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J DENT RES 2011 90: 1405 originally published online 15 September 2011

DOI: 10.1177/0022034511422064

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J Dent Res 90(12):1405-1410, 2011

ABSTRACT

The Hall Technique (HT) is a method for managing carious primary molars. Decay is sealed under pre-formed metal crowns without any caries removal, tooth preparation, or local anesthesia. The aim of this study was to compare HT clinical/radiographic failure rates with General Dental Practitioners' (GDPs) standard (control) restorations. We conducted a split-mouth, randomized control trial (132 children, aged 3-10 yrs, GDPs $n = 17$) in Scotland. There were 264 study teeth with initial lesions, 42% of which were radiographically > half-way into dentin, and 67% of which had Class II restorations. Teeth were randomized to HT (intervention) or GDPs' usual treatment (control). Annual clinical/radiographic follow-up data were recorded. Ninety-one patients (69%) had 48 months' minimum follow-up. At 60 months, 'Major' failures (irreversible pulpitis, loss of vitality, abscess, or unrestorable tooth) were recorded: HT, 3 (3%); control restorations, 15 (16.5%) ($p = 0.000488$; NNT 8); and 'Minor' failures (reversible pulpitis, restoration loss/wear/fracture; or secondary caries): HT, 4 (5%); control restorations, 38 (42%) ($p < 0.000001$; NNT 3). Overall, there were follow-up data for 130 patients (2-60 mos): 'Major' failures: HT, 3 (2%); control restorations, 22 (17%) ($p = 0.000004$; NNT 7); and 'Minor' failures, HT, 7 (5%); control restorations, 60 (46%) ($p < 0.000001$; NNT 3). Sealing in caries by the Hall Technique statistically, and clinically, significantly outperformed GDPs' standard restorations in the long term (Trial registration no. ISRCTN 47267892).

KEY WORDS: caries, primary teeth, restoration, general dental practice, The Hall Technique, sealing caries.

DOI: 10.1177/0022034511422064

Received June 3, 2011; Last revision August 5, 2011; Accepted August 9, 2011

A supplemental appendix to this article is published electronically only at <http://jdr.sagepub.com/supplemental>.

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INTRODUCTION

The management of dental caries has evolved from the exclusive domain of techniques based on complete removal of carious tissue prior to tooth restoration, to include a range of techniques where some, or even all (Mertz-Fairhurst *et al.*, 1998), caries is sealed in beneath restorations or sealants (Kidd, 2004).

There is a significant, and growing, evidence base (Ricketts *et al.*, 2006; Thompson *et al.*, 2008) supporting these techniques as caries management strategies. The techniques are somewhat heterogeneous, ranging from the well-established indirect pulp cap, through stepwise caries removal (superficial caries is removed, sealed, and the cavity re-entered at a later time to remove remaining caries), partial caries removal (variable amounts of superficial caries are removed and remaining caries sealed in permanently), to restorative techniques involving no caries removal.

However, with the exception of the study reported in this article, there have been no randomized control trials (RCTs) on sealing in caries, with no caries removal in primary teeth. In addition, there have been no RCTs on the management of carious primary teeth by general dental practitioners (GDPs) in Primary Care. In the UK, the efficacy of restorative management of carious primary teeth has been questioned (Levine *et al.*, 2002; Tickle *et al.*, 2002). This study was based in Primary Care to increase the generalizability of the results.

Dr. Norna Hall, a GDP working in Scotland, began using pre-formed metal crowns (PMCs) to seal caries in primary molars in the 1980s. The PMCs were cemented over carious primary molars, with a glass-ionomer (GI) luting cement, with no caries removal, tooth preparation, or local anesthesia. A retrospective analysis of Dr. Hall's practice records (Innes *et al.*, 2006) showed that the outcomes for this technique (the Hall Technique) were similar to those reported for more conventional restorations (Chadwick *et al.*, 2002).

The RCT reported here found the Hall Technique to be significantly more successful, at two-year follow-up, than conventional restorations GDPs were providing (Innes *et al.*, 2007). However, a potential problem with sealing in caries is that the carious process might only be slowed, rather than arrested, simply postponing any consequences of not removing infected dentin. Other studies of partial caries removal in primary teeth (Ribeiro *et al.*, 1999; Lula *et al.*, 2009) have reported only short-term outcomes of one-year follow-up. Therefore, the overall aim of this pragmatic trial was to determine whether the Hall Technique for sealing in caries offered long-term benefits over current GDP practice.

The aims of this study were to compare long-term (at 5 yrs) outcomes for carious primary molars managed by GDPs' standard conventional restorative methods (control) with the Hall Technique in general dental practice.

Table 1. Outcome Criteria for the Clinical and Radiographic Assessment of Restorations and Teeth

	Control Restoration	Hall Technique
Successful	<ul style="list-style-type: none"> restoration appears satisfactory and no intervention required no clinical signs or symptoms of pulpal pathology no pathology visible on radiographs 	<ul style="list-style-type: none"> restoration appears satisfactory and no intervention required no clinical signs or symptoms of pulpal pathology no pathology visible on radiographs
'Major' failure	<ul style="list-style-type: none"> tooth has exfoliated with no 'Minor' or 'Major' failures irreversible pulpitis or dental abscess requiring pulp therapy or extraction inter-radicular radiolucency restoration loss and tooth unrestorable internal root resorption 	<ul style="list-style-type: none"> tooth has exfoliated with no 'Minor' or 'Major' failures irreversible pulpitis or dental abscess requiring pulp therapy or extraction inter-radicular radiolucency restoration loss and tooth unrestorable internal root resorption
'Minor' failure	<ul style="list-style-type: none"> secondary caries, or new caries clinically or radiographically restoration fracture or wear requiring intervention restoration loss and tooth restorable reversible pulpitis treated without requiring pulp therapy or extraction 	<ul style="list-style-type: none"> new caries (around margins) crown perforation crown associated with impaction of erupting first permanent molar restoration loss and tooth restorable reversible pulpitis treated without requiring pulp therapy or extraction

The null hypotheses tested were that, in this increased caries risk population, for teeth restored with GDPs' standard restorations and those restored with the Hall Technique, there were no differences in the incidences of:

- (1) 'Major' failure (as defined in Table 1) or
- (2) 'Minor' failure (as defined in Table 1).

MATERIALS & METHODS

This split-mouth RCT (Tayside Committee on Medical Research Ethics approval 108/00) was set in general dental practice in Tayside (2000 regional dmft 2.47, d_3 1.71, mt 0.54, ft 0.22 [NDIP, 2003]), Scotland (Trial registration number: ISRCTN 47267892). Further details of study methodology, including power calculations, entry criteria, randomization, dentist recruitment/training, patient recruitment, and data relating to restoration placement have previously been reported (Innes *et al.*, 2007). Briefly, between 2001 and 2004, 17 GDPs recruited 132 children (aged 3-10 yrs) with caries affecting matched pairs of asymptomatic primary molar teeth. One tooth was allocated to restoration with the intervention, the Hall Technique, and the contralateral tooth provided the control (the restorative technique the GDP would usually choose for that case). The protocol for the Hall Technique crown is detailed in Appendix 1. Briefly, food could be removed from the cavity, but there was no other cavity preparation. The correct size of crown was selected, filled with GI luting cement, and seated with digital pressure before the child was instructed to bite down hard, fully seating the crown. Excess GI was removed. The child continued biting until cement had set.

The GDPs accessed computer-generated randomization for treatment allocation and order (blocked at every 10th generation) by telephoning a central administrator. Clinical and radiographic findings were recorded annually, and at emergency appointments.

Details of patient recruitment and follow-up at 60 mos are listed in the CONSORT flow diagram (Fig.) (Boutron *et al.*, 2008). The dentists assessed 'Major' or 'Minor' failure using standard clinical outcome measures. Radiographs were assessed by two calibrated researchers (DE & NI). Intra- and inter-evaluator agreements have been reported (Innes *et al.* 2007). Restoration differences meant masking was not possible.

Data from annual recalls, emergency appointments, and bite-wing radiographs were entered into a database (Microsoft Access) and outcomes ascribed as 'Successful', 'Major' failures (primary outcome), or 'Minor' failures (secondary outcome) (Table 1). It was also recorded when teeth had exfoliated, or were censored, *i.e.*, tooth extraction for reasons unrelated to a 'Major' or 'Minor' failure.

Data were analyzed for the period of 1 to 60 mos for:

- (1) only patients with 48-month minimum follow-up, or for whom both the Hall Technique and control teeth had reached an end-point (extracted, exfoliated, censored) prior to this time; and
- (2) follow-up data for all patients between 1 and 60 mos.

Data for teeth experiencing 'Major' or 'Minor' failures were extracted from the database (repeat failures are not reported here). Since these were matched pairs, two-tailed exact probability for McNemar's Test (Everitt, 1977; Sheskin, 2007) was used for analysis; level of significance was 0.05. Data analyses followed the intention-to-treat principle.

RESULTS

There was a 48-month minimum follow-up, or both teeth had reached an endpoint for 91 patients (69% of the 132 enrolled). Both teeth had exfoliated in 42 patients (48%). Three patients (3%) had both teeth extracted under general anesthesia because of 'Major' failures of the teeth with control restorations.

Table 2. 'Major' Failures of Hall and Control Teeth and Their Distribution between Split-mouth Pairs

(a)	Control Restoration (teeth with minimum of 48-month follow-up)			(b)	Control Restoration (all teeth with follow-up data)				
	Hall Technique (teeth with minimum of 48-month follow-up)	'Major' Failure	No 'Major' Failure		Total	Hall Technique (all teeth with follow-up data)	'Major' Failure	No 'Major' Failure	Total
	'Major' failure	3*	0	3		'Major' failure	3*	0	3
	No 'Major' failure	12	76	88		No 'Major' failure	19	108	127
	Total	15	76	91		Total	22	108	130

*One tooth did not have a crown fitted but was analyzed in this arm as part of the intention-to-treat principle. (a) Teeth with 48-month minimum follow-up (n = 91 pairs); p = 0.000488 with an odds ratio of infinity; and (b) all teeth with follow-up data (n = 130 pairs); two-tailed exact probability for McNemar's test, p = 0.000004 with an odds ratio of infinity.

Although there was no associated pathology, clinically or radiographically, for the Hall Technique teeth, these were also extracted as *per* local policy because they had been restored, with the outcome recorded as successful (censored).

There were 130 patients with follow-up data between 1 and 60 mos (range, 2-60 mos), mean 40.5 mos (qL27, qU56). Two patients did not return for any follow-up.

Outcome: 'Major' Failures

For the 91 patients with 48-month minimum follow-up, 18 teeth experienced at least one 'Major' failure. Three 'Major' failures (3%) were in the Hall Technique arm, with failure times at 3, 17, and 31 mos. Fifteen (16.5%) were in the control restoration arm. Time to first failure ranged from 1 to 60 mos, mean 23 mos (qL 12, qU 31). Failure categories for the Hall Technique were abscess (n = 2) and irreversible pulpitis (n = 1), and for the control restoration, abscess (n = 12), irreversible pulpitis (n = 2), and broken down and unrestorable (n = 1).

There was a statistically significant increased risk (p < 0.000488) for 'Major' failures when a control restoration had been placed compared with a Hall Technique PMC. All three patients with a Hall Technique 'Major' failure also experienced a 'Major' failure of the control tooth (Table 2a shows the distribution of 'Major' failures between matched pairs for patients with 48-month minimum follow-up). Failure rates for the intervention and control arms gave an absolute risk reduction (ARR) value of 0.132 (95% CI = 0.0457-0.224) and numbers-needed-to-treat (NNT) of 8 teeth.

There were 130 patients with follow-up data from 1 to 60 mos. Table 2b shows the distribution of the 3 Hall Technique and 22 control restoration 'Major' failures (P = 0.000004), an ARR of 0.146 (95% CI = 0.077-0.221), and NNT of 7 teeth.

Outcome: 'Minor' Failures

For the 91 patients with 48-month minimum follow-up, 42 teeth were recorded as having at least 1 'Minor' failure. There were 4 'Minor' failures in the Hall Technique arm (5%), ranging from 3 to 31 mos, mean 17.6 mos (qL 12, qU 27), and 38 'Minor'

failures (42%) for the control restorations (Table 3a). The time to first failure ranged from 5 to 36 mos, mean 16.9 mos (qL 12, qU 23). Failure categories for the Hall Technique were caries at margin of crown (n = 1), crown worn through (n = 1), crown lost (n = 1), first permanent molar impacting and separator placed (n = 1); and for the control restorations, restoration loss (n = 21), secondary caries (n = 13), restoration fracture/wear (n = 3), and radiographic caries progression (n = 1).

There was a statistically significant increased risk (p < 0.000001) for 'Minor' failure with a control restoration compared with the Hall Technique, an ARR of 0.37 (95%CI = 0.258-0.479), and NNT of 3 teeth.

There were 130 patients with follow-up data from 1 to 60 mos. Table 3b shows the distribution of the 7 Hall Technique and 60 control restorations' 'Minor' failures (p < 0.000001), an ARR of 0.40 (95%CI = 0.309-0.498), and NNT of 3 teeth.

Outcome: 'Successful'

For the 91 patients with 48-month minimum follow-up, 84 of the 91 teeth (92%) in the Hall Technique arm and 47 of the 91 teeth (52%) in the control arm were ascribed as 'Successful' (Table 1), *i.e.*, not experiencing a 'Major' or 'Minor' failure. No Hall Technique teeth experienced both 'Major' and 'Minor' failures. Eight control teeth initially experienced a 'Minor' failure and a subsequent 'Major' failure, while 1 control tooth experienced a 'Major' failure (abscess, managed by pulp therapy) and a subsequent 'Minor' failure (loss of restoration).

DISCUSSION

Sequential screening of all potentially eligible patients was not a requirement, and this may have introduced a degree of selection bias. However, this was the first RCT in general dental practice in Scotland involving a novel intervention. This meant striking a balance between methodological integrity and generalizability. The trial was designed to encourage GDP participation, allowing them to focus on the trial during less busy periods. However, patients enrolled in the trial were representative of general practice attendees in that age group (Innes *et al.*, 2007).

Table 3. 'Minor' Failures of Hall and Control Teeth and Their Distribution between Split-mouth Pairs

(a)	Control Restoration (teeth with minimum of 48-month follow-up)			(b)	Control Restoration (all teeth with follow-up data)		
Hall Technique (teeth with minimum of 48-month follow-up)	'Minor' Failure	No 'Minor' Failure	Total	Hall Technique (all teeth with follow-up data)	'Minor' Failure	No 'Minor' Failure	Total
'Minor' failure	2	2	4	'Minor' failure	3	4	7
No 'Minor' failure	36	51	87	No 'Minor' failure	57	66	123
Total	38	53	91	Total	60	70	130

(a) Teeth with 48-month minimum follow-up (n = 91 pairs); $p < 0.000001$ with odds ratio 18 (95%CI 4.33-74.76; and (b) all teeth with follow-up data (n = 130 pairs); $p < 0.000001$ with odds ratio of 14.25 (95%CI 5.17-39.27).

This study's principal finding was that the Hall Technique was significantly more effective in the long term than the GDPs' standard restorations. For patients with 48-month minimum follow-up, there were 3 Hall Technique 'Major' failures, the last occurring 31 mos after crown placement. This was in contrast to 15 control restoration 'Major' failures, where a quarter of the failures occurred after 31 mos. These results were surprising. While there is increasing evidence supporting sealing-in caries management strategies (indirect pulp caps; partial, and stepwise, caries removal), all involve some removal of caries and, therefore, of superficial plaque biofilm. With the Hall Technique, this layer, considered to be the most significant part of the biofilm for lesion progression (Kidd, 2004), is left *in situ* and sealed-in along with the caries. Analyses of these data indicates that this may arrest lesion progression, and at least slows it sufficiently to be of little clinical consequence in the management of carious primary teeth. However, caution should be exercised in translating this finding to the management of permanent teeth. Hall crowns allow an effective, durable seal to be readily obtained by GDPs in the busy environment of Primary Care. Achieving the same quality of seal for a multi-surface cavity, with plastic restorative materials, in the same clinical environment, might be more problematic and requires further research.

In comparison, the longevity of GDPs' control restorations was poor. One audit-based study reported that GDPs' restorations for carious primary teeth did not influence pain and infection rates compared with teeth left unrestored (Tickle *et al.*, 2002). However, a more recent analysis of GDP restorations found significant benefit to restoring primary teeth (Stephenson *et al.*, 2010). In the current study, 16.5% of control teeth experienced 'Major' failures. This number approaches those reported in another Primary Care-based study where carious primary teeth were left unrestored (Levine *et al.*, 2002). Restoration survival rates for the Hall Technique were comparable with those of conventional restorations placed by specialists, and in Secondary Care settings (Chadwick *et al.*, 2002).

One explanation for the poor performance of GDPs' restorations was their extensive use of GI (used for 73% of restorations, with 68% of the lesions being proximal). There is now good evidence for GI being an unsuitable restorative material for multisurface cavities (Chadwick and Evans, 2007). It is also

of interest that no pulp therapies were provided by GDPs for any control teeth at the initial appointment, despite a considerable proportion of primary molars having advanced dental caries. Radiographs of diagnostic quality were available for 87% of the initial 132 teeth, and in 42% of these, caries extended over half-way through dentin (Innes *et al.*, 2007). Cavity preparation on teeth with extensive dental caries may have further stressed the pulp. Subsequent placement of an inadequately sealed restoration could exacerbate the insult, precipitating 'Major' failure. However, since the lesions were matched for site and extent, success rates for the Hall Technique further support slowing, and possible arrest, of caries lesion activity and progression.

While GDPs were generally rigorous in completing paperwork and adhering to protocol, where breaches occurred, these were with respect to radiographic follow-up. The dentists had been requested to take radiographs in line with current guidelines (FGDP, 2004). However, GDPs do not routinely take radiographs of children (Taylor and Macpherson, 2004), and the pattern of radiograph prescribing within the trial regressed from recommended guidelines toward a pattern of few or no radiographs being taken. The impact of the radiographic findings on outcomes at two-year follow-up (where 94% of radiographs were available) was minimal. Only 2 of the 22 'Major' failures (3 Hall; 19 control) and 5 of 63 'Minor' failures (6 Hall; 57 control) were detected radiographically alone (Innes *et al.*, 2007). It is unlikely therefore that full compliance of GDPs with radiographic protocols would have had a significant effect on the reported outcomes.

CONCLUSION

The null hypotheses for no differences in 'Major' and 'Minor' failure rates in the long term, between GDPs' standard restorations and the Hall Technique, were both rejected. At 60 mos, for teeth with a minimum of 48 mos' follow-up, sealing-in caries by the Hall Technique statistically, and clinically, significantly outperformed the GDPs' standard restorations. Hall Technique outcomes were comparable with those of standard restorations in studies in Secondary Care. These results strongly support the Hall Technique as a predictable restorative option, with low failure and, therefore, re-treatment rates, for managing carious primary molars in a Primary Care environment.

ACKNOWLEDGMENTS

We thank the children who took part in this trial, the participating dentists in Tayside who recruited and provided care for the participants, and Mrs. Valarie Wilson for assisting with data collection and input.

As discussed with the editor, an earlier publication of this work was published as Innes NP, Evans DJ, Stirrups DR (2007). The Hall Technique; A randomized controlled clinical trial of a novel method of managing carious primary molars in general dental practice: Acceptability of the technique and outcomes at 23 months. *BMC Oral Health*. <http://www.biomedcentral.com/1472-6831/7/18>.

This trial was supported through a research training fellowship grant (Chief Scientist Office, Scottish Executive) and financial support from 3M/ESPE and EastRen. The sponsors of this trial had no role in its design; the collection, analysis, or interpretation of data; or the dissemination of results. The authors had final responsibility for the decision to submit for publication. The views expressed in this report are those of the authors and do not necessarily represent those of the funding bodies.

The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

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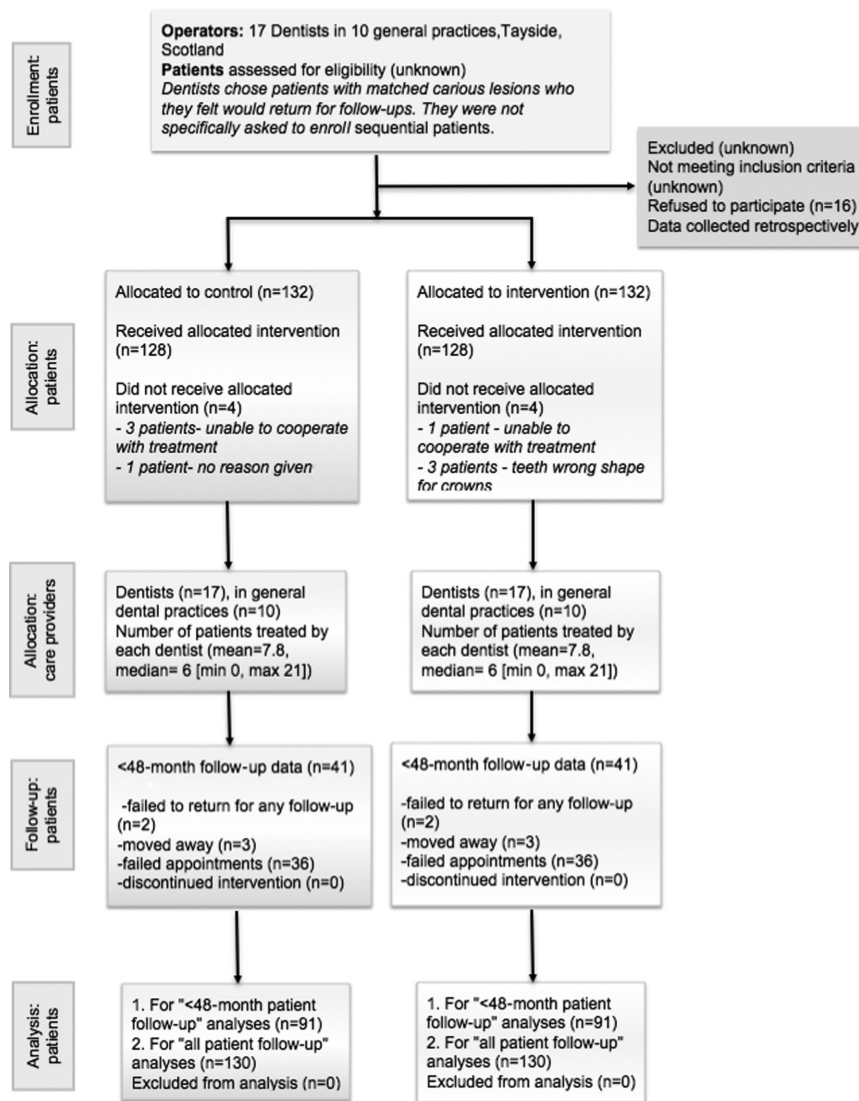


Figure. CONSORT flow diagram detailing patient recruitment and follow-up at 60 months.

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