Alternative caries management options for primary molars

Santamaria, Ruth M.; Innes, Nicola; Machiulskiene, V.; Schmoeckel, J.; Alkilzy, M.; Splieth, Christian H.

Published in:
Caries Research

DOI:
10.1159/000477855

Publication date:
2017

Document Version
Peer reviewed version

Alternative caries management options for primary molars

Santamaria, Ruth M.; Innes, Nicola; Machiulskiene, V.; Schmoeckel, J.; Alkilzy, M.; Splieth, Christian H.

Published in:
Caries Research

Publication date:
2017

Document Version
Peer reviewed version

https://doi.org/10.1159/000477855

Citation for published version (APA):
Santamaria, R. M., Innes, N., Machiulskiene, V., Schmoeckel, J., Alkilzy, M., & Splieth, C. H. (2017). Alternative caries management options for primary molars: 2.5-yr outcomes of a randomised clinical trial. Caries Research. 51:605-614 available https://doi.org/10.1159/000477855

Title

Alternative caries management options for primary molars: 2.5-yr outcomes of a randomised clinical trial

Names of authors

Santamaría RM[a], Innes NPT[b], Machiulskiene V[c], Schmoeckel J[a], Alkilzy M[a], Splieth Ch H[a]

Affiliation

[a]Department of Preventive and Paediatric Dentistry University of Greifswald, Greifswald, Germany;

[b] School of Dentistry, University of Dundee, Dundee, UK;

[c] Clinic of Dental and Oral Pathology, Faculty of Odontology, Lithuanian University of Health Sciences, Kaunas, Lithuania

Short title

RCT of three caries treatment methods for primary molars

Key words

caries, primary teeth, Non-Restorative Caries Treatment, Hall Technique, multisurface cavities.

Corresponding author data

Ruth Santamaría
Department of Preventive & Paediatric Dentistry
University of Greifswald
Rotgerberstrasse 8
17487 Greifswald, Germany
Phone +49 3834 867101 - +49 3834 867136 (Clinics)
E-mail address: ruth.santamaria@uni-greifswald.de

Declaration of interest:

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

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 three carious lesion treatment approaches: The Hall Technique (HT), Non-Restorative Caries Treatment (NRCT), and Conventional Restorations (CR), for management of occluso-proximal caries lesions (ICDAS 3-5) in primary molars. Results at 2.5 years are presented.

169 children (3-8-year-olds) were enrolled in this secondary care-based, three-arm parallel-group, randomized 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: Non-parametric Kruskal-Wallis analysis of variance, Mann-Whitney U-test and Kaplan-Meier survival analyses.

142 participants (84.02%; HT=40/52; NRCT=44/52; CR=58/65) had follow-up data of one to 33 months (mean= 26). Overall, 25 (HT=2, NRCT=9, CR=14) of 142 participants (17.6%) presented with at least one 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 one Major failure (irreversible pulpitis, abscess, unrestorable tooth; p=0.043, CI=0.034-0.045). Independent comparison between two samples found NRCT-CR - no statistically significant difference in failures (p>0.05) but for CR-HT (p=0.037, CI=0.030- 0.040) and 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 GreifswaldUniversity/Germany, Paediatric DentistryDepartment (Trial registration no.NCT01797458).

Introduction

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 (Jin et al., 2016; Petersen et al., 2005). 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 remains 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 & fill" approach to manage carious lesions have been advocated (Kuzmina and Ekstrand, 2015; Innes and Evans, 2013; Kidd, 2011). Non-Restorative Caries Treatment (NRCT; recently called Non-Restorative Cavity Control; Innes et al., 2016) 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 teeth with carious lesions into dentine in long-term clinical trials.

This is the first randomised control trial (RCT) to compare the alternative caries management strategies of NRCT and the HT to conventional restorations (CR) in

children. The acceptability of the three techniques to parents and dentists and children's behaviour and pain perception at time of treatment have been previously reported (Santamaria et al., 2015) as have the short-term results (1-yr) 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, pre-cooperative 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 is to investigate 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 occluso-proximal carious lesions at the dentine level in primary molars compared with conventional restorations (control arm with complete caries removal and compomer fillings) in 3-8 yr-old children. This paper reports the long-term outcomes (2.5 years) for the three 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 and Santamaria et al., 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, three-arm, parallel-group, patient RCT 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 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 patients lists, 181 children were assessed for eligibility (2011 – 2012) and 169 children (mean age =5.6 ± 1.5 yr.) were recruited and randomised. The inclusion criteria were: (1) children aged 3–8 years old; (2) a primary molar with an occluso-proximal, two-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 one tooth per child was included in the study. A computer generated random number list with allocation concealment was used to assign children to one of three arms: HT, NRCT, and CR (see Consort diagram, Figure 1).

The null hypothesis tested was that there were no differences between any of the three 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 treatment, 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 re-treated 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 (HT)

No caries removal or tooth preparation were 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 separators elastics were inserted and left in place for 2-3 days before placement of the crown in the next appointment.

- Non-Restorative Caries Treatment (NRCT)

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 varnish fluoride (Duraphat®, GABA, Lörrach, Germany) was applied. Site specific toothbrushing instructions were given to parents/children using a bucco-lingual technique.

- Conventional Restorations (CR)

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®, Biogglo, 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.

Patients 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, two trained examiners (RS, CS) 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. Chicago: SPSS Inc.). 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 three 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 ANOVA 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 year-olds; 5.56 (SD=1.45) participated in the study. Treatment events were distributed as following: HT=52, NRCT=52, CR=65. No significant differences between the three groups were observed for: gender distribution [p=0.51, confidence interval (CI)=0.49 to 0.52]; $d_3$mft values (p=0.25, CI=0.25 to 0.27); or ICDAS categories (p=0.35, CI=0.35 to 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 has 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 one to 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). Participants dropouts were censored, thus, participant survival data was 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). 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 five cases (HT=3; CR=2) parents/children who did not attend recalls could be 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 one 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 to 0.018) out of 142 teeth (Table 1) at least one Minor failure was recorded. Independent comparison between two samples found no statistically significant difference in failures between NRCT-CR (p=0.81, CI=0.80 to 0.82). However, significant differences were observed between both CR-HT (p=0.037, CI=0.030 to 0.040) and NRCT-HT (p=0.011, CI=0.010 to 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 to 24 months (mean=15.4 ± 5.7) and the main reason for failure was secondary caries (n=9/14). In the HT arm, two 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 (Figure 3).

Outcome: Major Failures

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

In the CR arm, failure times ranged from 6 to 12 months (mean=9 ± 3.2 mo.) 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 corresponded to 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 2 shows the Kaplan-Meier survival curve for patients treated in the three 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, seven 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 initial lesion and treatment failure (baseline ICDAS score, p=0.72; type of tooth [first or second primary molar], p=0.27).

Discussion

Managing occluso-proximal lesions in young children is highly challenging 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 randomized control trial and the first study to investigate the Hall Technique 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 Hall Technique where similar success rates were found. We found NRCT (70%) and CR (67%) to have statistically and clinically significantly lower success rates that the HT after 2.5 years in 3-8-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 managed successfully through non-operative methods including biofilm disruption (toothbrushing) and remineralisation (fluorides) as in the case of the NRCT (Mijan et al., 2014; Santamaria et al., 2014; Gruythuysen et al., 2010), through 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 occluso-proximal 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 tooth-brushing 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 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 program, actively involving parents/carers. Motivational interviewing and counselling are recommended tools (Kidd, 2012; Rollnick et al., 2009) 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 standardize 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 the present study 69% of children in the NRCT-arm with treatment failures failed to attend regularly the 3-months 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 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 (Innes et al., 2016; Nainar, 2012). This technique challenges not only a well described, widely used and successful, albeit with poor evidence base (Innes et al., 2015), but also very invasive method of restoring primary molars using stainless steel crowns (SSCs) placed with conventional placement methods (use of local anaesthesia, complete caries removal, and tooth preparation). It mainly questions the surgical approach to manage carious lesions, which was considered until recently the ‘gold standard’. However, this ‘unusual’ technique, which does not require caries removal, tooth preparation nor 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 three teeth with HT presented a failure (two Minor failures= 5% and only one 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 RCT on the HT, which compared its effectiveness to mostly glass ionomer fillings, likely increasing risk of failure (Chadwick and Evans, 2007; Qvist et al., 2004a). After 23 months, the HT showed less failures (Minor= 5%, Major= 2%) than CR (Minor= 46%, Major= 15%; Innes et al., 2007) and similarly after 5-yrs follow-up: HT (Minor= 5%, Major= 3%) vs. 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-yrs 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 dentin), however without signs or symptoms of pulpal pathology (including pain). However, there were neither significant differences at baseline in the ICDAS distribution among treatment arms (p= 0.35) nor a statistically significant effect related to the cavity extention (ICDAS 3-5) in the treatment failures after 2.5-yrs 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 two-surface carious lesions in a population where more than 50% of the first graders present with no extractions, fillings or caries lesions in the primary dentition and a $d_3$mft value of 1.62 for the 6-7 yr-olds (Piper et al., 2009). The overall baseline $d_3$mft value of the study population was 5.59 ± 3.08 with no differences among groups (p= 0.25, CI=0.25 to 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 would be acceptable to patients causing the child no stress or discomfort does not exist. The three methods that we compared, although each complete in their own right were empirically different in several ways. They ranged from two 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 multi-component and aimed to slow lesion progression through parental behavior change, toothbrushing and fluoride application (NRCT arm). Even the parental involvement in the three arms was quite different, with participants attending every three months for follow-up in the NRCT arm to participants who only came for an annual assessment. Despite these fundamental differences, each treatment was considered an option with possible advantages at the tooth or patient level. Conventional restorative treatment is often reported as unsuccessful (Innes et al., 2011; Foster et al., 2006), challenging for children (Kidd, 2012), time consuming, etc. However, CRs are a treatment option when re-establishment of aesthetics, function, or the occlusion is

mandatory and to manage noncleansable 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 effectively through NRCT (Hansen and Nyvad, 2017). 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 (Santamaria et al., 2015; Kidd, 2012). However, these young children cannot carry out adequate oral hygiene measures alone to achieve improvement in their oral health. The main challenge of this approach, therefore, is to achieve enough parental compliance to control the lesion(s). This relies on excellent clinician sill 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 (Santamaria et al., 2015; Innes et al., 2011) and cost-effectiveness (Schwendicke et al., 2015), etc., make it attractive for treatment of (multi-surface) 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 SSCs, 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 biofilm management to prevent caries disease manifestations at the macroscopic level and to slow down lesion progression once manifest (Schwendicke et al., 2016; Kidd and Fejerskov, 2013) . 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 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- to the 2.5-year follow-up. Furthermore, there were no statistically or clinically relevant difference 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 occluso-proximal lesions; generally agreed as the most challenging group and teeth 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 occluso-proximal two-surface carious lesions in the primary dentition with relevant caries activity. It supports the use of alternative caries management options based on biofilm control for treatment of primary molars.

Acknowledgments

The authors thank the children, their parents, and the dentists who took part in this study. Preliminary data from this study were presented at the 2014 EAPD and 2015 and 2016 ORCA meetings. This study has been supported by the Paediatric Dentistry Department of Greifswald University, Germany.

The authors contributions were as follows: Conception and study designed (RS, NI, VM, CS); performance of the clinical examination (RS, CS); treatments' performance

(RS, CS, MA, JS); data analysis (RS, CS, NI); writing of the paper (RS, CS, NI); review of the paper (VM, JS, MA).

References

Amin M, Nouri MR, Hulland S, ElSalhy M, Azarpazhooh A: Success Rate of Treatments Provided for Early Childhood Caries under General Anesthesia: A Retrospective Cohort Study. Pediatr Dent. 2016;38:317-24.

Chadwick BL, Evans DJ: Restoration of class II cavities in primary molar teeth with conventional and resin modified glass ionomer cements: a systematic review of the literature. Eur Arch Paediatr Dent. 2007;8:14-21.

Chu CH, Lo EC: Promoting caries arrest in children with silver diamine fluoride: a review. Oral Health Prev Dent. 2008;6:315-21.

Ekstrand KR, Martignon S, Ricketts DJ, Qvist V: Detection and activity assessment of primary coronal caries lesions: a methodologic study. Oper Dent. 2007;32:225-35.

Foster T, Perinpanayagam H, Pfaffenbach A, Certo M: Recurrence of early childhood caries after comprehensive treatment with general anesthesia and follow-up. J Dent Child. 2006;73:25-30.

Gruythuysen R: Non-restorative cavity treatment: managing rather than masking caries activity. Ned Tijdschr Tandheelkd. 2010;117:173–180.

Innes N, Santamaria R, Duggal M, Splieth C: Letter to the Editor. 2016;38:278-279.

Hansen NV Nyvad B. Non-Operative Control of Cavitated Approximal Caries Lesions in Primary Molars: A Prospective Evaluation of Cases. J Oral Rehabil. 2017. doi: 10.1111/joor.12508. [Epub ahead of print]

Innes NP, Evans DJ, Stirrups DR: Sealing caries in primary molars: randomized control trial, 5-year results. J Dent Res. 2011;90:1405-10.

Innes NP, Evans DJ: Modern approaches to caries management of the primary dentition. Br Dent J. 2013;214:559-66.

Innes NP, Frencken JE, Bjørndal L, Maltz M, Manton DJ, Ricketts D, Van Landuyt K, Banerjee A, Campus G, Doméjean S, Fontana M, Leal S, Lo E, Machiulskiene V, Schulte A, Splieth C, Zandona A, Schwendicke F: Managing Carious Lesions: Consensus Recommendations on Terminology. Adv Dent Res. 2016;28:49-57.

Innes NP, Ricketts D, Chong LY, Keightley AJ, Lamont T, Santamaria RM: Preformed crowns for decayed primary molar teeth. Cochrane Database Syst Rev. 2015 DOI: 10.1002/14651858.CD005512.pub3.

Jameson K, Averley PA, Shackley P, Steele J: A comparison of the 'cost per child treated' at a primary care-based sedation referral service, compared to a general anaesthetic in hospital. Br Dent J. 2007;203(6):E13.

Jin LJ, Lamster IB, Greenspan JS, Pitts NB, Scully C, Warnakulasuriya S: Global burden of oral diseases: emerging concepts, management and interplay with systemic health. Oral Dis. 2016;22:609-19.

Kassebaum NJ, Bernabé E, Dahiya M, Bhandari B, Murray CJ, Marcenes W: Global burden of untreated caries: a systematic review and metaregression. J Dent Res. 2015;94:650-8.

Kidd E, Fejerskov O: Changing concepts in cariology: forty years on. Dent Update. 2013;40:277-8, 280-2, 285-6.

Kidd E: Should deciduous teeth be restored? Reflections of a cariologist. Dent Update. 2012; 39:159-62, 165-6.

Kidd E: The implications of the new paradigm of dental caries. J Dent. 2011;39:3-8.

Kuzmina I, Ekstrand KR: Outcomes 18 years after implementation of a nonoperative caries preventive program - the Nexö-method - on children in Moscow, Russia. Community Dent Oral Epidemiol. 2015;43:308-316.

Marcenes W, Kassebaum NJ, Bernabé E, Flaxman A, Naghavi M, Lopez A, Murray CJL. Global burden of oral conditions in 1990-2010: a systematic analysis. J Dent Res. 2013;92:592–597.

Mertz-Fairhurst EJ, Curtis JW Jr, Ergle JW, Rueggeberg FA, Adair SM: Ultraconservative and cariostatic sealed restorations: results at year 10. J Am Dent Assoc. 1998;129:55-66.

Mijan M, de Amorim RG, Leal SC, Mulder J, Oliveira L, Creugers NH, Frencken JE: The 3.5-year survival rates of primary molars treated according to three treatment protocols: a controlled clinical trial. Clin Oral Investig. 2014;18:1061-9.

Nainar SM: Success of Hall technique crowns questioned. Pediatr Dent. 2012;34:103.

533 Petersen PE, Bourgeois D, Ogawa H, Estupinan-Day S, Ndiaye C: The global burden
534 of oral diseases and risks to oral health. Bull World Health Organ. 2005;83:661-9.

535 Pieper K. Epidemiologische Begleituntersuchungen zur Gruppenprophylaxe 2009.
536 Bonn, Druckerei Gerhards GmbH, 2010.

537 Qvist V, Laurberg L, Poulsen A, Teglers PT:. Class II restorations in primary teeth: 7-
538 year study on three resin-modified glass ionomer cements and a compomer. Eur J
539 Oral Sci. 2004a; 112:188-96.

540 Qvist V, Manscher E, Teglers PT: Resin-modified and conventional glass ionomer
541 restorations in primary teeth: 8-year results. J Dent. 2004b;32:285-94.

542 Randall RC, Vrijhoef MM, Wilson NH: Efficacy of Preformed Metal Crowns vs.
543 Amalgam Restorations in Primary Molars: a Systematic Review. J Am Dent Assoc.
544 2000;131:337-43.

545 Ricketts D, Lamont T, Innes NP, Kidd E, Clarkson JE: Operative caries management
546 in adults and children. Cochrane Database Syst Rev 2013 DOI:
547 10.1002/14651858.CD003808.pub3.

548 Rollnick S, Miller WR, Butler CC: . Motivational Interviewing in Health Care: Helping
549 Patients Change Behavior. New York, The Guilford Press. 2008.

550 Santamaria RM, Innes NP, Machiulskiene V, Evans DJ, Alkilzy M, Splieth CH:
551 Acceptability of different caries management methods for primary molars in a RCT.
552 Int J Paediatr Dent. 2015; 25:9-17.

553 Santamaria RM, Innes NP, Machiulskiene V, Evans DJ, Splieth CH: Caries
554 management strategies for primary molars: 1-yr randomized control trial results. J
555 Dent Res. 2014;93:1062-9.

556 Schüler IM, Hiller M, Roloff T, Kühnisch J, Heinrich-Weltzien R: Clinical success of
557 stainless steel crowns placed under general anaesthesia in primary molars: an
558 observational follow up study. J Dent. 2014;42:1396-403.

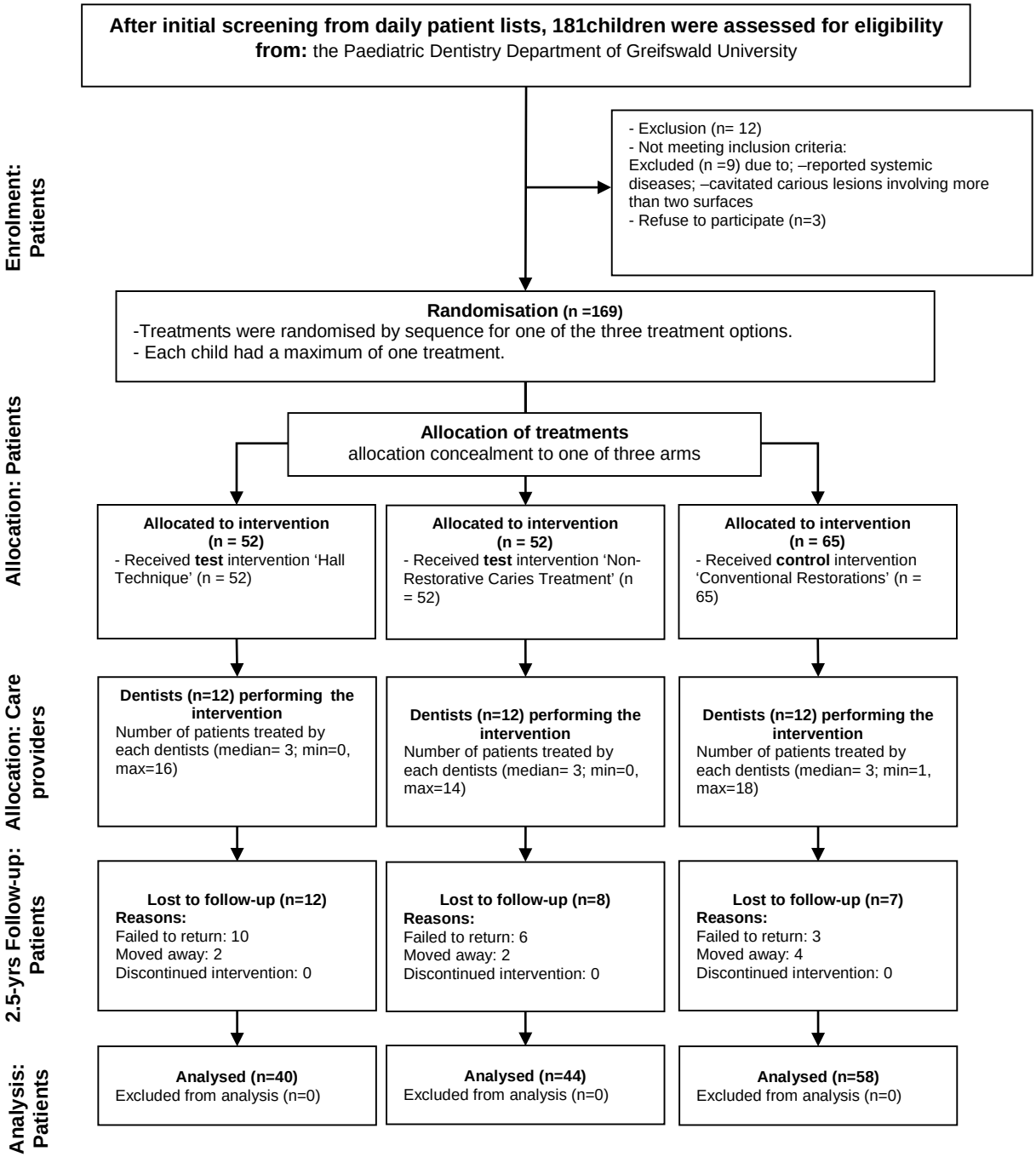
559 Schwendicke F, Stolpe M, Innes N. Conventional treatment, Hall Technique or
560 immediate pulpotomy for carious primary molars: a cost-effectiveness analysis. Int
561 Endod J. 2015. doi: 10.1111/iej.12537. [Epub ahead of print]

562 Schwendicke F, Frencken JE, Bjørndal L, Maltz M, Manton DJ, Ricketts D, Van
563 Landuyt K, Banderjee A, Campus G, Doméjean S, Fontana M, Leal S, Lo E,

564 Machiulskiene V, Schulte A, Splieth C, Zandona AF, Innes NPT: 'Managing carious
565 lesions: consensus recommendations on carious tissue removal'. Advances in Dental
566 Research. 2016;28:58-67.

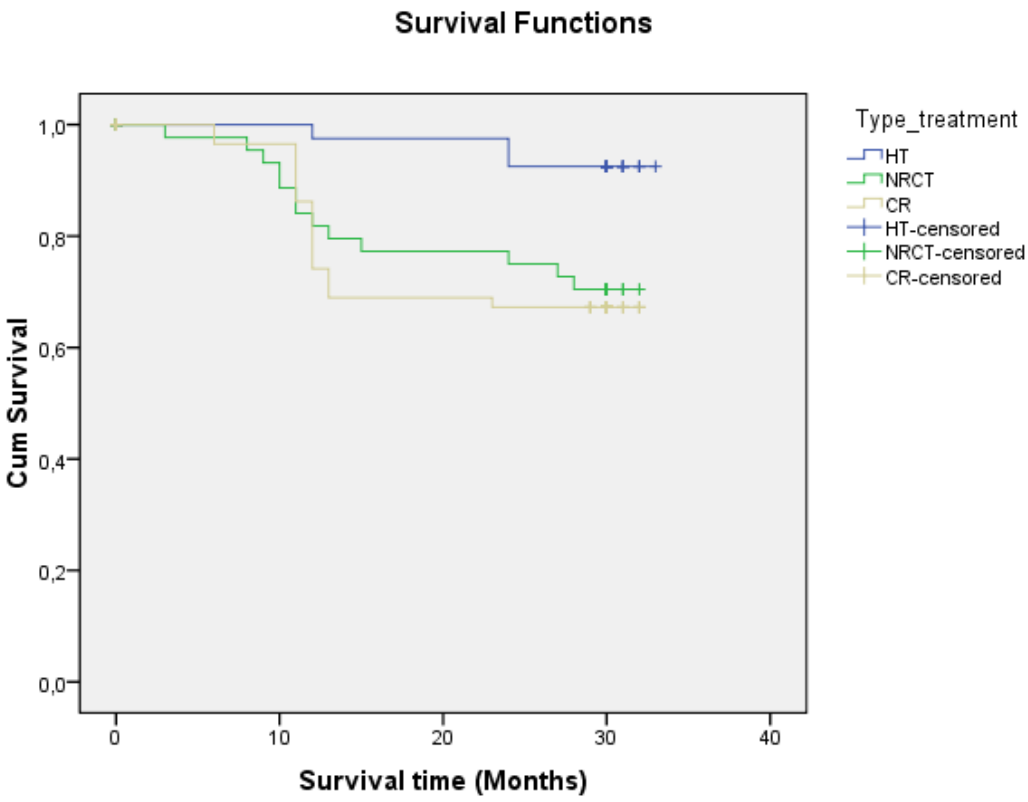
567 Figures
568

Figure 1. Study CONSORT diagram



569
570
571
572

573 Figure 2. Cumulative survival rates (Minor and Major failures combined) after 2.5-
574 years of treated primary molars in the three treatment groups: Hall-Technique, Non-
575 Restorative Caries Treatment, and Conventional Restoration.



576

Type of treatment	HT			NRCT			CR		
2.5-yrs 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

577 p= 0.012

578 (HT: Hall-Technique; NRCT: Non-Restorative Caries Treatment; CR: Conventional Restoration;
579 CE= Cumulative number of events [Minor and Major failures]; SE= Standard Error)

580

581

582
583

Table

Table 1. Baseline (n=169) and 2.5 years (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 (%)		n (% of total)	
Tooth of treatment	Baseline	2.5 yrs.	Baseline	2.5 yrs.	Baseline	2.5 yrs.	Baseline	2.5 yrs.
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)
Drop-out	12 (23)		8 (15)		7 (11)		27 (16)	

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

593 Table 2. Treatment success rates and reasons for failures after 2.5-years follow-up
594 by arm.

595
596 HT: Hall-Technique; NRCT: Non-Restorative Caries Treatment; CR: Conventional Restoration.
597 NRCT (Caries arrested, no clinical signs or symptoms of pulpal pathology, or tooth exfoliated

Outcomes (Cumulative)		HT (%)	NRCT (%)	CR (%)	Total (%)
Successful	Crown/Restoration appears satisfactory or caries arrested	37 (92.5)	31 (70)	39 (67)	107 (75)
Minor Failure*	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	Irreversible Pulpitis	1 (2.5)	1 (2)	1 (2)	10 (7)
	Abscess	0	3 (7)	4 (7)	
Total		**40**	**44**	**58**	**142**

598 without Minor or Major failure); HT (Crown appears satisfactory, no clinical signs or symptoms of
599 pulpal pathology, or tooth exfoliated without Minor or Major failure); CR (Restoration appears
600 satisfactory [intact tooth surface adjacent to restoration, stained margins consistent with non-
601 carious lesions], no clinical signs or symptoms of pulpal pathology, or tooth exfoliated without
602 Minor or Major failure).
603 Kruskal Wallis test for comparison among the three treatment groups* (p=0.013; CI=0.012-
604 0.018), Bonferroni-corrected Mann-Whitney U test for independent comparisons among non-
605 restorative caries treatment and conventional restorations (p=0.81; CI=0.80- 0.82).