The Hall Technique; retrospective case-note follow-up of 5-year RCT

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IN BRIEF

- Discusses evidence that the Hall Technique is an effective caries management technique for children with carious primary molars.
- Highlights that crowns placed using the Hall Technique have high success rates over the lifetime of primary teeth.
- Suggests clinicians should consider the Hall Technique for carious primary molars with approximal lesions into dentine.

RESEARCH

Background and aim Few paediatric dental restorative trials present outcomes for more than two years, leaving clinicians uncertain of long-term implications for their patients. This study aimed to establish the Hall Technique's success over the lifetime of primary teeth compared to conventional restorations (CR), by following up participants in the Tayside (Scotland), UK trial. **Design** Following the Phase 1 prospective, split-mouth randomised control trial with 132 children (264 teeth) in 17 general practices in Scotland, 142/264 (54%) teeth had reached an endpoint of exfoliation or extraction. Through practices, Phase 2 follow-up data were collected retrospectively from case-notes, using original trial outcomes. Phase 1/ 2 outcome data were combined. **Results** Data were obtained up until exfoliation/extraction for 184 teeth (73%) in matched pairs. Major failures: 16 CR; 4 HT (P = 0.0015); ARR = 0.13 (95%CI: 0.04;0.22), numbers needed to treat (NNT) 8 (95%CI: 4;25) favouring HT. Minor failures: 37 CR; 5 HT (P <0.0001); ARR = 0.35 (95%CI: 0.23;0.45) and NNT = 3 (95%CI: 2;4). Repeat failures occurred mostly in the conventional restoration arm for both major and minor failures. **Conclusions** The HT continued to outperform GDP's standard restorations in primary molar teeth with significant caries involvement over the lifetime of the teeth.

INTRODUCTION

The Hall Technique (HT) is a method for managing carious lesions in primary molar teeth by cementing a preformed metal crown (PMC) over the tooth, with no local anaesthetic, caries removal or tooth preparation. In line with other more biological and less 'surgical' approaches to managing dental caries[1] it is growing in use.[2] The carious lesion is effectively 'sealed in' by the PMC, slowing or arresting progression of the lesion toward the pulp, and preventing pain and infection (abscess). Two published randomised control trials (RCTs), of one-year[3] and five-year[4] follow-up, have reported the HT to be successful in managing dental caries. Other observational studies in Australia[5] and New Zealand[6] support its success in other environments, and a retrospective analysis of patient records in a US specialist private practice found the HT to perform as well as conventional crowns.[7]

A problem with generalising clinical trials of caries management options to patient care in practice, is the generally short follow-up times (commonly six months, one year or two years), compared to the length of time that the restoration is expected to perform for the patient. In children, this is until exfoliation, so in a study where children are recruited from three years of age, the performance of the intervention until the tooth exfoliates could be up to nine years. In addition, there is very little long-term data on sealing in caries, and one concern is that the caries process continues within the sealed environment, although more slowly, and that failures still occur, but are delayed.

The initial HT trial ran between 2001 and 2009.[8] As well as significantly outperforming the dentists' conventional restorations, the HT was successful in its own right and was preferred by child participants, parents and the dentists, a finding replicated in an ongoing trial in Germany.[9] Despite participant follow-up times ranging from 2–60 months, only 142/264 teeth (54%) had reached an endpoint of extraction or exfoliation by the end of the trial. This meant that 122 teeth (46%) still hadn't reached endpoints.

This follow on observational study aimed to collect retrospective data for the study teeth from GDP's notes, to supplement previous data, using the same outcomes, and present a picture of the fate of the teeth in the HT trial until exfoliation.

The null hypotheses tested were that, in this increased caries risk population, for teeth restored with GDPs' standard restorations and those restored with the HT in a UK general practice setting, there was no difference at exfoliation in major failure rate, minor failure rate or survival rate of the teeth.

MATERIALS AND METHODS

The full reports of the HT RCT have been published.[4,8] Briefly, the trial was set in general dental practice in Scotland, UK, and ran between 2001 and 2009.[8] The patient level, split-mouth RCT, compared the HT to conventional restorations (complete caries removal and placement of a restoration of the general dental practitioner's choice based on usual care) in children (3–10 years old) with matched carious lesions on contralateral primary molars. Participant follow-up data were collected on a proforma annually for up to five years. This prospective phase of the HT RCT is termed Phase 1 and the subsequent retrospective data collection and report from practice records, reported here is Phase 2.

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Refereed Paper
Accepted 14 September 2015
DOI: 10.1038/sj.bdj.816
©British Dental Journal 2015; 219: 395–400

Access to data

We confirmed that Ethics Committee and Caldicott Guardian approval were not required. Principal GDPs at practices who took part in the initial study, were asked for access to the dental records to abstract information on trial teeth (treated in the split mouth trial with either the HT or a conventional restoration) for the original trial participants.

Participant eligibility

From the trial records, participants were identified who: were part of the 132 recruited to the Tayside Hall Trial in 2001; and had no recorded terminal outcome (either extraction or exfoliation) for one or both teeth when the trial came to an end.

Phase 2 data collection/ abstraction

One researcher (GS, NI or MS) reviewed the notes for each patient and completed a (piloted) data collection proforma. This was pseudonymised using the participants' original trial randomisation number to allow data to be linked back to the original participant data (Phase 1).

Information collected on the proforma included:

Major failures: date and type of any signs or symptoms of irreversible pulpitis (history of spontaneous pain or precipitated pain caused by thermal or other stimuli) or dental abscess requiring pulp therapy or extraction or where the restoration was lost and the tooth recorded as unrestorable;

- Minor failures: date and type of any signs or symptoms of reversible pulpitis (no spontaneous pain) requiring pulp therapy or extraction or caries around the restoration requiring intervention or restoration or crown fracture/ wear/ loss where the tooth is restorable and requiring intervention including repeat episodes; and
- Date when succeeding permanent tooth noted as present on dental chart (inference that primary tooth had exfoliated).
- Data were abstracted from the proformas by two researchers and discussed to agree a consensus on ascribing outcomes as either 'successful', 'major failure' or 'minor failure' using the previous trial outcome definitions (further detailed in Appendix 1).

When there was no record that the trial teeth had experienced a dental intervention, or was extracted but the dental chart showed a permanent successor present, an assumption was made that the tooth exfoliated without a major or minor failure.

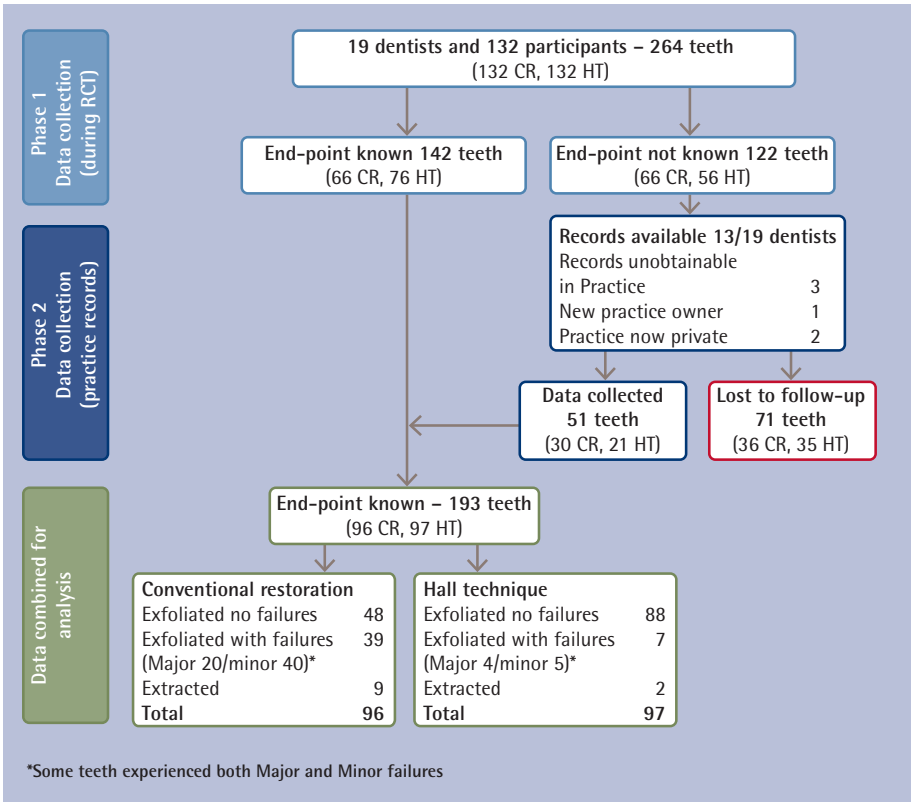

Fig. 1 Flow chart of participants' teeth follow-up and data collection.

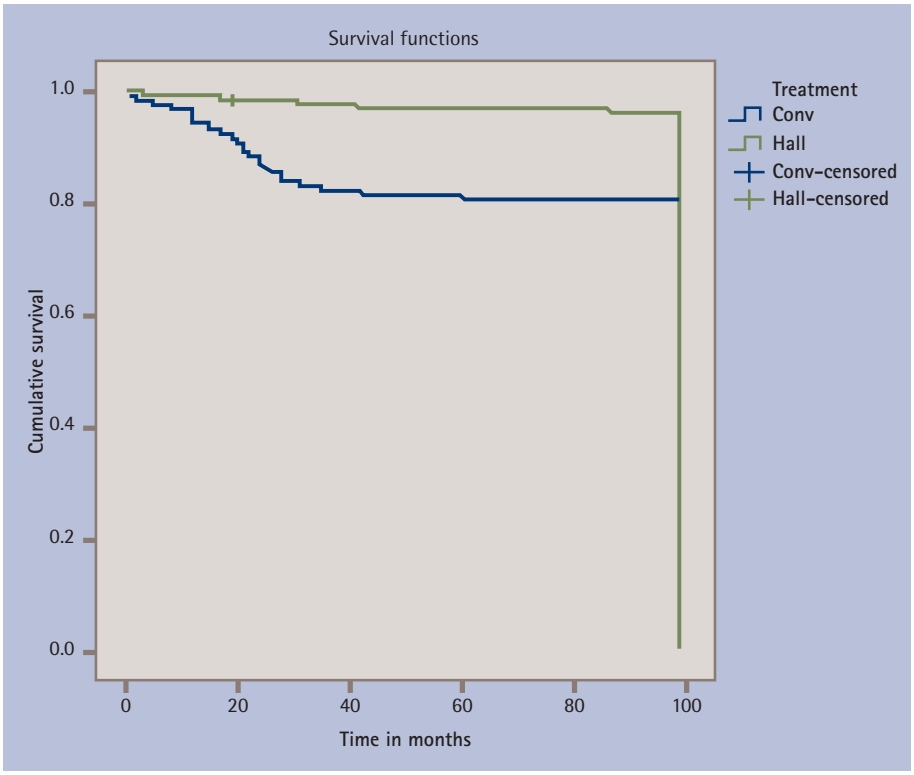

Fig. 2 Kaplan–Meier survival curve for time to first major failure by treatment arm

Data analysis

Data were analysed in SPSS version 20 (SPSS Inc., Chicago, IL, USA).

Kaplan-Meier survival curves were calculated by combining Phase 1 and Phase 2 data for all 132 teeth in the trial until exfoliation, extraction or loss to follow-up based on all available data for each arm (HT and CR). Separate analyses were carried out for major and minor failure data using 'time to first failure' or 'time last seen' as the endpoint.

For teeth where outcome data were known for both teeth in the split mouth pair (Phase 1 and Phase 2 data combined), McNemar's test (with continuity correction) was used to test for difference in the major failure and minor failure outcomes between the CR and HT restorations.

RESULTS

Data collection

In total, data were available for 193 (73%) teeth (96 CR, 97 HT) in 101 of the original 132 participants (77%) allowing survival analysis.

However, an endpoint was known for both trial teeth (matched pairs) for only 92 (70%) participants; 184 teeth, because in nine participants, only one tooth had a confirmed endpoint (4 CR, 5 HT). These matched pairs were suitable for McNemar analysis. Figure 1 shows the two phases of data collection and the information obtained at each stage to give the final complete dataset.

Outcomes

Phase 2 data (n = 51 teeth), 30 CR, 21 HT in 32 participants: 20 teeth (15 HT, 5 CR) exfoliated successfully, 27 (4 HT, 23 CR) exfoliated following at least one major and/or minor failure and four teeth (2 HT, 2 CR) were extracted.

Phase 1 and Phase 2 data combined (n = 193 teeth), 96 CR, 97 HT in 101 participants, 50% CR teeth (48/96) and 91% HT teeth (88/97 including three censored as extracted under GA) successfully exfoliated over the lifetime of the teeth. Detail is shown in Table 1.

Major failures (survival analysis)

The survival curve is shown in Figure 2. For the 193 (96 CR, 97 HT) teeth with data until exfoliation/extraction, 24 teeth (20 CR, 4 HT) experienced at least one major failure. All initial CR major failures occurred during Phase 1; however two repeat major failures occurred during Phase 2. In the HT arm, two of the initial major failures occurred in Phase 1. There were two major failures in the HT arm that occurred late (41 and 86 months). None of the HT teeth with data until exfoliation/extraction experienced repeat major failures.

Major failures (matched pairs)

Table 2 shows failures within their matched pairs (data available for 184/193 teeth). For CR teeth, 16 pairs experienced a minor failure, with four of these pairs also experiencing minor failure of the HT. No teeth experienced a major failure in the HT alone within the matched pairs. There was a statistically and clinically significant increased risk of major failure (CR 16; HT 4) with the CR treated teeth ($\chi 2 = 10.083$, P = 0.0015) with an absolute risk reduction (ARR) of 0.13 (95%CI: 0.04 to 0.22) and numbers needed to treat (NNT) value of eight (95%CI: 4 to 25) in favour of the HT. Matched pair failure times ranged from CR; 1-60 months and HT; 3-86 months. The most common reason for major failures was irreversible pulpitis or dental abscess (CR 29; HT 4). Cases where the restoration or crown was lost and the tooth unrestorable were uncommon, with no cases in the HT arm (CR 2; HT 0). Repeat failures occurred mainly in the conventional restoration arm (Fig. 3).

Table 1 Endpoint data collected from Phase 1 (initial prospective RCT) and Phase 2 (retrospectively through case notes) to give total dataset of 193 teeth

	Conventional restoration	Hall Technique	Total*	
Successfully exfoliated with no minor or major failures	48	88 (includes 3 censored XGA)*	136	
Exfoliated following a major failure	11	2	5	46
Exfoliated following a minor failure	28	5	33	
Exfoliated following both a major and a minor failure	8	0	8	
Extracted	9	2	11	
Total	96	97	193	

*Asymptomatic teeth extracted as child was undergoing general anaesthesia (GA) for extraction of symptomatic teeth and local policy at the time was to extract all restored primary molars to reduce the risk of repeat GA.

Table 2 Major failures of conventional restorations and HT crowns and their distribution between the 92 split mouth pairs

		Hall Technique (split mouth pairs)		
		Major failure	No major failure	Total
Conventional restorations (split mouth pairs)	Major failure	4	12	16
	No major failure	0	76	76
	Total	4	88	92*

*184 of 193 teeth followed up were in split mouth pairs (92 pairs, 95%)

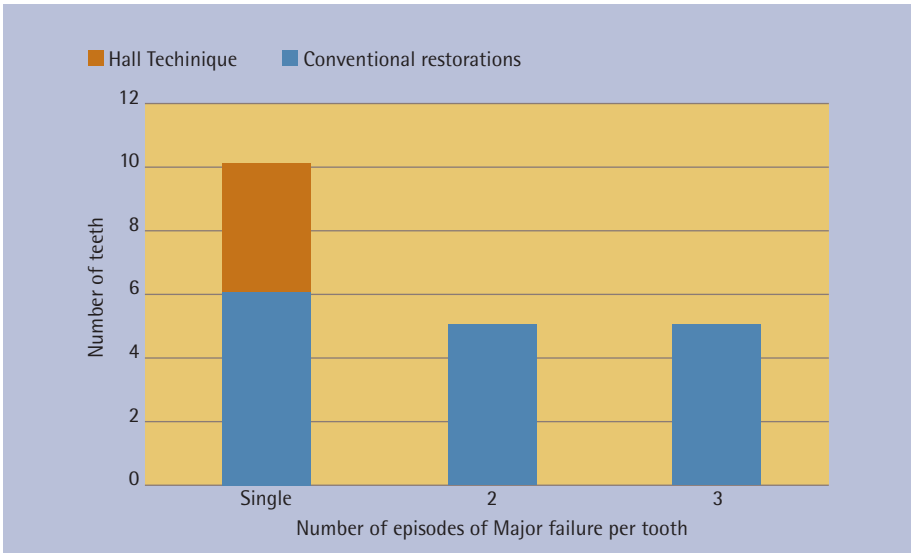

Fig. 3 Major failures; single or repeat failures (20 teeth, CR = 16 HT = 4)

Minor failures (survival analysis)

The survival curve is shown in Figure 4. For the 193 (96 CR, 97 HT) teeth with data up until exfoliation/extraction, 45 teeth (40 CR, 5 HT) experienced at least one minor failure. All of the initial minor failures in the CR and HT arms occurred during Phase 1 of the trial.

However, there was one additional minor failure recorded in the CR (at 49 months) in a tooth that, at the end of Phase 1, had already experienced minor failures on four occasions (12, 20, 26 and 35 months).

Minor failures (matched pairs)

There was a higher risk of minor failure for CR teeth compared to HT teeth (Table 3). 37 pairs had a minor failure in the CR tooth with 3 of these pairs also experiencing failure in the HT. An additional 2 teeth experienced failure only in the HT tooth ($\chi 2$ = 26.694, P <0.0001) with an ARR = 0.35 (95%CI: 0.23 to 0.46) and NNT value of three (95%CI: 2 to 4). This gave a statistically significant, clinically important improved outcome for the HT compared with CR.

Matched pair failure times were CR; 5–55 months and HT; 6–29 months. The two most common reasons for failures were restoration or crown loss but where the tooth was restorable (CR 40, HT 1), and further caries around the restoration or crown requiring intervention (CR 25, HT 1). Further detail can be found in Appendix 2. Restoration or crown fracture, or wear failures requiring intervention were seen in a few teeth (CR 6, HT 2) but no teeth were recorded as experiencing reversible pulpitis. Repeat failures occurred mainly in the conventional restoration (Fig. 5).

DISCUSSION

This is an unusual dataset as it follows restorative interventions for the lifetime of the teeth as studies of primary teeth restorative interventions generally only follow up with patients for one or two years. It gives further insight into the long-term outcomes for primary molars treated using the HT. Our principal findings were that there were still failures occurring for both the HT and the CR in the longer term but the survival functions dropped most steeply during the first 30 months for both major and minor failures for the CR and for minor failures for the HT. This shows continuation of the trajectory seen in previous follow-up data; with the HT vastly outperforming the CR with most failures in the first 30 months.

Although the HT has been viewed with a mixture of scepticism from a traditional dental point of view, and support from a cariology perspective, it has become a standard treatment option in the UK for managing carious primary molars. A survey in 2013 of all dental and dental therapist schools in the UK, found that all taught the HT to undergraduate dental students and only one did not use it routinely.[2] A Cochrane review[1] concluded that for symptomless and vital teeth, a biological (sealing) approach had

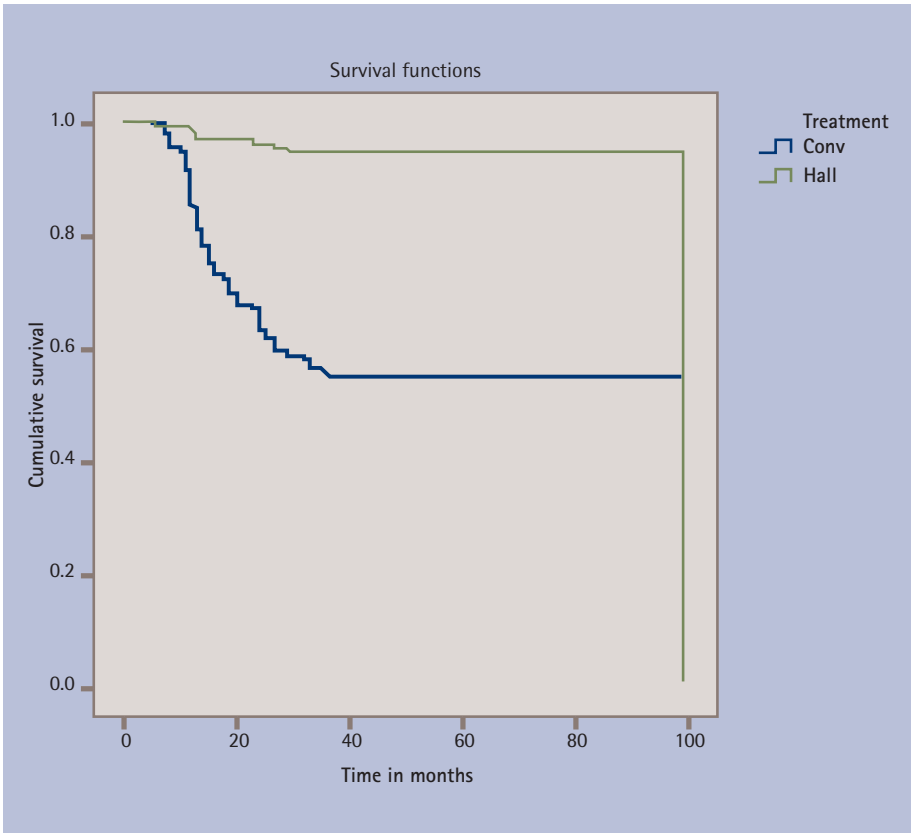

Fig. 4 Kaplan–Meier survival curve for time to first minor failure by treatment arm

Table 3 Minor failures of conventional restorations and HT crowns and their distribution between the 92 split mouth pairs.

		Hall Technique (split mouth pairs)		
		Major failure	No major failure	Total
Conventional restorations	Major failure	3	34	37
(split mouth pairs)	No major failure	2	53	55
	Total	5	87	92*

*184 of 193 teeth followed up were in split mouth pairs (92 pairs, 95%)

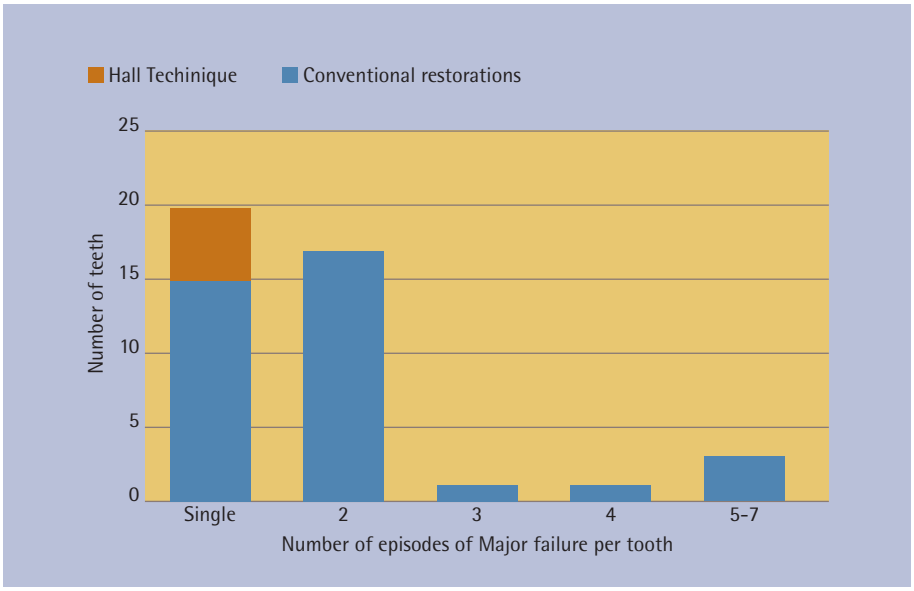

Fig. 5 Minor failures; single or repeat failures (42 teeth, CR = 37 HT = 5)

advantages over complete caries removal; notably reducing the incidence of pulp exposure and having no detriment on restoration longevity. However, sealing in caries lesions is still relatively new compared to traditional caries management techniques, with few long-term studies and, as using the HT to do this was novel when this trial was run, we did not know whether there were any long-term adverse events from sealing in the biofilm. Mertz-Fairhurst's study[10] of permanent teeth sealed with composite or amalgam is a notable exception. Like our study, they did not find any long-term clinical problems sealing in caries, even at ten year follow-up and so provided the start of a clinical picture showing that sealing in lesions/ biofilm changes their properties, making them less active/ cariogenic.[11] Our findings add to this picture. At two years[8] we reported major failure rates of CR 15% and HT 2%; at 5 years[4] CR 17% and HT 2% and now in this follow-up CR 17% and HT 4%. The study by Santamaria,[9] also comparing HT and CR as part of their study found failure rates of CR 3% and HT 0% at one year.

This follow-up data had a NNT of eight; only eight children needed to be treated with a Hall crown, rather than have a conventional restoration, to avoid one major failure (an increase from NNT of seven at the five-year mark).

The NNT for minor failures remained the same when including this longer follow-up data, at NNT of three at five years. This means that over the lifespan of the tooth, only three children needed to be treated with a Hall crown rather than a conventional restoration to avoid a minor failure.

Repeat failures were common for the CR and uncommon for the HT for both major and minor failures. These have implications for both children and parents, such as repeated treatment events and time off school/work. This could also impact on the dental team; accommodating urgent appointments for failed treatment, increased time pressures, and reduced belief in efficacy of treatment. If these failure rates are an indication of those nationally, the cost of replacing these restorations annually could be substantial to the health service. However, it should be noted that the majority (68%) of cavities were multisurface lesions and dentists chose to restore most (69%) of all lesions with glass ionomer cement.[8] These materials have undergone major improvements over the last few years, but at the time the standard glass ionomer cements were not considered adequate for multisurface lesions.[12]

A strength of this study is that it includes long-term data with a high follow-up (73%) to endpoint for the teeth in the study. The Phase 1 was a tightly controlled split mouth RCT with data collected contemporaneously by the examining dentists on proformas. Although the data have been collected through two separate mechanisms (Phase 1; a prospective RCT and Phase 2; a retrospective cohort approach), the outcomes collected were standardised, and the researchers collecting the data were calibrated. A significant limitation of Phase 2 lay in the actual data collection via GDP records. These were of variable quality and often very brief. We made the assumption that no failure had taken place when a tooth had exfoliated without a problem or any dental intervention being noted in the records. This may have led to under recording of failures, but is likely to have been similar across both arms. For major failures, which would have resulted in a significant intervention (pulp therapy or extraction), it is likely that these would have been recorded in the notes. It is also likely that more children attended for treatment who had experienced a problem with a tooth than those who didn't, increasing our confidence in the level of failures detected from the GDP notes. Experiencing pain is a driver for attendance at a dentist. Radiographs were taken in the original study and it is another limitation of the Phase 2 data that there were no radiographs for the children. This meant that only clinical data from the participant records were able to be collected and, again, may have led to under reporting. However, in the first follow-up of Phase 1, only two out of 19 major failures (both in CR teeth) were noted as having periradicular pathology on radiographs where this was not detected/reported as clinical failures by the examining dentists.[4]

Only one additional minor failure for CR teeth in Phase 2 was picked up. This was a repeat failure and there were no additional minor failures for HT teeth. However, it is possible that there may have been under-recording for minor failures, particularly within the HT arm. While a lost conventional restoration is likely to have been recorded (to allow the dentist to submit for claim for payment), it is possible that worn or perforated crowns with no signs or symptoms were, therefore, unlikely to have required treatment, and may not have been recorded in the notes. Most minor failures occurred during the initial follow-up times and were dealt with. Another explanation for no additional first minor failures being detected could be that the dentists did not routinely replace restorations when they were lost after the child was no longer part of the trial. The care index in Scotland (the proportion of teeth with dentinal caries that have been restored) is very low at around 13%, that is only around one in 10 carious primary teeth that are restored.[13] In addition, restoration problems related to quality or material during placement, or reasons for failure related to the child's mouth or behaviour are likely to have happened before five years.

CONCLUSION

In this increased caries risk population, for teeth restored with GDPs' standard restorations and those restored with the HT in a UK general practice setting, the HT teeth experienced statistically and clinically less major failures, minor failures and had a better survival rate over the lifetime of the teeth. The HT continued to outperform GDPs standard restoration in teeth with significant caries involvement.

In summary:

- The Hall Technique is an effective caries management technique for carious primary molars in children
- Crowns placed using the Hall Technique have high success rates over the lifetime of primary teeth.

Acknowledgements

We would like to thank the children, their parents and all of the Tayside General Dental Practitioners who so assiduously took part in the original Hall Technique RCT as well as those dentists who allowed us to access their records and complete that initial piece of work. This study was supported by the University of Dundee, UK.

Conflict of Interest

Nicola Innes and Dafydd Evans received partial sponsorship in 2000, from 3M/ESPE, for the randomised control clinical trial investigating the use of preformed metal crowns to seal caries into primary molar teeth using the HT. The idea for this study, collection and analysis of Phase 2 data was supported only by the individuals' institutional funding and did not have any external funding. The other authors declare no conflict of interest. Only the authors were involved in: conceiving the study design; collection; analysis and interpretation of the data; and writing the manuscript.

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Appendix 1 Outcome criteria for Hall Technique and control restorations

Outcome	Conventional restoration	Hall Technique
Major failure	Signs or symptoms of irreversible pulpitis (history of spontaneous pain or precipitated pain caused by thermal or other stimuli) or dental abscess requiring pulp therapy or extraction	Signs or symptoms of irreversible pulpitis (history of spontaneous pain or precipitated pain caused by thermal or other stimuli) or dental abscess requiring pulp therapy or extraction
	or	or
	restoration loss and tooth is unrestorable	crown loss and tooth is unrestorable
Minor failure	Signs or symptoms of reversible pulpitis (no spontaneous pain) requiring pulp therapy or extraction	Signs or symptoms of reversible pulpitis (no spontaneous pain) treated without requiring pulp therapy or extraction
	or	or
	caries around the restoration requiring intervention	new caries (around margins) requiring intervention
	or	or
	restoration fracture or wear requiring intervention	crown perforation
	or	or
	restoration loss and tooth restorable	crown loss and tooth is restorable

Appendix 2 Minor failures of conventional restorations and Hall Technique crowns and their distribution between split mouth pairs (n = 184) with data for repeat failures

Outcome	Conventional restoration	First failure outcome for teeth experiencing major or minor failure	Total number of major and minor failures	Hall Technique	First failure outcome for teeth experiencing major or minor failure	Total number of major and minor failures
Major failure	Signs and/or symptoms of irreversible pulpitis (history of spontaneous pain or precipitated pain caused by thermal or other stimuli) or dental abscess requiring pulpotomy or extraction	16	29	Signs and/or symptoms of irreversible pulpitis (history of spontaneous pain or precipitated pain caused by thermal or other stimuli) or dental abscess requiring pulpotomy or extraction	4	4
	Restoration loss and tooth is unrestorable.	0	2	Crown loss and tooth is unrestorable	0	0
	Total	16	31	Total	4	4
Minor failure	Secondary caries (visible dentin in the interfacial space with signs of caries requiring intervention)	15	25	New caries (around margins of crown)	1	1
	Restoration fracture or wear requiring intervention	3	4	Crown perforation	2	2
	Restoration loss but tooth is restorable	19	40	Restoration loss but the tooth is restorable	1	1
	Signs or symptoms of reversible pulpitis treated without requiring pulpotomy or extraction	0	0	Signs or symptoms of reversible pulpitis treated without requiring pulpotomy or extraction.	0	0
	Other	0	0	1st molar impacting under distal of HT so separator placed	1	1
	Unclear	0	4		0	0
	Total	37	73	Total	5	5