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Alternative Caries Management Options for Primary Molars: 2.5-Year Outcomes of a Randomised Clinical Trial

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Abstract
Less invasive caries management techniques for treating cavitated carious primary teeth, which involve the concept of caries control by managing the activity of the biofilm, are becoming common. This study aimed to compare the clinical efficacy (minor/major failures) and survival rates (successful cases without any failures) of 3 carious lesion treatment approaches, the Hall Technique (HT), non-restorative caries treatment (NRCT), and conventional restorations (CR), for the management of occlusoproximal caries lesions (ICDAS 3–5) in primary molars. Results at 2.5 years are presented. A total of 169 children (3- to 8-year-olds) were enrolled in this secondary care-based, 3-arm parallel-group, randomised controlled trial. Participants were allocated to: HT ($n = 52$; sealing caries with stainless-steel crowns without caries removal), NRCT ($n = 52$; opening up the cavity and applying fluoride varnish), CR ($n = 65$; control arm, complete caries removal and compomer restoration). Statistical analyses were: non-parametric Kruskal-Wallis analysis of variance, Mann-Whitney U test and Kaplan-Meier survival analyses. One hundred and forty-two participants (84%; HT = 40/52; NRCT = 44/52; CR = 58/65) had follow-up data of 1–33 months (mean = 26). Overall, 25 (HT = 2, NRCT = 9, CR = 14) of 142 participants (17.6%) presented with at least 1 minor failure (reversible pulpitis, caries progression, or secondary caries; p = 0.013, CI = 0.012–0.018; Mann-Whitney U test). Ten (HT = 1, NRCT = 4, CR = 5) of 142 participants (7.04%) experienced at least 1 major failure (irreversible pulpitis, abscess, unrestorable tooth; $p = 0.043$, CI = 0.034–0.045). Independent comparisons between 2 samples found that NRCT-CR had no statistically significant difference in failures ($p > 0.05$), but for CR-HT ($p = 0.037$, CI = 0.030–0.040) and for NRCT-HT ($p = 0.011$, CI = 0.010–0.016; Kruskal-Wallis test) significant differences were observed. Cumulative survival rates were HT = 92.5%, NRCT = 70.5%, and CR = 67.2% ($p = 0.012$). NRCT and CR outcomes were comparable. HT performed better than NRCT and CR for all outcomes. This study was funded by the Paediatric Dentistry Department, Greifswald University, Germany (Trial registration No. NCT01797458).

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In spite of a general overall improvement in oral health, a large proportion of children worldwide are still affected by untreated dental caries [Kassebaum et al., 2015]. Across Europe around 50% of young children, increasing to 100% in growing market economy countries, are affected, involving several teeth [Petersen et al., 2005; Pieper, 2010; Jin et al., 2016]. Traditional restorative dental care is expensive resulting in caries being the fourth most costly disease to treat in most industrialised countries [Marcenes et al., 2013]. Implementation of effective strategies to control this disease remains a challenge. The contemporary view is that caries progression can be stopped at any stage of carious lesion development, particularly by mechanical disruption of its main aetiological factor, the cariogenic "biofilm," and supporting remineralisation with fluoride application [Kidd and Fejerskov, 2013; Schwendicke et al., 2016]. Despite acceptance of these simple caries control concepts, untreated carious lesions in primary teeth remain the 10th most prevalent health condition, affecting 621 million children worldwide [Kassebaum et al., 2015].

Even with good access to dental treatment, the standard approach to treating cavitated primary tooth carious lesions has shown limited effectiveness in controlling the carious process [Kidd, 2012]. Less invasive alternatives to the "drill and fill" approach to manage carious lesions have been advocated [Kidd, 2011; Innes and Evans, 2013; Kuzmina and Ekstrand, 2015]. Non-restorative caries treatment (NRCT; recently called non-restorative cavity control [Innes et al., 2016a]), involving no caries removal, opening up the carious lesion to make it cleansable, effective plaque removal instruction, and fluoride application in individual patient-based scenarios, has shown encouraging results within an efficacy framework (under ideal and controlled circumstances) [Gruythuysen, 2010]. However, there are limited long-term investigations into its effectiveness (performance in a more "real-world" situation). Additionally, sealing carious lesions with no tooth or biofilm removal as with the Hall Technique (HT) [Innes et al., 2011] or conventional fillings for permanent teeth [Mertz-Fairhurst et al., 1998] have shown potential for the management of teeth with carious lesions into dentine in long-term clinical trials.

This is the first randomised controlled trial to compare the alternative caries management strategies of NRCT and the HT to conventional restorations (CR) in children. The acceptability of the 3 techniques to parents and dentists and children's behaviour and pain perception at the time of treatment have been previously reported [Santamaria et al., 2015] as have the short-term results (1-year) that found the HT to outperform NRCT and CR [Santamaria et al., 2014]. However, NRCT and CR treatment success rates were comparable. Although shown to be successful in the short term, using these alternative methods to treat carious lesions in primary teeth in young, precooperative or anxious children, the results are not sufficient to justify the use of one over another or until cooperation allows conventional restorations to be placed.

The aim of this study was to investigate the potential of the HT (sealing in caries with stainless-steel crowns without caries removal) and NRCT (opening up the carious lesion, oral health education and fluoride application), as permanent treatment options, for occlusoproximal carious lesions at the dentine level (ICDAS codes 3–5) in primary molars compared with conventional restorations (control arm with complete caries removal and compomer fillings) in 3- to 8-year-old children. This paper reports the long-term outcomes (2.5 years) for the 3 treatments and the final results of the study.

Materials and Methods

The study design has been previously reported with detailed methodology on the trial processes (including power calculation, randomisation, dentists' recruitment and training, patients' recruitment) and how the interventions (HT, NRCT, CR) were carried out [Santamaria et al., 2014, 2015]. A brief summary is given here.

Ethical Aspects

Ethical clearance was obtained from the Research Ethics Committee of Greifswald University, Germany (BB 39/11; trial registration No. NCT01797458). Informed consent was obtained from parents for their children to participate.

Study Design

This secondary care-based, 3-arm, parallel-group, patient randomised controlled trial was set in the Department for Preventive and Paediatric Dentistry of Greifswald University where all dentists (7 paediatric specialists and 5 postgraduate paediatric students) were trained to deliver each of the 3 treatment arms. All children who attend the department (regular, new or referred patients) were considered as potential participants for this study. After initial screening for proximal lesions in primary molars from the daily patient lists, 181 children were assessed for eligibility (2011–2012), and 169 children (mean age = 5.6 ± 1.5 years) were recruited and randomised. The inclusion criteria were: (1) children aged 3–8 years, (2) a primary molar with an occlusoproximal, 2-surface caries lesion at the dentine level (ICDAS codes 3–5 [Ekstrand et al., 2007]), (3) no clinical or radiographic signs or symptoms of pulpal or periradicular pathology, (4) no systemic diseases that required special considerations for dental treatment, and (5) willingness to participate.

Only 1 tooth per child was included in the study. A computer-generated random number list with allocation concealment was used to assign children to 1 of 3 arms: HT, NRCT, and CR (see CONSORT diagram, Fig. 1).

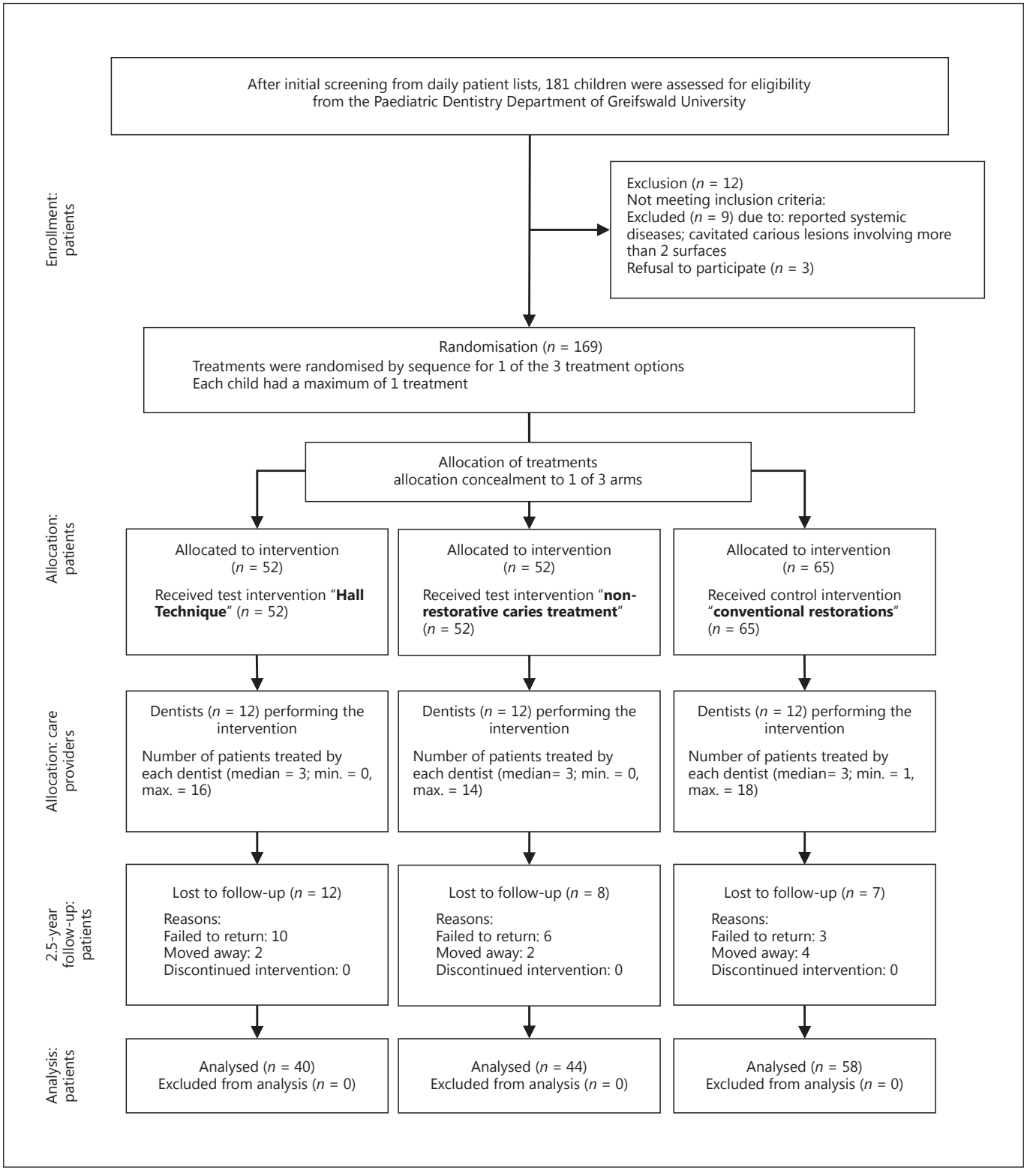


Fig. 1. Study CONSORT diagram.

The null hypothesis tested was that there were no differences between any of the 3 arms for the primary outcome of minor failure, a composite measure defined as caries progression, secondary caries, loss of restoration, or reversible pulpitis at the 2.5-year follow-up. The secondary outcome was: major failure, also a composite measure of failure, but defined as irreversible pulpitis or dental abscess. Thus, teeth assessed as having a minor failure have the potential to be retreated and restored maintaining the pulp vitality while the ones categorised as having a major failure would require a pulpotomy or dental extraction.

Clinical Procedures

Hall Technique. No caries removal or tooth preparation was carried out, and no local anaesthesia was placed before cementing the stainless-steel crowns with glass ionomer luting cement (GC Fuji TRIAGE®, GC Corporation, Tokyo, Japan). If the contact points were tight, orthodontic separator elastics were inserted and left in place for 2–3 days before placement of the crown at the next appointment.

Non-Restorative Caries Treatment. The lesions were opened using a high-speed bur removing the overhanging enamel to make the cavity accessible for plaque removal. The residual biofilm on the cavity was cleaned using a rotary bristle brush, and 22,600-ppm fluoride varnish (Duraphat®, GABA, Lörrach, Germany) was applied. Site-specific toothbrushing instructions were given to parents/children using a buccolingual technique and this was followed up with reinforcement of diet and oral hygiene instruction.

Conventional Restorations. Complete caries removal was performed before the restoration was placed. Local anaesthesia was used when needed. A matrix band and a porta-matrix (Henry Schein Inc., Melville, NY, USA) or a T-Band (Pulpdent®, Watertown, MA, USA), and a wedge (Interdental Wedge, Kerr®, Bioggio, Switzerland) were used to restore the cavities. All cavities were restored with Compomer (Dyract®, Dentsply, Konstanz, Germany).

All trial participants (parents/children) were provided with dietary advice and age-specific oral hygiene instructions.

Patient Follow-Up

For the HT and CR arms, the participants underwent routine dental check-ups twice per year while children in the NRCT arm were asked to attend every 3 months to monitor the lesion's status and to reinforce dietary and oral hygiene advice to assist the caries arrest process, including Duraphat application on clinically active carious lesions. After 2.5 years, 2 trained examiners (R.M.S., C.H.S.) re-assessed teeth according to specific assessment criteria, including a complete oral examination.

Data Analysis

Data were analysed in SPSS for Windows (version 17.0, SPSS Inc., Chicago, IL, USA). For the long-term data analysis, only information from patients with a minimum follow-up of 29 months was included. Data from recalls, emergency appointments, exfoliated teeth or censored teeth (dropouts, lost to follow-up, tooth extracted for different reasons to minor or major failures, etc.) were collected for analysis.

Differences in clinical outcomes (successful, minor and major failures) between the 3 arms were analysed using non-parametric Kruskal-Wallis analysis of variance and Bonferroni-corrected Mann-Whitney U test. Age and $d_3$mft comparisons were performed using analysis of variance. Kaplan-Meier survival analyses with Mantel-Cox statistics were also calculated. The null hypothesis was rejected at the 5% level.

Results

Overall 169 children (3–8 years old; mean = 5.56, SD = 1.45) participated in the study. Treatment events were distributed as follows: HT = 52, NRCT = 52, CR = 65. No significant differences between the 3 groups were observed for: gender distribution (p = 0.51, confidence interval [CI] = 0.49–0.52); $d_3$mft values (p = 0.25, CI = 0.25–0.27), or ICDAS categories (p = 0.35, CI = 0.35–0.70). The baseline and follow-up distribution of teeth included in the study and the ICDAS categories are presented in Table 1. Additional baseline data have been previously reported in Santamaria et al. [2014].

Of the 169 baseline participants, 142 patients (84.02%; HT = 40/52; NRCT = 44/52; CR = 58/65) had follow-up data of 1–33 months with a mean time of 26.04 months (±11.15) for the last follow-up. There were no statistically significant differences regarding follow-up time between arms (p = 0.15). Participant dropouts were censored; thus, participant survival data were censored at the point when they were last seen.

Twenty-seven patients did not return for any follow-up with similar proportions between arms (15.9%; HT = 12; NRCT = 8; CR = 7). The main reasons for dropout were: failure to return (n = 19, 70.4%), patients moved to another city/country (n = 8, 29.6%). Dropout analyses showed no statistically significant differences between dropout cases and participants for mean age (p = 0.90), gender distribution (p = 0.49), $d_3$mft values (p = 0.74), ICDAS categories (p = 0.91), kind of treated tooth (first or second primary molar, p = 0.32), or type of treatment (p = 0.93). In 5 cases (HT = 3; CR = 2), parents/children who did not attend recalls were reached by telephone. Parents reported no pain experience, eating difficulties, or emergency treatment during the previous years related to the study tooth. However, this information is only reported descriptively and was not included for the analysis.

Overall, 35/169 (24.6%) children presented with at least 1 failure. The majority of these were minor failures (n = 25; 71.4%).

Outcome: Minor Failures

In 25 (17.6%; HT = 2, NRCT = 9, CR = 14; p = 0.013, CI = 0.012–0.018) out of 142 teeth (Table 2) at least 1 minor failure was recorded. Independent comparison be-

Table 1. Baseline (n = 169) and 2.5-year (n = 142) distribution of teeth included in the study and ICDAS categories according to the type of treatment

	Hall Technique, *n* (%)		Non-restorative caries treatment, *n* (%)		Conventional restoration, *n* (%)		Total, *n* (%)	
	baseline	2.5 years	baseline	2.5 years	baseline	2.5 years	baseline	2.5 years
Tooth of treatment								
54/64	17 (33)	15 (37.5)	22 (42)	19 (43)	23 (35)	19 (33)	62 (37)	53 (38)
55/65	7 (13.5)	6 (15)	8 (15)	7 (16)	14 (22)	13 (22)	29 (17)	26 (18)
74/84	21 (40)	14 (35)	16 (31)	14 (32)	17 (26)	15 (26)	54 (32)	43 (30)
75/85	7 (13.5)	5 (12.5)	6 (12)	4 (9)	11 (17)	11 (19)	24 (14)	20 (14)
Total	52	40	52	44	65	58	169 (100)	142 (100)
ICDAS								
3	3 (6)	3 (7.5)	1 (2)	0 (0)	2 (3)	2 (4)	6 (3)	5 (3)
4	11 (21)	9 (22.5)	7 (13)	6 (14)	7 (11)	6 (10)	25 (15)	21 (15)
5	38 (73)	28 (70)	44 (85)	38 (86)	56 (86)	50 (86)	138 (82)	116 (82)
Total	52	40	52	44	65	58	169 (100)	142 (100)
Dropout	12 (23)		8 (15)		7 (11)		27 (16)	

The International Caries Detection and Assessment System (ICDAS): 3 = localised enamel breakdown; 4 = underlying dentine shadow; 5 = distinct cavity with visible dentine.

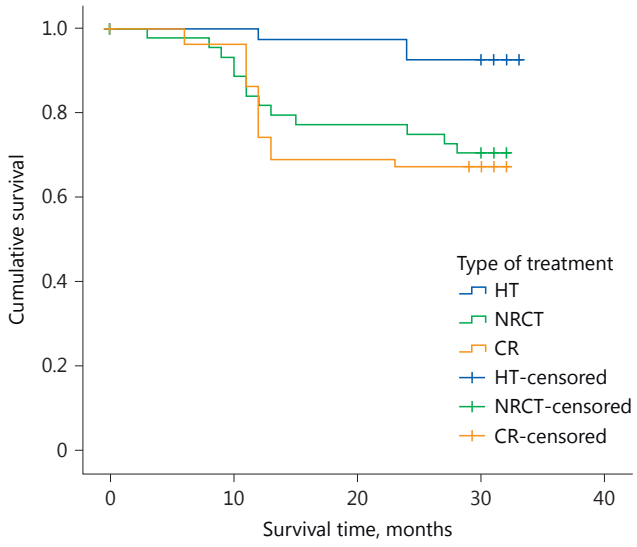
Table 2. Treatment success rates and reasons for failures after the 2.5-year follow-up by arm

Outcomes (cumulative)		HT, *n* (%)	NRCT, *n* (%)	CR, *n* (%)	Total, *n* (%)
Successful	Crown/restoration appears satisfactory or caries arrested	37 (92.5)	31 (70)	39 (67)	107 (75)
Minor failure[1]	Caries progression/secondary caries	1 (2.5)	7 (16)	9 (15)	25 (18)
	Restoration loss/fracture	1 (2.5)	0	5 (9)	
	Pulpitis (pulpotomy not required)	0	2 (5)	0	
Major failure	Reversible pulpitis	0	0	2 (3)	10 (7)
	Irreversible pulpitis	0	1 (2)	0	
	Abscess	1 (2.5)	3 (7)	3 (5)	
Total		40	44	58	142

HT, Hall Technique (crown appears satisfactory, no clinical signs or symptoms of pulpal pathology, or tooth exfoliated without minor or major failure); NRCT, non-restorative caries treatment (caries arrested, no clinical signs or symptoms of pulpal pathology, or tooth exfoliated without minor or major failure); CR, conventional restoration (restoration appears satisfactory, i.e., intact tooth surface adjacent to restoration, stained margins consistent with non-carious lesions; no clinical signs or symptoms of pulpal pathology, or tooth exfoliated without minor or major failure). [1] Kruskal-Wallis test for comparison between the 3 treatment groups (p = 0.013; CI = 0.012–0.018), Bonferroni-corrected Mann-Whitney U test for independent comparisons between non-restorative caries treatment and conventional restorations (p = 0.81; CI = 0.80–0.82).

tween 2 samples found no statistically significant difference in failures between NRCT-CR (p = 0.81, CI = 0.80–0.82). However, significant differences were observed between both CR-HT (p = 0.037, CI = 0.030–0.040) and NRCT-HT (p = 0.011, CI = 0.010–0.016).

In the NRCT arm, failure times ranged from 3 to 28 months (mean = 15.1 ± 8.9), and the main reason for failure was caries progression (n = 7/9). In the CR arm failure times were recorded between 11 and 24 months (mean = 15.4 ± 5.7), and the main reason for failure was secondary caries (n = 9/14). In the HT arm, 2 minor failures were detected at 12 and 23 months (mean = 18 ± 8.5). The first was because of caries around crown margins and the second loss of the crown (Fig. 2).



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Type of treatment	HT			NRCT			CR		
2.5-year follow-up	*n* (%)	CE	SE	*n* (%)	CE	SE	*n* (%)	CE	SE
	40 (77)	3	0.6	44 (85)	13	1.4	58 (89)	19	1.3

$p = 0.012$. HT, Hall Technique; NRCT, non-restorative caries treatment; CR, conventional restoration; CE, cumulative number of events (minor and major failures); SE, standard error.

Fig. 2. Reasons for minor and major failures of treated primary molars for each of the 3 treatment groups: Hall Technique, non-restorative caries treatment, and conventional restoration.

Outcome: Major Failures

Ten out of 142 patients (7.04%; HT = 1, NRCT = 4, CR = 5) experienced at least 1 major failure ($p = 0.043$, CI = 0.034–0.045; Table 2). For NRCT, failure times ranged from 8 to 11 months (mean = 10 ± 1.41 months). The main reasons were abscess ($n = 3$) and irreversible pulpitis ($n = 1$).

In the CR arm, failure times ranged from 5 to 12 months (mean = 9 ± 3.2 months) due to dental abscess ($n = 3$) and reversible pulpitis (requiring pulpotomy; $n = 2$).

One major failure was observed in the HT arm after 24 months presenting with a dental abscess.

Survival Analysis

Overall, the cumulative survival rates were 92.5% for the HT, 70.5% for the NRCT, and 67.2% for CR, with statistically significant differences between the arms ($p = 0.012$).

Figure 3 shows the Kaplan-Meier survival curve for patients treated in the 3 arms. Over the study period of 2.5 years, the cumulative number of events (minor and major failures combined) were: HT = 3, NRCT = 13, and CR = 19.

There were no statistically significant effects of age ($p = 0.11$), gender ($p = 0.21$), baseline $d_3$mft ($p = 0.76$), or dentists' level of experience (postgraduate student vs. specialist, $p = 0.49$) on treatment success for any arm. Overall, 7 teeth (4.9%) were extracted: HT = 1, NRCT = 3, CR = 3. All were first molars, and the majority (6/7) of them were diagnosed at baseline as ICDAS "5." Nevertheless, a statistically significant effect was not found for extent of the lesion at baseline and treatment failure (baseline ICDAS score, $p = 0.72$; type of tooth [first or second primary molar], $p = 0.27$).

Discussion

Managing occlusoproximal lesions in young children is highly challenging and it is often difficult to achieve good long-term outcomes, especially with persistent high caries activity. In order to achieve high success rates, additional sedation or even general anaesthesia [Amin et al., 2016] with the associated much higher costs and professional time are required [Jameson et al., 2007]. This study sought to test less invasive dental treatments which young children find easier to tolerate and comply with, possibly also improving the outcomes associated with them. To the best of our knowledge, it is the first study comparing NRCT in a randomised control trial and the first study to investigate the HT compared to conventional restorative management in a secondary care environment.

Similar to other trials [Innes et al., 2015] and observational studies [Schüler et al., 2014; Randall et al., 2000] evaluating conventionally placed stainless-steel crowns in primary molars, in this study, the HT showed a very high success rate (93%). This is also in line with another study of the HT where similar success rates were found. We found NRCT (70%) and CR (67%) to have statistically and clinically significantly lower success rates than the HT after 2.5 years in 3- to 8-year-old children. Thus, the null hypothesis of no differences between any of treatments for minor treatment failures was rejected.

Advances in the field of cariology regarding the understanding of caries have challenged the conventional surgical approach to manage existing carious lesions [Ricketts et al., 2013]. Cavitated carious lesions can be

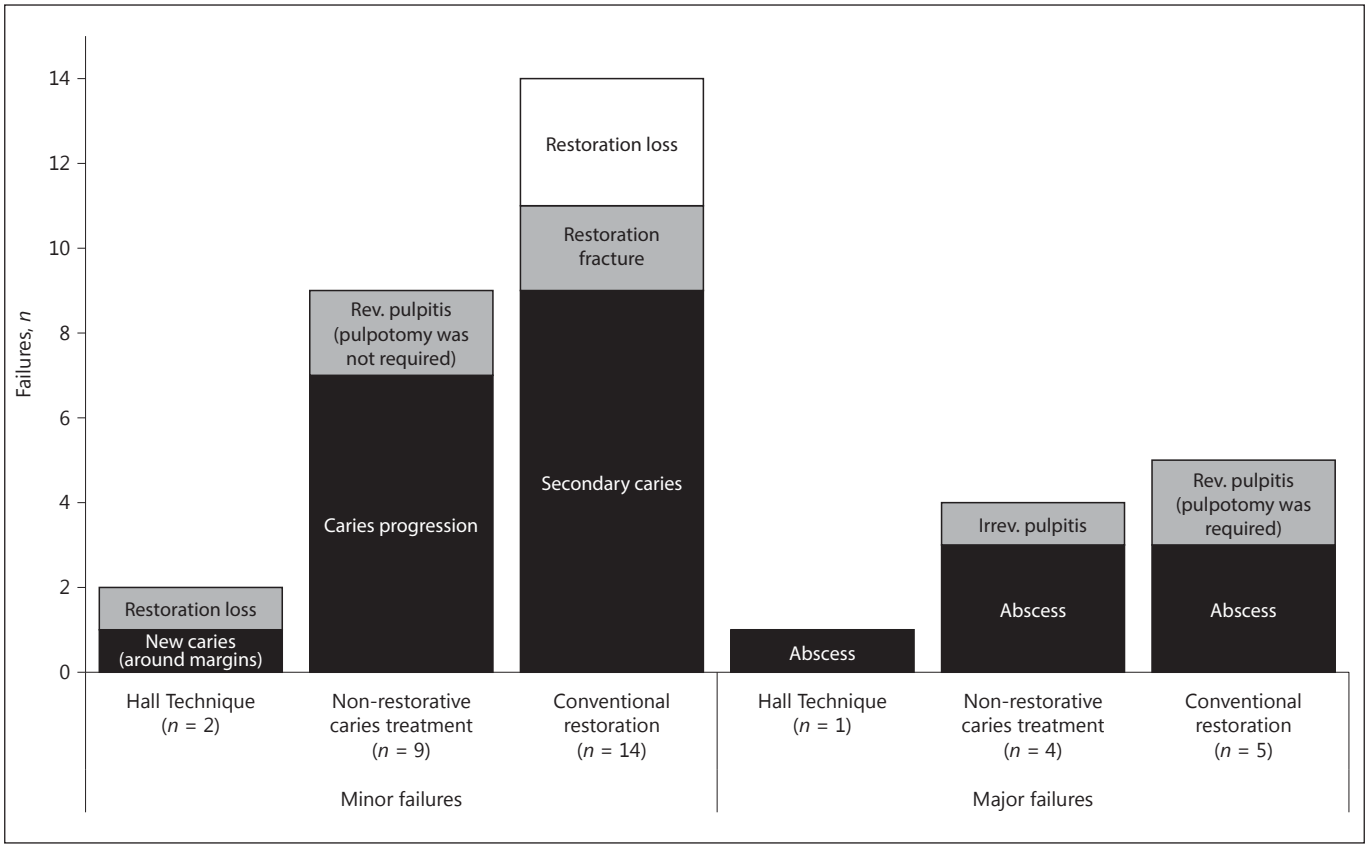

Fig. 3. Cumulative survival rates (minor and major failures combined) after 2.5 years of treated primary molars in the 3 treatment groups: Hall Technique, non-restorative caries treatment, and conventional restoration.

managed successfully by non-operative methods including biofilm disruption (toothbrushing) and remineralisation (fluorides) as in the case of the NRCT [Gruythuysen, 2010; Mijan et al., 2014; Santamaria et al., 2014], by use of silver fluoride solutions [Chu and Lo., 2008], or by sealing the carious lesion, as in the case of the HT [Innes et al., 2011]. Although these methods seem to be very different from each other, these approaches essentially serve the same purpose – to manage/arrest the carious lesion without removing the carious dentine tissue, weakening the structural integrity of the tooth and compromising the pulp.

NRCT was used here to manage occlusoproximal dentine carious primary molars. Because most proximal lesions were "not cleansable" at the time of diagnosis, the lesions were opened up to allow biofilm removal by patients/carers, and oral hygiene practices, detailed age-specific toothbrushing with fluoridated toothpaste and healthy dietary practices were advised. Although the success rate of the NRCT was only 70%, these results are comparable to the conventional restoration arm (CR = 67%), which involved complete caries removal and placement of a restoration. NRCT is a technically simple procedure to perform in terms of dexterous skills and was preferred by dentists in comparison to the more invasive conventional fillings [Santamaria et al., 2015]. However, the major challenge and a different type of clinical skill for this approach lies in keeping parents/carers motivated as being the main people responsible for biofilm removal from the lesion, to control its progression. A recent prospective case study, which evaluated the suitability of NRCT for the treatment of cavitated approximal carious lesions, found that failures were mainly related to poor compliance with brushing lesions and/or the lesion/patient was not suitable for being treated with this method [Hansen and Nyvad, 2017]. NRCT must unquestionably be part of a comprehensive caries management programme, actively involving parents/carers. Motivational interviewing and counselling are recommended tools [Rollnick et al., 2008; Kidd, 2012] to be used by clinicians to facilitate positive behaviour

change. These techniques are particularly beneficial for control of largely preventable chronic diseases like dental caries, in which behaviour change is key and patient motivation a common challenge. For the NRCT, there is not a standard treatment scheme indicating the frequency of follow-up appointments. However, it is advisable to standardise short-term recalls based on child/parental motivation, caries risk, etc., to allow lesion activity monitoring and, if necessary, another treatment approach to be implemented. In this study 69% of children in the NRCT arm with treatment failures failed to regularly attend the 3-month recalls. On the other hand, even the standard approach of conventional fillings does not protect the tooth from further caries development; in this study "secondary" caries was the most common reason for treatment failure. In summary, the failure rates for NRCT and CR seem to be equivalent, with NRCT being less invasive and quicker, and it may therefore have some advantages over standard fillings.

In recent years, the HT has received increasing attention and at the same time significant rejection from some paediatric dentistry arenas [Nainar, 2012; Innes et al., 2016b]. This technique challenges the need for conventional caries removal and preparation of teeth, a well-described, widely used, and successful treatment, albeit with a poor evidence base [Innes et al., 2015]. In addition, it also challenges a very invasive method of restoring primary molars, where stainless-steel crown placement requires use of local anaesthesia, complete caries removal, and tooth preparation. Ultimately, the HT mainly questions the whole surgical approach to manage carious lesions, which was until recently considered the "gold standard." However, this "unusual" technique, which does not require caries removal, tooth preparation, or even the use of local anaesthesia, has proven its effectiveness for the treatment of carious primary molars and a clear superiority to the conventional restorative approach. In this study, after 2.5 years, only 3 teeth with the HT presented a failure (2 minor failures = 5% and only 1 major failure = 3%), while the conventional restorations exhibited a 24% minor failure rate, mostly due to secondary caries and a higher rate with major problems of irreversible pulpitis or abscess (9%). Similar outcomes were reported from the first randomised controlled trial on the HT, which compared its effectiveness to mostly glass ionomer fillings, likely increasing the risk of failure [Qvist et al., 2004a; Chadwick and Evans, 2007]. After 23 months, the HT showed fewer failures (minor = 5%, major = 2%) than CR (minor = 46%, major = 15% [Innes et al., 2007]) and similarly after a 5-year follow-up: HT (minor = 5%, major = 3%) versus CR (minor = 42%, major = 17% [Innes et al., 2011]) matching success rates in this study.

A clinically relevant failure rate was observed in the CR arm, where almost 1/3 of fillings showed a failure. Similar results after 2 years were reported by a study, which analysed the clinical success of primary teeth class II compomer fillings (33.3% [Qvist et al., 2004b]). The majority of lesions included in this arm (86%) were large cavities (ICDAS code 5; distinct cavity with visible dentine), however without signs or symptoms of pulpal pathology (including pain). However, there were neither significant differences at baseline in the ICDAS distribution between treatment arms ($p = 0.35$) nor a statistically significant effect related to the cavity extent (ICDAS 3–5) in the treatment failures after 2.5 years in any of the treatment arms ($p = 0.72$). In this study, the majority of failures were minor failures (73.7%) with pulp vitality preserved. Failures in the CR arm tended not to be associated with dentists or material performance such as restoration loss ($n = 3$; 5%) or fracture ($n = 2$; 3%), but there were biological complications such as secondary caries ($n = 9$; 16%). Overall, the children who took part in this study were high caries risk patients with 2-surface carious lesions in a population where more than half of the first graders present no caries experience ($d_3mft = 0$) in the primary dentition. The mean caries experience in this population of 6- to 7-year-olds in Germany is 1.62 at the d_3mft level [Pieper, 2010], while the overall baseline d_3mft value of the study population was 5.59 ± 3.08 with no differences between groups ($p = 0.25$, CI = 0.25–0.27).

To date, there is no single ideal therapy for managing primary molars with carious lesions extending into dentine, for disease control or restoration longevity. The ideal treatment option that would guarantee the tooth would remain symptomless until it exfoliated naturally and that would be acceptable to patients causing the child no stress or discomfort does not exist. The 3 methods that we compared, although each complete in their own right, were empirically different in several ways. They ranged from 2 single component interventions: an essentially surgical approach involving complete caries removal (CR arm) and a less invasive approach focused on caries lesion control by sealing the lesion (HT arm). The third intervention was multicomponent and aimed to slow lesion progression through parental behaviour change, toothbrushing and fluoride application (NRCT arm). Even the parental involvement in the 3 arms was quite different, with participants attending every 3 months for follow-up in the NRCT arm to participants who only came for an annual assessment. Despite these fundamental differenc-

es, each treatment was considered an option with possible advantages at the tooth or patient level. Conventional restorative treatment is often reported as unsuccessful [Foster et al., 2006; Innes et al., 2011], challenging for children [Kidd, 2012], time consuming, etc. However, CR is a treatment option when re-establishment of aesthetics, function, or the occlusion is mandatory and to manage non-cleansable cavitated dentine carious lesions [Schwendicke et al., 2016] in cooperative children. Instead, asymptomatic dentine carious lesions that can be transformed into cleansable lesions can be managed through NRCT. This approach has a genuine potential to biologically control the caries process, preserving dental hard tissue, and avoiding initiation of the restorative cycle. In addition, NRCT is well accepted by children, including anxious children, by allowing gradual introduction of treatment items while concurrently managing the carious lesions [Kidd, 2012; Santamaria et al., 2015]. However, these young children cannot carry out adequate oral hygiene measures alone to achieve improvement in their oral health. Therefore, the main challenge of this approach is to achieve enough parental compliance to control the lesion(s) [Hansen and Nyvad, 2017]. This relies on an excellent skill of the clinician in achieving and maintaining motivation in carers/children to brush the lesion(s). A further drawback of this approach is the additional cost for both carers and providers because of the increased dental visit frequency for lesion(s) follow-up. An additional consideration is that in most countries NRCT is not considered as a treatment option itself, thus payment will be mostly private or mixed public-private. A cost-effectiveness analysis for NRCT is not yet available. On the other hand, the well-known advantages of the HT including its high clinical success rate, ease of use, acceptance [Innes et al., 2011; Santamaria et al., 2015], and cost-effectiveness [Schwendicke et al., 2015], etc., make it attractive for treatment of (multisurface) carious primary molars, especially for young children with limited cooperative abilities and has the added advantage of being independent of parental involvement in oral home care. However, apart from possible aesthetic concerns of restoring an already damaged tooth using a stainless-steel crown, the main concern around the HT is that, similar to the CR, both treatments mask the disease process and only treat a single tooth, having no effect on caries activity and risk at the patient level.

Based on the current knowledge on caries aetiology, development, and therapy, caries control must primarily focus on behaviour change and biofilm management to prevent caries disease manifestations at the macroscopic level and to slow down lesion progression once manifest [Kidd and Fejerskov, 2013; Schwendicke et al., 2016]. Thus, independent of treatment choice at the tooth level, efforts have to be made to educate parents/carers including training in plaque removal using a fluoride-containing toothpaste, and encouraging and convincing them that their efforts will contribute to their child's oral health in the long term [Kidd, 2012]. In brief, for treatment success an accurate caries and pulpal diagnosis, good patient management, and excellent parental cooperation to brush their children's teeth are essential. Accordingly, treatment decisions should be made with all tooth, patient and family factors in mind, regarding when either a restoration, lesion sealing or lesion inactivation without caries removal are each required and/or beneficial for the patient.

The trend for a clear, clinically or statistically significant superiority of the HT compared to either NRCT or CR increased between the 1- and the 2.5-year follow-up. Furthermore, there were no statistically or clinically relevant differences in the failures between the NRCT and CRs with most caries progression occurring within the first year after treatment, and mainly due to recurrent caries.

In conclusion, the HT showed a very high success rate (93%) after 2.5 years in high caries risk, young children with occlusoproximal lesions, generally agreed as the most challenging group to obtain good clinical success in, without resorting to sedation or general anaesthesia to treat. Although the success of the NRCT was significantly lower compared to the HT, 70% of lesions in this group did not show signs/symptoms of pulp damage during the study period, and these results were comparable to the control arm (CR). The results of this study strongly highlight doubts over the established standard treatment of surgical caries removal and filling material placement for occlusoproximal 2-surface carious lesions in the primary dentition with relevant caries activity. More so, this study supports the use of alternative caries management options like the HT and NRCT, which are based on biofilm control for the treatment of primary molars.

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

Author Contributions

Conception and study designed: R.M.S., N.P.T.I., V.M., C.H.S.; performance of the clinical examination: R.M.S., C.H.S.; treatment performance: R.M.S., C.H.S., M.A., J.S.; data analysis: R.M.S., C.H.S., N.P.T.I.; writing of the paper: R.M.S., C.H.S., N.P.T.I.; review of the paper: V.M., J.S., M.A.

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