each. In Group A (HT)- crowns were placed using the HT and in Group B (MHT)- MHT and follow-up were done at 3, 6, and 12 months. The acceptability of the technique for both the parents and children was evaluated with the questionnaire. The data analysis was carried out using a Statistical Package for Social Sciences (SPSS Version 21). Statistical significance was set at p<0.05.

Results: In the HT group, the majority of crowns 26 (86.7%) were successful with 2 (6.6%) minor failures and 2 (6.6%) major failures, whereas the MHT group showed 100% success with no failures. On comparing Group A with Group B no significant differences were observed (p>0.05). Children's acceptability and preference were more towards the MHT.

Conclusion: The MHT was well accepted by children and the parents showed preference towards both the techniques.

Keywords: Dental caries, Hall technique, Local anaesthesia, Paediatric dentistry, Preformed metal crowns, Survival

INTRODUCTION

Dental caries are ubiquitous throughout the world and affects all populations irrespective of age, gender, and socioeconomic level. This situation is attracting much care in developing countries due to a lack of access to oral health care services, especially in rural areas [1]. Conventional management for carious primary molars include restoration with glass ionomer, composite resin, compomer, and SSC [2,3]. Nowadays Silver Diamine Fluoride (SDF) is being used as a non invasive treatment option for carious lesions [4].

Despite the fact that SSC are recommended as an optimum treatment option for primary molars where caries involves two or more surfaces [5,6]. General Dental Practitioners (GDPs) are not widely using this technique due to the difficulty in the procedure, the child's ability to accept the invasive treatment as it involves local anaesthesia and tooth preparation [7].

The Preformed Metal Crowns (PMC) are the "gold standard" restoration of choice, as it protects tooth from fracture, minimise the possibility of leakage, and ensure a biological seal [3].

The purpose of the HT is to seal the carious lesion and, thus, isolate the tooth from the rest of the oral environment. This technique involves the use of SSC cemented over carious primary molars without the use of rotary instruments and dental anaesthesia to eliminate the discomfort associated with it [8]. The HT was developed by Dr. Norma Hall while she was working in high caries-risk children in rural Scotland. In this novel approach, the SSC is placed without local anaesthesia, caries removal, or tooth preparation. An appropriate size of preformed SSC is chosen, filled with glass ionomer cement and then, the crown is fitted over the carious primary molar by applying the dentist's finger pressure, or the child's biting force [9].

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HT works with the direct biological principle in which the superficial plaque layer, which is the most biogenic layer for caries progression is sealed from the oral environment. As a result, the plaque biofilm composition is altered with less cariogenic flora. Hence, this technique may arrest or at least slows down caries progression in primary teeth [10]. Midani R et al., modified the HT in cases where tight approximal contacts made the immediate placement of the crown difficult [11]. In the current study, modifications were 0.5 mm-1 mm occlusal reduction with tapered fissure bur (size 0.5 mm) and crown crimping before cementation.

So far, in the available literature no clinical study compared the HT and MHT.

Hence, this study aims to evaluate and compare the clinical success and failure rates of the HT and MHTs at 3, 6 and 12 months followup and also to assess the children and their parents acceptability of the HT and MHT

MATERIALS AND METHODS

The present randomised clinical trial with two parallel arms (1:1 allocation ratio) was designed and carried out among rural school children in Nellore from 1 December 2017 to 1 February 2019.

Ethical clearance was obtained from Institutional Ethical Committee (IEC) Ref No: NDC/IECC/PEDO/12-17/03, Narayana Dental College and Hospital. Informed consent was given by participants' parents/ legal guardians before starting the procedures.

Inclusion criteria:

Children aged between 6-9 years

Proximal caries was diagnosed using ICDAS criteria codes 4 and 5 [12].

Code 4- An underlying dark shadow from dentin with or without localised enamel breakdown.

Code 5- Distinct cavity with visible dentin.

Multi surface carious lesions, occlusal lesions, cavitated if the child was unable to accept selective caries removal, teeth without tenderness

Exclusion criteria:

Irreversible pulpitis and acute infection

Severely mutilated teeth,

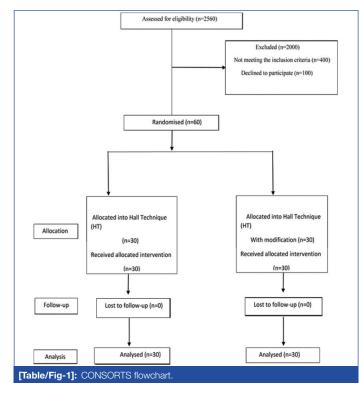
Medically compromised children,

Uncooperative children

Teeth treated with pulpotomy and pulpectomy,

Children with suspected nickel allergy to SSC.

Methodology: Out of 2560 children examined, 60 children who met the inclusion criteria were selected. All the children were examined by a single calibrated examiner, and values were recorded with the help of an assistant. The primary investigator recorded basic demographic data of all participants in a specially designed proforma and cases was selected based on the International Caries Detection, and Assessment System (ICDAS II, codes 4 and 5) [12], randomisation was done using table of random numbers. The odd numbers were allocated to Group A, even numbers assigned to Group B [Table/Fig-1].



Group A: Control group of 30 children, treated with SSCs using the HT.

Group B: Study group of 30 children treated with SSCs using MHT. The modifications were occlusal reduction of 0.5-1 mm made by using tapered fissure bur (size 0.5 mm), and crown crimping before cementation [11].

Prior to the treatment, orthodontic separators were used if there were tight contact points one day before the procedure.

The Treatment Procedure for Group A (HT)

The treatment was carried out according to the HT protocol of Innes NP et al., [13]. No local anaesthesia was administered no caries was removed only debris or any food material was removed from the cavity with gauze. An appropriate size of a PMC was selected for the tooth, covering all cusps and giving the feeling of "spring-back" when placed up to, but not through, the contact points. Later Glass Ionomer Cement (GIC) was mixed for 10 seconds according to the manufacturer's instructions. The crown was loaded with GIC (at least two-thirds full) and placed over the tooth; seated the crown into place by finger pressure, or asking the child to bite it into place. Excess cement was removed, followed by flossing between the contacts. Occlusion was checked, and postrestorative instructions were given.

The Treatment Procedure for Group B (MHT)

The basic procedure was carried out similar to Group A, but the only difference is an occlusal reduction of 0.5-1 mm and crown crimping before cementation.

Acceptability of the two groups of children and parents was taken using closed-ended questionnaire. Four questions were asked to the children regarding the pain with the technique (yes/no), appearance (positive/negative), general opinion (positive/negative), and preference of the method (agree/disagree), whereas, two questions were asked to the parents about appearance and the general opinion of the technique.

Treated teeth were evaluated after 3, 6, and 12 months posttreatment. Children were kept under regular review intervals, with clinical data being recorded at every interval.

The treatments were classified as "success" when they presented clinically satisfactory. Failures were scored as "Minor failures" and "Major failures" [Table/Fig-2-4].

	Hall technique (HT)	Modified Hall Technique (MHT)				
Successful	SSC appears satisfactory, no intervention is required, no clinical signs/symptoms of pulpal pathology, tooth exfoliate	SSC appears satisfactory, no intervention is required, No clinical signs/symptoms of pulpal pathology, tooth exfoliated				
'Minor' failure	Crown perforation, SSC lost, tooth restorable reversible pulpitis treated without requiring pulpotomy or extraction	Crown perforation, SSC lost, tooth restorable, reversible pulpitis treated without requiring pulpotomy or extraction				
Major' failure	Irreversible pulpitis or dental abscess requiring pulpotomy or extraction of tooth unrestorable internal root resorption	Irreversible pulpitis or dental abscess requiring pulpotomy or extraction tooth unrestorable internal root resorption				
[Table/Fig-2]: Successful, minor failure, and major failure [13].						



[Table/Fig-3]: Major failures in Hall Technique (HT). a) Pre-op treatment; b) At 3 months.



[Table/Fig-4]: Minor failures in Hall Technique (HT). a) Pretreatment; b) Posttreatment; c) At 3 months.

STATISTICAL ANALYSIS

The data analysis was carried out using SPSS Version 21. The basic description was presented in terms of frequency, percentage, mean, and standard deviation. Fisher's-exact test was used for all independent variables. The level of significance was set at p<0.05 for all tests.

RESULTS

Sixty primary molars (42 primary first molar, 18 primary second molar) in 60 children (33 boys and 27 girls) with an age range of 6-9 years, mean age (7.44+1.23 boys, 7.14+1.02 years girls) were restored with SSC. The dropout rate was 0%.

Group A (HT group) comprised 19 (63.3%) boys and 11 (36.7%) girls whereas Group B (MHT group) constitutes 14 (46.7%) boys and 16 (53.3%) girls. There was no statistically significant difference in gender, arch and tooth type among the

two groups (p=0.625), (p=0.54) and (p=0.090), respectively [Table/Fig-5]. The total success rates in the HT and MHT groups at a different intervals are shown in [Table/Fig-6,7]. The success rate was 86.7% and 100% in HT and MHT groups respectively, which was not statistically significant (p=0.112) [Table/Fig-8]. Regarding appearance, 18 (60%) children, 23 (76%) parents in HT group, and 19 (63.3%) children and 21 (70%) parents in MHT group gave positive response [Table/Fig-9,10].

	Gender		Ar	ch	Tooth Type		
Groups	Boys	Girls	Maxilla	Mandible	First Molar	Second Molar	
HT	19 (63.3%)	11 (36.7%)	8 (26.7%)	22 (73.3%)	18 (60.0%)	12 (40.0%)	
MHT	14 (46.7%)	16 (53.3%)	6 (20.0%)	24 (80.0%)	24 (80.0%)	6 (20.0%)	
p-value	0.625 (NS)		0.54	(NS)	0.090 (NS)		
[Table/Fig-5]: Distribution of sample over gender, arch, and tooth and tooth type among the two groups. Chi-square test.							

	3 Month	ns % (n)	6 Months % (n)		12 Mont	hs % (n)	Total % (n)	
Groups	Success	Failure	Success	Failure	Success	Failure	Success	Failure
HT	86.7 (26)	13.3 (4)	86.7 (26)	13.3 (4)	86.7 (26)	13.3 (4)	260.1 (78)	39.9 (12)
MHT	100 (30)	0	100 (30)	0	100 (30)	0	300 (90)	0
Total% (n)	186.7 (56)	13.3 (4)	186.7 (56)	13.3 (4)	186.7 (56)	13.3 (4)	560.1 (168)	39.9 (12)
[Table/Fig-6]: Su	ccess and failure (%) observed at differe	ent intervals of both	the arouns				

Groups	Success	Major Failures	Minor Failures	Total		
HT	26 (86.7%)	2 (6.3%)	2 (6.3%)	30 (100%)		
MHT	30 (100%)	0 (0)	O (O)	30 (100%)		
Total	56 (93.33%)	2 (3.3%)	2 (3.3%)	60 (100%)		
[Table/Fig-7]: Percentage of success, minor failures and major failures for Hall and MHT groups.						

	Suc	ccess	Fai	ure	Significance of Difference		
Group	Count	Percent	Count	Percent	χ^2	p-value	
HT	26	86.7	4	13.3	4.000	0.112	
MHT	30	100	0	0	4.286		
[Table/Fig-8]: Overall success and failure in both different groups.							

When intergroup comparison was done on pain during and after the treatment, significantly lesser number of children reported no discomfort in MHT group. (p=0.018, p=<0.001, respectively) [Table/Fig-11].

DISCUSSION

The success rate of the HT group and MHT group was 86.7% and 100%, respectively at 12 months follow-up. Thus, in this study modified HT showed a high success rate with no failures.

In terms of HT, these results were inconsistent with other studies. Innes NP et al., reported a success rate of 93% and 92% in 2 and 5 years follow-up and Evans DJ et al., reported a success rate of 91.83% [13,14]. Furthermore, Ludwig KH et al., Clark W et al., found 97%, Santamaria RM et al., 98%, Boyd DH et al., 94%,

Themes	Sub-category	Resp	oonse	Subgroups of	each response
	During the start	No discomfort	8 (26.6%)	With trying on crowns	9 (40.9%)
Pain with Hall Technique (HT) (asked	During treatment	Discomfort	22 (73.3%)	With crown not fitting	13 (59.0%)
the child)		No discomfort	5 (16.6%)	Sensitivity to hot/cold	2 (8%)
	After treatment	Discomfort	25 (83.3%)	High occlusion	23 (92%)
	Child	Positive	18 (60%)		
Appearance (asked child and	Child	Negative	12 (40%)		
parent)	Devent	Positive	23 (76.6%)		
	Parent	Negative	7 (23.3%)		
	Child	Positive		General opinion	11 (84.6%)
			13 (43.3%)	Opinion on procedure	1 (7.6%)
				Crown vs filling	1 (7.6%)
		Negative	17 (56.6%)	Procedure	9 (52.9%)
The general opinion of the technique				Worry about peer response	8 (47%)
(asked the child and parent)				General opinion	8 (57.1%)
		Positive	14 (46.6%)	Opinion on procedure	2 (14.2%)
	Parent			Crown vs filling	4 (28.5%)
			10 (50 00()	Procedure	11 (68.7%)
		Negative	16 (53.3%)	Worry response about peer	5 (31.2%)
		Agree	19 (63.3%)		
Preference of Hall Technique (HT)	Child	Disagree	11 (36.6%)	Would recommend procedure	19 (100%)

Dhigvijay Arepogu et al., Success Rate and the Acceptance of Modified Hall Crowns in Children

Themes	Sub-category Response		Subgroups of each res	ponse	
	During to start and	No discomfort	17 (56.6%)	With trying on crowns	11 (84.6%)
Pain with Hall Technique with modification	During treatment	Discomfort	13 (43.3%)	With crown not fitting	2 (15.3%)
(asked the child)	After treatment	No discomfort	28 (93.3%)	Sensitivity to hot/cold	0
	Alter treatment	Discomfort	2 (6.6%)	High occlusion	2 (100%)
	Child	Positive	19 (63.3%)		
Appearance (asked child and parent)	Child	Negative	11 (36.6%)		
Appearance (asked child and parent)	Parent	Positive	21 (70%)		
	Fareni	Negative	9 (30%)		
		Positive		General opinion	5 (45.4%)
	Child		11 (36.6%)	Opinion on procedure	0
				Crown vs filling	6 (54.5%)
		Negative	10 (62 20/)	Procedure	9 (47.3%)
The general opinion of the technique (asked			19 (63.3%)	Worry about peer response	10 (52.6%)
the child and parent)				General opinion	6 (35.2%)
		Positive	17 (56.6%)	Opinion on procedure	4 (23.5%)
	Parent			Crown vs filling	7 (41.1%)
		Negotivo	10 (40.00/)	Procedure	7 (53.8%)
		Negative	13 (43.3%)	Worry Response about peer	6 (46.1%)
	Child	Agree	28 (93.3%)	Mould recommend the pro	00
Preference hall of technique	Child	Disagree	(2) (6.6%)	Would recommend the procedure	28

Themes		HT G	roup	MHT G	p-value		
	During	No discomfort	8 (26.6%)	No discomfort	17 (56.6%)	0.018*	
Pain	treatment	Discomfort	22 (73.3%)	Discomfort	13 (43.3%)	0.016	
Falli	After	No discomfort	5 (16.6%)	No discomfort	28 (93.3%)	<0.001*	
	treatment	Discomfort	25 (83.3%)	Discomfort	2 (6.6%)	<0.001	
	Child	Positive	18 (60%)	Positive	19 (63.3%)	0.79	
Appearance	Grilla	Negative	12 (40%)	Negative	11 (36.7%)	(NS)	
	parent	Positive	23 (76.6%)	Positive	21 (70%)	0.56 (NS)	
		Negative	7 (23.3%)	Negative	9 (30%)	(145)	
	Child	Positive	13 (43.3%)	Positive	11 (36.6%)	0.6 (NS)	
The general opinion		Negative	17 (56.6%)	Negative	19 (63.3%)	0.0 (NS)	
of the technique	Damast	Positive	14 (46.6%)	Positive	17 (56.6%)	0.43	
	Parent	Negative	16 (53.3%)	Negative	13 (43.3%)	(NS)	
Preference of	Child	Agree	19 (63.3%)	Agree	28 (93.3%)	0.00.4*	
technique	Child	Disagree	11 (36.6%)	Disagree	2 (6.6%)	0.004*	

Fisher's-exact test , p<0.05 (significant), p>0.05 (Not significant).

and Midani R et al., 91.5% [11,15-18], respectively. This may be because diagnostic radiographs were not taken, since the study was carried out in the rural school setting. The total survival rates were high in this study (>93%). These survival probabilities are in line with previous reports [11,13,14]. However, this is primarily valid for the standard HT, as the less number of studies are reported on MHT, this limits the discussion. No failures were found in MHT group. Contrary to this, Midani R et al., found three major failures [Table/Fig-3] [11].

At three months follow-up, two minor failures were found in the HT due to crown loss. This may be due to decementation or improper crown fit or force from the adjacent tooth. It is also assumed that the Hall SSCs might be susceptible to occlusal perforations as they are fitted without occlusal reduction but this was not found in this study. However, no failures were observed in Hall group with Modifications.

Midani R et al., modified the HT in cases where tight approximal contacts made the immediate placement of the crown difficult [11]. Ludwig KH et al., also used a comparable protocol [15]. In this study, two HT protocols were performed: the standard HT and the MHT. Modification is through minimal reduction of the occlusal surface. In the current study, no crowns were lost using the MHT, compared to standard HT where 4 (36.4%) crowns were lost. This could lead to the assumption that minimal occlusal reduction improved the fitting of the crown.

The level of discomfort experienced by child in the present study were inconsistent with other studies [13,17], where authors

S. no.	Author's name and year	Place of study	Number of subject	Age of the children considered	Objective	Conclusion
1	Santamaria RM et al., (2014) [17]	Germany	169	3-8 years	Clinical efficacy for three caries management options for occluso proximal cavitated lesions in primary molars:	HT was significantly more successful clinically
2	Innes NP et al., (2007) [13]	Scotland	132	3-10 years	Compared the clinical effectiveness of HT with conventional methods	HT comes out to be an effective treatment option for carious primary molars.
3	Innes NP et al., (2011) [7]	Scotland.	132	3-10 years	Investigated survival of carious primary teeth treated with PMCs placed using the HT	94.5% success rate for 1 year follow-up
5	Bell SJ et al., 2010 [21]	UK.	62	6.6 years	Assessed child and parent acceptability of PMCs	PMCs were well accepted by children and their parents.

6	Page LA et al., (2014) [20]	New Zealand	98	6-9 years	Investigated acceptability of SSCs placed by dental therapists using HT.	Both parents and children showed high degree of acceptance for SSC placement using the HT		
7	Santamaria RM et al., (2015) [19]	Germany	169	3-8 years	Compared children's pain perception, technique acceptability	For all the techniques, children's pain perception and parent acceptability were similar		
8	Present study	Nellore	60	6-9 years	Success and acceptability of SSCs using MHTs in children.	100% clinical success rate was found in MHTs during 12 months follow-up. children accepted this technique and Parents accepted both techniques		
[Table/	[Table/Fig-12]: Comparison of previous studies [7,13,17,19-21].							

observed 89% discomfort. This may be due to increased occlusion vertical dimension. On inter group comparison, it was found that children did not experience any discomfort in MHT Group, this may be due to occlusal reduction of the tooth. Children accepted the appearance in both the groups with a response of 60% and 63%; parent's response was 76.6% and 70% in HT and MHT Groups. These results were consistent with other studies [13,19-21]. Similar studies from the literature have been compared in [Table/Fig-12] [7,13,17,19-21].

Page LA et al., Bell SJ et al., reported that parents raised concerns about their children being teased by their peers about silver-coloured crown in their mouth [20,21]. However, in this study, only 23.3-30% of the parents rated appearance as negative. Most parents stated that appearance did not bother these younger children suggesting that aesthetics are not a primary concern of parents or children receiving SSC.

Initially, parents have fear of the peer group response due to the appearance of SSC, but later on, response was good among the children, they used to ask for a crown rather than restoration. Some children used to come and ask for the SSC crowns after seeing their peer group having SSC. This could be due to effective communication and encouraging patient involvement, which generated greater acceptance of the technique.

The qualitative findings support the parent's positive reaction toward HT. A common theme that arose was the parental perception of the longevity of the Hall crown over dental fillings. Parents raised this issue as a concern suggesting that this repetitive work may be detrimental to children and families. A concern that a degree of social stigma may be involved with this procedure (or with SSCs) has been highlighted in earlier research, with the assertion that the use of this technique may be more appropriate for children and families from more deprived groups.

Child responses regarding the preference of the HT were 63.3%, whereas in the MHTs was 93.3%, respectively. This response was in contrast with other studies done by Innes NP et al., reported that 77% of children, preferred HT., and Clark W et al., stated that Hall crown was the treatment approach preferred by both children and dentists [13,16]. Page LA et al., found that 90% of children responded positively and preferred the HT [20]. On intergroup comparison, majority of the children preferred MHTs rather than HT; this could be because the children did not experience discomfort during and after the treatment procedure. Overall, the success rate and the acceptance of modified Halls techniques were superior to than HT.

Limitation(s)

The limitation of this study was that diagnostic radiographs were not taken as it was carried out in a school-based setting in rural areas.

CONCLUSION(S)

Highest clinical success rate was found in MHTs and children accepted MHTs. This can be an effective addition to the treatment

options for carious primary molars for restricted cases where tight proximal contacts are seen

Longitudinal studies are required on the success rate and effectiveness of the combination of different non invasive caries arresting approaches.

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PARTICULARS OF CONTRIBUTORS:

- 1. Senior Lecturer, Department of Paediatric and Preventive Dentistry, CKS Teja Institute of Dental Sciences, Chadalawada Nagar, Tirupathi, Andhra Pradesh, India.
- 2. Professor, Department of Paediatric and Preventive Dentistry, Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India.
- Senior Lecturer, Department of Paediatric and Preventive Dentistry, CKS Teja Institute of Dental Sciences, Chadalawada Nagar, Tirupathi, Andhra Pradesh, India.
 Professor and Head, Department of Paediatric and Preventive Dentistry, Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR: Dr. SVSG Nirmala,

Professor, Department of Pedodontics and Preventive Dentistry, Narayana Dental College and Hospital, Nellore-524003, Andhra Pradesh, India. E-mail: nimskrishna2007@gmail.com

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