CLAUDIA LÓPEZ GALLEGOS

Hall technique survival for restoring decayed primary molars - A systematic review and single-arm meta-analysis

São Paulo

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Corrected Version

Thesis presented to the Faculty of Dentistry of the University of São Paulo, by the Graduate Program in Dental Sciences to obtain the title of Doctor of Science.

Concentration Area: Pediatric Dentistry and Orthodontics.

Supervisor: Profa. Dra. Daniela Prócida Raggio.

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“Hardships often prepare ordinary
people for an extraordinary destiny.”
– C.S. Lewis”

RESUMO

López Gallegos CJ. Sobrevida da *Hall Technique* para restaurar molares deciduos cariados - Uma revisão sistemática e meta-análise de braço único [tese]. São Paulo: Universidade de São Paulo, Faculdade de Odontologia; 2022. Versão Corrigida.

O objetivo desta revisão sistemática e meta-análise foi avaliar a taxa de sobrevida das coroas metálicas pré-formadas utilizando a *Hall Technique* para restaurar molares deciduos cariados e investigar fatores que pudessem influenciar na sobrevida do tratamento (registro no PROSPERO: CRD42021204415, *preprint* do protocolo - DOI: 10.31219/osf.io/fxvz7). Uma busca sistemática nas seguintes bases de dados (Medline/PubMed, Embase, Scopus, Web of Science, LIVIVIVO e ProQuest) foi realizada para estudos que atendessem aos critérios de inclusão: Ensaios Clínicos Randomizados (ECRs) e Estudos de Intervenções Não-Randomizados (EINRs) (coortes prospectivas/retrospectivas e estudos não randomizados) até Novembro de 2022; crianças com molares decíduos cariados restaurados usando a *Hall Technique*; e relatando a sobrevida para pelo menos 1 mês de pós-tratamento. A meta-análise de braço único avaliou a proporção cumulativa (95% CI) das taxas de sobrevivência de HT usando o software RStudio. O risco de viés foi avaliado utilizando as ferramentas Cochrane RoB 2 para ECRs e ROBINS-I para EINRs, e a certeza da evidência avaliada utilizando a abordagem GRADE. A pesquisa identificou inicialmente 1278 referências, sendo que 22 publicações (11 ECRs e 11 EINRs) preencheram os critérios de inclusão e foram submetidas a análise quantitativa. Os períodos de acompanhamento variaram de 1 a 89 meses. Houve uma taxa de sobrevivência de mais de 90% para 19 dos 22 estudos, e todos relataram taxa de sobrevida acima de 76%, independente do tempo avaliado. As meta-análises mostraram taxas médias de sobrevivência de: para ECRs 95% (IC 95%: 92-97) com baixa heterogeneidade (I^2: 0%, p=0,53), e EINRs: 97% (IC 95%: 94-98) com heterogeneidade moderada (I^2: 34%, p= 0,14). O risco geral de viés para ECRs (55%) variou de baixo a preocupante, enquanto a maioria dos EINRs (64%) eram de qualidade moderada a baixa. A certeza de evidência foi considerada baixa para ECRs e moderada para EINRs. A *Hall Technique* apresenta alta taxa de sobrevida global, portanto pode ser considerado tratamento alinhado a Mínima Intervenção adequado para restaurar molares

decíduos. A maioria dos estudos mostrou risco de viés moderado a alto, e certeza de evidência de moderada a baixa.

Palavras-chave: Dente Decíduo. Criança. Odontopediatria. Taxa de Sobrevida. Revisão Sistemática. Metanálise.

ABSTRACT

López Gallegos CJ. Hall technique survival for restoring decayed primary molars - A systematic review and single-arm meta-analysis [thesis]. São Paulo: Universidade de São Paulo, Faculdade de Odontologia; 2022. Corrected Version.

We aimed to evaluate the survival rate of preformed metal crowns using the Hall Technique to restore carious primary molars and investigated factors that might influence survival. It was registered in PROSPERO database (CRD42021204415), and the protocol preprint was published (DOI: 10.31219/osf.io/fxvz7). A systematic search (Medline/PubMed, Embase, Scopus, Web of Science, LIVIVO and ProQuest) was carried out for studies meeting the inclusion criteria: Randomized Clinical Trials (RCTs) and Non-Randomized Studies of Interventions (NRSIs) (prospective/retrospective cohorts and non-randomized studies) until November 2022; children with decayed primary molars restored using the Hall Technique; and reporting survival for at least 1-month post-treatment. A single-arm meta-analysis assessed the cumulative proportion (95% CI) of HT survival rates using the RStudio Team software. Risk of bias was assessed using the Cochrane RoB 2 tools for RCTs and ROBINS-I for NRSIs, and certainty of evidence assessed using the GRADE approach. The search initially identified 1278 references, and 22 publications (11 RCTs and 11 NRSIs) met the inclusion criteria and underwent quantitative analysis. The follow-up periods ranged from 1 to 89 months. There was a survival rate of over 90% for 19 out of 22 studies (follow-up of 1 to 89 months), and all studies reported a survival rate of over 76%. The meta-analyses showed mean survival rates for RCTs 95% (95% CI: 92-97) with low heterogeneity (I^2: 0%, p=0.53), and NRSIs: 97% (95%CI: 94-98) with moderate heterogeneity (I^2: 34%, p= 0.14). The overall risk of bias for RCTs (55%) ranged from low to concerning, while the majority of NRSIs (64%) were of moderate to low quality. The certainty of evidence was considered low for randomized studies and moderate for non-randomized studies of intervention. Preformed metal crowns according to the Hall Technique present an overall high survival rate, hence can be considered a Minimum Intervention treatment suitable for restoring primary molars. Most studies showed moderate to high risk of bias and moderate to low certainty of evidence.

Keywords: Tooth. Deciduous. Child. Pediatric Dentistry. Survival rate. Systematic Review. Meta-analysis.

LIST OF ILLUSTRATIONS

LIST OF ABBREVIATIONS AND ACRONYMS

CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CIV	Cimento de ionômero de vidro
CMP	Coroas metálicas preformadas
CNPq	Conselho Nacional de Desenvolvimento Científico e Tecnológico
DOI	Digital Object Identifier
ECRs	Ensaios clínicos randomizados
EINRs	Estudos de intervenção não randomizados
Embase	Excerpta Medica Database
GIC	Glass ionomer cement
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
K	Kappa value
MeSH	Medical Subject Headings
NRSI	Non-randomized studies of intervention
OSF	Open Science Framework
PMC	Preformed metal crown
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized clinical trial

SUMMARY

1 INTRODUCTION

Children's teeth are prone to caries since the moment of their eruption. By the time they reach 6 years of age, and their primary dentition is complete, the reported worldwide prevalence of dental caries is 48% (1), making it the 10th most common condition in the world (2). This preventable, biofilm-mediated, lifestyle-driven disease harms children's health and wellbeing (3), impacting negatively on their quality of life, resulting in pain, early tooth loss along with impaired function, growth, esthetics (4,5) and loss of time at school (6).

Current evidence shows that for cavitated asymptomatic decayed primary teeth, the use of less invasive techniques reduces pulp exposure and restoration failure (7,8). However, there is a high failure rate with different restorative treatments for primary (9–11) with treatment success compromised due to child's age, cognitive development, cooperation, caries risk, cavity size, number of surfaces, adaptation problems, moisture control, and the materials themselves (12–14).

The stainless-steel crown is more durable and has a much higher success rate than cavity filling materials (10–12). When used conventionally their fitting require local anaesthetic to be placed, rotary instruments to prepare the teeth and trimming of the crowns. The Hall Technique uses the advantages of stainless-steel crowns and builds on their high success rates (15–17) but removes the need for carious removal and tooth preparation with rotary instruments and local anaesthetic is not used (16–19).

The Hall Technique was presented (20) as a simple, non-invasive, "child-friendly" technique suitable for restoring primary molars with occlusal or occluso-proximal lesions, without pulp involvement, which seals and inactivates the lesion, with no carious tissue removal (18,19,21). This technique has been studied for over 20 years, proving to be superior in comparison to other plastic restorative materials and equivalent to stainless steel crowns, because of its low failure rates (22), high acceptability (20,23), and for being highly cost-effective (24–26).

So far, the available systematic reviews (27–31) mainly focus on the evaluation of different restorative materials or treatments for restoring caries lesions in children. However, the overall survival of the Hall Technique available in different types of studies has not been investigated. Therefore, as there is a gap in the literature on the

subject, we are faced with the need to evaluate the overall survival rate of the Hall Technique and the associated factors that contribute to its success, as well as the certainty of the available evidence, which will allow us to establish recommendations on the use of this technique for the effective treatment of caries lesions.

2 LITERATURE REVIEW

Dental caries is caused by biofilm deposition on the tooth surface and modulated by diet. If the balance between demineralization and remineralization of dental hard tissues is compromised, it results in mineral loss and leading to the formation of carious lesions (32,33). As a multifactorial non-communicable behavioral disease, it can be successfully managed through biofilm disruption (toothbrushing with fluoride toothpaste) and sugar intake reduction, preventing the initiation and progression of lesions (34).

Such lesions evolve through different stages ranging from mild demineralization to extensive cavities (32). Early-stage lesions can be inactivated and reversed using fluoride along with hygienic / dietary adjustments (35,36). Unfortunately, these lesions can remain active and cause enamel micro cavitations which, when undetected and untreated, will progress and lead to the formation of large, deep dentine cavitations favoring biofilm retention, requiring infected tissue removal and cavity restoration with filling materials (37,38), thus initiating a lifelong cycle of repair (39). Further, a more aggressive stage may exist when diagnosis or treatment fails, resulting in extensive destruction of tooth tissue and pulpal infection, in which case root canal treatment or tooth extraction may be necessary (40).

The presence of this disease has serious consequences for the child's health, such as pain, anxiety, hospitalization for severe dental infection, loss of schooling and hospital visits (41–43). Dental treatment in such cases is challenging and can sometimes require the use of sedation or general anesthesia to treat the decayed teeth (44). Other studies have concluded that the severity of caries negatively affects and impacts the quality of life of both the child and the family (45,46). Children living in poorer communities are more likely to suffer from caries than those living in more privileged areas (47,48).

As a means of repairing severely damaged and decayed teeth, stainless steel crowns became popular in the 1950s and were considered the best restorative option (49). They outperformed other materials, such as amalgam and composite, because of their low cost and good retention in the tooth remnant (50). Their use was recommended for primary teeth after pulpotomy/pulpectomy, teeth with developmental defects, and teeth with large multi-surface carious lesions where other dental materials

have failed. However, its main disadvantage is that, to cement the crown, the teeth must be prepared and trimmed on their occlusal and interproximal surfaces, so it can be considered an extremely invasive restorative treatment (51).

Through research and based on the minimal intervention approach (33,52), understanding the caries disease process and the proper management of caries lesions has been achieved (53), allowing teeth to be kept in the mouth for as long as possible while controlling the factors that cause tissue demineralization (54). Hence, to determine the type of intervention needed, key factors such as lesion activity, cavitation type, and cleanability should be considered (55,56).

In this manner, for the treatment of micro-cavitated or cavitated carious lesions, minimally invasive non-operative treatments can be performed, such as sealing the affected surface with a restorative material of choice (57), resinous infiltration of demineralized tissue (58), or application of Silver Diamine Fluoride (SDF) to arrest carious lesions (59–61). For the treatment of single-surface carious lesions, high viscosity glass ionomer cement (HVGIC) restoration proved to be a suitable option (62,63). Where moderate or deep asymptomatic multi-surface cavities exist, scientific literature suggests selective removal of carious tissue to reduce the risk of pulp exposure (7,64), or treatment with non-operative techniques (non-removal of carious tissue and sealing the cavity with metal crowns) as it has shown less failure compared to traditional restorative techniques (29,63).

The Hall technique was developed in Scotland, inspired by traditional metal crowns, and has been used for over 20 years (65). It was first published in 2006 as a retrospective analysis of the results of patients treated by Dr. Norna Hall in her private practice (66). The aim of the technique is to treat multi-surface caries lesions in primary molars (extending into the dentin without affecting the dental pulp) by sealing the caries under a preformed metal crown so that nutrients are inaccessible, and the lesion can no longer progress (21). This technique is considered easy to perform, easy to teach and does not require anesthesia or any type of instrument for its application. It is contraindicated in cases of clinical or radiographic signs and symptoms of pulp involvement, dental abscess, or non-physiological mobility, and when evaluated radiographically, a clear band of dentin must exist between the carious lesion and the pulp (18). Currently, multiple studies have demonstrated that the Hall technique is more reliable than most other restorative treatments (19,22,23,67). After cementation,

the occlusal vertical dimension (OVD) may increase, but returns to baseline measures within 2 to 4 weeks (68,69) .

In healthcare, the use of best available evidence is key in clinical decision making. Thus, evidence can be obtained from different research designs (70). Well-defined randomized clinical trials have established themselves as the gold standard of research, providing high-quality evidence that guarantees the efficacy and safety of the treatments under investigation (71). Likewise, non-randomized interventional studies, which include non-randomized clinical trials and cohort studies (prospective or retrospective), although considered to be of lower quality, offer additional evidence necessary to address gaps within the research (72).

In this sense, this systematic review with meta-analysis allows us to identify and synthesize the best available evidence on the Hall Technique survival, and furthermore, to analyze the internal validity and certainty of the evidence of the primary studies, allowing us to find reliable and solid evidence. Therefore, we will be able to present substantial scientific evidence for the treatment of decayed primary molars.

3 PROPOSITION

The aim of this systematic review with single-arm meta-analysis was to evaluate the success rate of preformed metal crowns using the Hall Technique to restore carious primary molars and investigate the factors that might influence survival by evaluating different types of intervention studies.

4 METHODS

4.1 PROTOCOL AND REGISTRATION

This systematic review has been written accordingly to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA Statement) guideline 2020 (Annex A) (73). The review is registered in the PROSPERO database (International Prospective Registry of Systematic Reviews) with the registration number CRD42021204415 (Annex B). The detailed protocol manuscript has been published in the Openscience Framework (OSF) platform as a preprint (74) (DOI 10.31219/osf.io/fxvz7).

4.2 DEVIATION FROM PROTOCOL

As stated in our research protocol, we anticipated that studies reporting less than 12 months of follow-up would be excluded. During the screening process, most reports did not provide the established follow-up time, but rather reported a median follow-up derived from a range of time from each participant's last visit, making it impossible to determine the exact time of the participants' final follow-up visit. Therefore, this specific item was modified to at least 1 month of follow-up, giving us the possibility to include valuable studies according to the eligibility criteria mentioned in the "Eligibility Criteria and Study Selection" section.

Additionally, the OpenGrey literature database was reported to be one of the databases to be searched; however, due to the official notification issued by them regarding their cessation of activity, the ProQuest database was chosen as an alternative.

4.3 SOURCES OF INFORMATION AND SEARCH STRATEGY

A search strategy was created and carried out using multiple electronic databases, including Medline (PubMed), Excerpta Medica Database (EMBASE), Scopus, Web of Science and LIVIVO, along with the ProQuest database for gray literature review. The Medline/PubMed strategy (Box 4.1) was adapted for the other databases (Appendix A) for each database's specific syntax rules. Keywords were obtained from the MeSH terms controlled vocabulary, and supplemented by free terms related to child, primary teeth, preformed metal crowns, and survival. Such terms were merged with Boolean operators to allow a systematic search across the Title/Abstract fields. A manual search of the reference lists of selected studies was performed to detect additional potentially eligible. The final search was completed on February 21 and updated in November, 2022. There were no restrictions on language or year of publication.

Box 4.1 - Medline/PubMed Search Strategy

(("tooth, deciduous"[MeSH Terms] OR "deciduous dentition"[Text Word] OR "deciduous teeth"[Text Word] OR "baby teeth"[Text Word] OR "primary molar"[Text Word] OR "deciduous molar"[Text Word] OR "primary teeth"[Text Word] OR " primary tooth" [Text Word]) AND ("preformed metal crown"[Text Word] OR "stainless steel crown" [Text Word] OR "metal crown"[Text Word] OR "hall technique" [Text Word]) AND (longevity[MeSH Terms] OR survival[Text Word] OR success[Text Word] OR effectiveness OR efficacy))

Source: The author.

4.4 ELIGIBILITY CRITERIA AND STUDY SELECTION

Potentially relevant studies were selected by two independent reviewers (CLG and GS) previously trained and calibrated in a pilot screening (blinded and in duplicate) according to the eligibility criteria (74). A brief synthesis is presented here:

- Randomized clinical trials (RCTs) and/or prospective/retrospective non-randomized studies of interventions (NRSIs);
- Studies investigating the treatment of primary molars with cavitated or non-cavitated carious lesions using preformed metal crowns placed following the Hall Technique were eligible for inclusion;
- Those who reported children, with pulp involvement in the decayed primary molar to be treated, without available survival information and lacking at least 1-month post-treatment follow-up were excluded.

  Disagreements at any stage of the investigation were solved in consultation with a third reviewer (DPR) considered to be an expert in the field.

4.5 INTER-EXAMINER TRAINING AND CALIBRATION

To avoid discrepancies during literature screening and inclusion phase, the reviewers (CLG and GS) were trained and calibrated through a pilot screening exercise on 10% of the articles retrieved (n= 118) during the database search. References were screened, blinded and independently, by title/abstract applying the inclusion criteria. A statistical analysis was performed using the Jamovi project (2021) computer software (Version 1.6) to measure inter-examiner reliability and agreement (Cohen's Kappa) where a k = 0.80 value was obtained with 92.4% agreement.

4.6 DATA MANAGEMENT AND DATA EXTRACTION

References identified in the databases were imported into the online EndNote Web software (https://www.myendnoteweb.com), and duplicates were removed, both by the software and manually, according to the similarity of authors, title, journal, year and abstract. Once this stage was completed, the remaining articles were exported to the Rayyan software (75) for a two-phase screening: firstly, by title/abstract where studies involving the placement of preformed metal crowns according to the Hall Technique approach for the treatment of caries lesions in primary molars were included, and then the remaining references were read in full text so that studies with no available information on survival, as well as no follow-up information and pulpal involvement in the decayed primary molar to be treated were excluded.

Data extraction was carried out by the same reviewers for pre-specified items (74) in standardized forms created in Excel (Microsoft Excel for Mac version 16.35). A detailed list of the data collected is presented here: publication details (author; year; country; study design), sample details (participants' age, brand of PMC; brand of GIC; setting; characteristics of operators); outcome details (baseline HT data, survival number; follow-up; criteria used to assess survival) and methodological details (registration protocol; blinding). Additional data was extracted and is currently stored in the main data table; however, these were not analyzed since not all studies had available data.

Restorative treatment was considered a success when the crowns placed were considered satisfactory, with no signs or symptoms of pulpal pathology, when no additional intervention was required after cementation and when the tooth exfoliated without failure. When the crown was lost, or when there were signs or symptoms of reversible or irreversible pulpitis after the crown was cemented, and further treatment was required, it was considered a failure.

References without abstracts were screened at full-text level and, when data were missing or unclear, the corresponding authors were contacted by e-mail requesting the necessary information, for subsequent decision on their eligibility within the research. Contact was attempted at three different times if no response was received (Appendix B).

4.7 AVAILABLE TIME POINTS

It was not possible to establish a common time point among the included studies because they measured survival at different time points (range 1 to 89.07 months). Most studies (55%) reported survival at several time points, whereas 45% of the studies reported survival only once. In the absence of a common time point at which the studies could be compared, we compiled the survival data reported in all studies in order to present the available short- and long-term evidence.

4.8 RISK OF BIAS OF INCLUDED STUDIES

Risk of bias assessment was performed by the same reviewers according to the Cochrane Handbook for Systematic Reviews of Interventions (version 6.3). The appropriate risk of bias tool was used for each study design.

The Cochrane risk of bias tool for randomized trials RoB 2 (76) was used for RCTs. This addresses five specific areas were potential bias may arise (randomization process, allocation deviations, missing outcome data, outcome measurement, and selective reporting). For overall rating: when the risk of bias was low in all domains, the final rating was low; if one domain had some concerns, the final rating was some concerns; and if two or more domains showed some concerns or a high risk of bias, the final rating was overall high risk of bias.

Non-randomized trials assessment of bias risk was performed using the Cochrane risk of bias tool for non-randomized studies - of Interventions ROBINS-I (77). This addresses seven domains and considers bias before, during and after the intervention (confounding, participant selection, intervention classification, deviations from planned interventions, missing data, outcome measurement and selection of the reported outcome). For overall grading, when the risk of bias was low in all domains, the final rating was low; if one domain had moderate risk, the final rating was moderate;

and, if two or more domains had moderate or high risk of bias, a high risk of bias was the final rating.

4.9 DATA SYNTHESIS AND STATISTICAL ANALYSES

Extracted data were analyzed using the "meta" and "metafor" packages in RStudio Team software (RStudio Team, 2022, Boston, MA), where an overall proportion rate and 95% confidence intervals (95%CI) were calculated out of a series of individual proportions. The single-arm meta-analyses were performed using the "metaprop" function to evaluate the cumulative proportion of success rates for the Hall Technique. Fixed and random effects models were used to identify significant heterogeneity ($p<0.10$), and the I^2 index was used to investigate the degree of statistical heterogeneity. A sensitivity analysis was performed to investigate the possible influence of each individual study in relation to the quality and stability of the outcomes. Subgroup analyses were performed to determine whether follow-up, risk of bias, or clinical setting influenced Hall Technique success, in addition to possible sources of heterogeneity. Publication bias was investigated through analyses of funnel plots and using the "metabias" function to assess the funnel plot asymmetry with "peters" test where there were 10 or more studies.

4.10 CERTAINTY OF EVIDENCE ASSESSMENT

The GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) (78) approach was applied through the evaluation of five domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias. For the evidence of NRSIs, the evidence assessments also considered three additional domains: effect magnitude, dose-response gradient, and residual confounding. The evidence was assessed in the GRADEPro (McMaster University, ON, Canada), in collaboration with

other assessors (CLG, TG, TKT, DPR), and was adequately classified into four levels: high, moderate, low and very low.

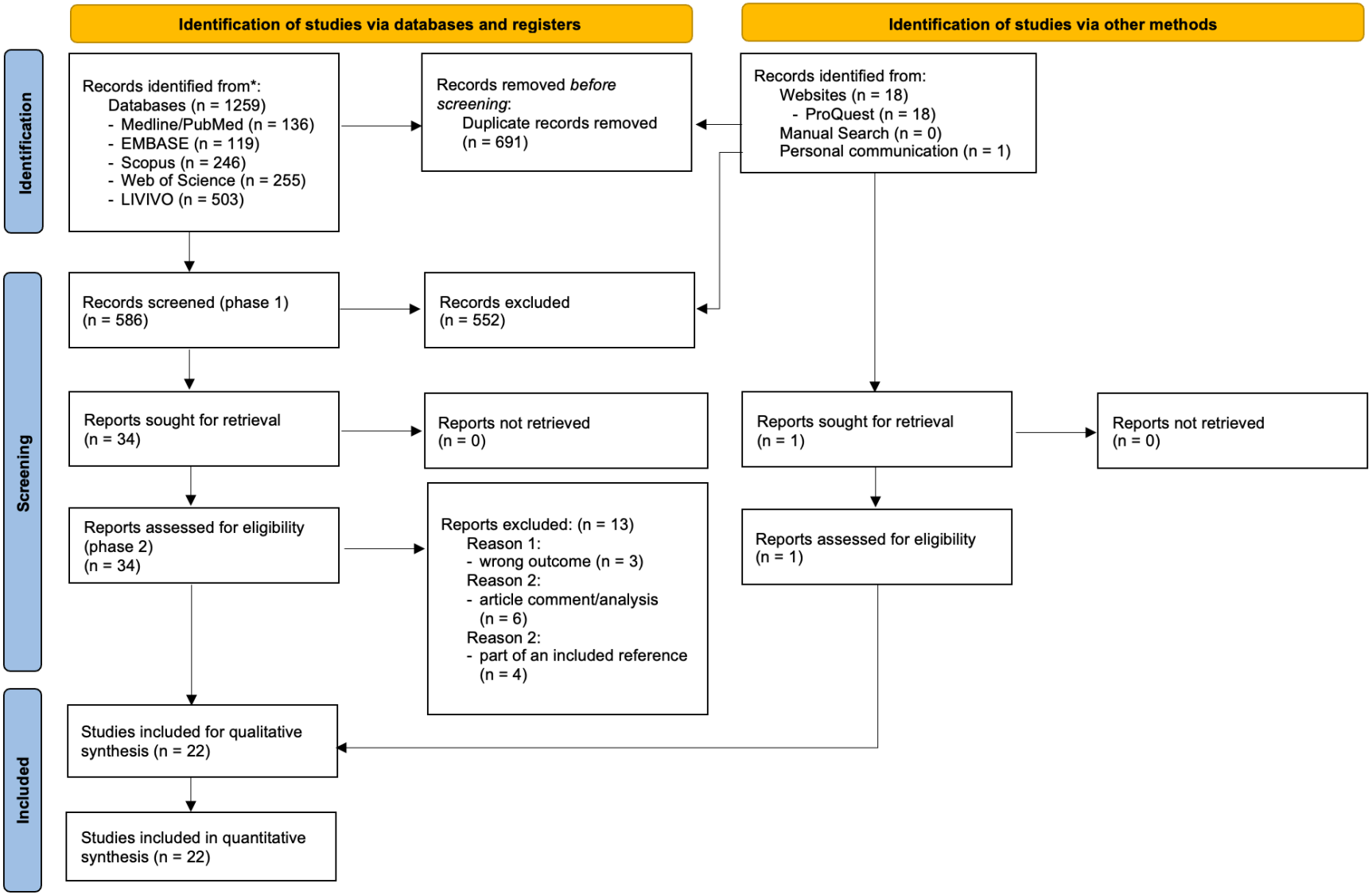
5 RESULTS

5.1 STUDY SELECTION

After the final search in databases, gray literature and manual search, one thousand one hundred and eighty-two (1,277) potentially relevant references were identified, in addition one (1) new reference was included by personal communication, giving a total of one thousand one hundred and eighty-three (1,278) articles. After removing 691 references considered duplicates, 587 references were screened by title/abstract (phase 1). Subsequently, after excluding 552 references considered non-relevant, and 35 references were selected and reviewed in full (phase 2). Thereafter, 13 references were excluded, and the main reasons for exclusion were wrong outcome (n=3), article commentary/analysis (n=6), and studies that were part of a more up-to-date included reference (n=4). Finally, a total of 22 publications (66,79–99) were included for qualitative and quantitative analysis, two of which (90,96) have been followed at different times and described in 5 different articles (20,22,23,26,67).

Detailed information about the process can be found in the PRISMA flow diagram (Figure 5.1).

Figure 5.1 - PRISMA Flow diagram of the study selection process



Source: The author.

5.2 DESCRIPTION OF STUDIES

Main information from the included studies is presented in Table 5.1. Of the 22 publications included, 11 (79–81,86,88,89,91,92,96,98,99) were randomized clinical trials while the remaining (66,82–85,87,90,93–95,97) were non-randomized studies of interventions, where 2,869 primary molars were analyzed from a reference sample of 3,256 primary molars. The studies were conducted across 14 countries (Nigeria, Australia, Brazil, China, Germany, India, Iran, New Zealand, Sudan, Syria, Turkey, United Kingdom, United Arab Emirates and USA). Among the eleven randomized clinical trials, six were registered in clinical trial open registry databases such as ClinicalTrials.gov, Australian New Zealand Clinical Trials Registry and Iranian Registry of Clinical Trials (79,80,86,88,89,96). For the NRSIs, only 1 (90) reported registration. Twenty-one articles were published in English, while one was in Chinese. The latter was translated using specialized translation tools in order to obtain the information reported, and the final translation was verified to avoid errors. Twelve studies were carried out in an academic setting (80–84,87,88,91,92,94,96,98), one in a field setting (79), one in a medical setting (99), four in a private setting (66,89,90,93), and four in a public setting (85,86,95,97).

The age ranges of the children spanned from two to 12 years old. The crown brands used was 3M/ESPE in nine studies (66,79,80,83,85,86,88,91,99), Kids Crown in four studies (81,89,92,98), while in the other nine studies (82,84,87,90,93–97) the brand was not reported. Eight studies (82,84,87,90,93–95,98) did not report the brand of glass ionomer cements used while fourteen studies (66,79–81,83,85,86,88,89,91,92,96,97,99) reported 6 different manufacturers.

Most of the studies used the Hall Technique criteria (20) to evaluate the survival of preformed crowns, except for two studies (80,99) that used their own criteria, and one study (95) that used FGDP (Faculty of General Dental Practice) criteria. Treatment follow-up was reported in months when all participants had an equal duration of follow up and as a mean time interval, where the minimum reported follow-up time was 1 month and the maximum 89 months.

Detailed information on the reasons for exclusion of phase 2 studies is described in the Characteristics of Excluded Studies table (Table 5.2).

Table 5.1 - Characteristics of the studies included in the systematic review

Study	Country	Study Design	Registration	Blinding	Setting	Operator qualification	Age (years or mean +- sd)	Follow up (months, mean)	PMC brand	GIC brand	Assessment Criteria
Araujo et al. 2020 (79)	Brazil	RCT	NCT02569047	None	Field setting	Postgraduate Dentist	5 to 10 yo	36 months	3M/ ESPE	Fuji I (GC Corp)	Hall Technique criteria
Arrow et al. 2020 (80)	Australia	RCT	ACTRN12616 001124426	Outcome assessor	Academic setting	Postgraduate Dentist	4.6 (4.3. 5.0)	12 months	3M/ ESPE	Fuji VII (GC Corp)	Own evaluation criteria
Ayedun et al. 2021 (81)	Nigeria	RCT	Unclear	One blind	Academic setting	Postgraduate Dentist	3 to 8 yo	12 months	Kids Crown	Hy-Bond Glasionomer CX (Shofu Inc)	Hall Technique criteria
BaniHani et al. 2017 (82)	England	NRSI	Unclear	Unclear	Academic setting	Postgraduate Dentist	4 to 9 yo	9 m (mean) (range: 1-63 m)	Unclear	Unclear	Hall Technique criteria
Bhatia et al. 2019 (83)	India	NRSI	Unclear	Unclear	Academic setting	Unclear	6 to 10 yo	6 months	3M/ ESPE	GC type 1 (GC Corp)	Hall Technique criteria
Binladen et al. 2020 (84)	United Arab Emirates	NRSI	Unclear	Unclear	Academic setting	Postgraduate Dentist	6.44 ± 1.48.	24 months	Unclear	Unclear	Hall Technique criteria
Boyd et al. 2017 (85)	New Zealand	NRSI	Unclear	None	Public setting	Dentist	5 to 8 yo	25 m (mean) (range: 21-35 m)	3M/ ESPE	RelyX Luting Plus (3M/ESPE)	Hall Technique criteria
Boyd et al. 2020 (86)	New Zealand	RCT	ACTRN12614 000844640	None	Public setting	Trained Dentist	3 to 8 yo	24 months	3M/ ESPE	RelyX Luting Plus (3M/ESPE)	Hall Technique criteria
Clark et al. 2017 (87)	USA	NRSI	Unclear	Unclear	Academic setting	Unclear	5.1 ±2.4	20.1 m (mean)	Unclear	Unclear	Hall Technique criteria
Ebrahimi et al. 2020 (88)	Iran	RCT	IRCT2018122 6042138N1	Practitioner	Academic setting	Postgraduate Dentist	4 to 9 yo	12 months	3M/ ESPE	Fuji Triage (GC Corp)	Hall Technique criteria
Elamin et al. 2019 (89)	Sudan	RCT	NCT03640013	Participants and Outcome assessor	Private setting	Dentist	5 to 8 yo	24 months	Kids Crown	Vitro Fil (DFL)	Own evaluation criteria
Innes et al. 2006 (66)	Scotland	NRSI	Unclear	None	Private setting	Dentist	2 to 11 yo	60 months	3M/ ESPE	AquaCem (Dentsply)	Hall Technique criteria
Innes et al. 2015 (90)	Scotland	NRSI	ISRCTN 47267893	None	Private setting	Trained Dentist	3 to 10 yo	60 months	Unclear	Unclear	Hall Technique criteria
Kaptan et al. 2021 (91)	Turkey	RCT	Unclear	Unclear	Academic setting	Unclear	4 to 8 to	12 months	3M/ ESPE	Nova Glass F (Imicryl)	Hall Technique criteria

To be continued

conclusion

Kezawie et al. 2021 (92)	Syria	RCT	Unclear	None	Academic setting	Posgraduate Dentist	6 to 7 yo	18 months	Kids Crown	Fuji I (GC Corp)	Hall Technique criteria
Ludwig et al. 2014 (93)	USA	NRSI	Unclear	None	Private setting	Posgraduate Dentist	2 to 10 yo	15 m (mean) (range: 4 to 37 m)	Unclear	Unclear	Hall Technique criteria
Midani et al. 2019 (94)	Germany	NRSI	Unclear	None	Academic setting	Posgraduate Dentist	2 to 11 yo	22.62 m (mean) (range: 6.01-89)	Unclear	Unclear	Hall Technique criteria
Robertson et al. 2020 (95)	England	NRSI	Unclear	Unclear	Public setting	Posgraduate Dentist	4 to 12 yo	32.4 m (mean) (range: 12 to 87 m)	Unclear	Unclear	FGDP criteria
Santamaria et al. 2018 (96)	Germany	RCT	NCT01797458	None	Academic setting	Posgraduate Dentist	3 to 8 yo	30 months	Unclear	Fuji Triage (GC Corp)	Hall Technique criteria
Sapountzis et al. 2021 (97)	Australia	NRSI	Unclear	Outcome assessor	Public setting	Dentist	5 to 11 yo	17 m (mean) (16.8 ± 6.1 m)	Unclear	G-Cem (GC Corp)	Hall Technique criteria
Thakkar et al. 2021 (98)	India	RCT	Unclear	None	Academic setting	Trained Postgraduate student	7 to 8 yo	15 months	Kids Crown	Unclear	Hall Technique criteria
Wang et al. 2018 (99)	China	RCT	Unclear	None	Medical setting	Unclear	3 to 9 yo	12 months	3M/ ESPE	GIC (3M)	Own evaluation criteria

Source: The author.

Table 5.2 -– Details of studies excluded after full-text screening and reasons for exclusion

Study	Label	Reason for exclusion
BaniHani et al. 2019	Wrong Outcome	Cost-effectiveness and patient acceptance analysis; Hall Technique survival data could not be separated from biological arm
Brignardello-Petersen 2018	Commentary/Analysis	Personal Commentary/Analysis on Santamaría RM, Innes NPT, Machiulskiene V, Schmoeckel J, Alkilzy M, Splieth CH. Alternative caries management options for primary molars: 2.5-year outcomes of a rando- mised clinical trial. Caries Res. 2017;51(6):605-614. https://doi.org/10.1159/000477855.
Fontana et al. 2012	Commentary/Analysis	Personal Commentary/Analysis on Sealing caries in primary molars: randomized control trial, 5-year results. Innes N, Evans D, Stirrups D. J Dent Res 2011;90:1405-10. Epub 2011 Sep 15.
Innes et al. 2007	Part of an included reference	Research/Publication reported in Innes N, Stewart M, Souster G, Evans D. The Hall Technique; retrospective case-note follow-up of 5-year RCT. British Dental Journal. 2015 Oct 23 [cited 2022 Apr 30];219(8):395–400. doi: 10.1038/sj.bdj.2015.816.
Innes et al. 2015	Commentary/Analysis	Personal Commentary/Analysis on The success of stainless steel crowns placed with the Hall technique: a retrospective study. Ludwig KH, Fontana M, Vinson LA, Platt JA, Dean JA. J Am Dent Assoc 2014;145(12):1248–53.
Rosenblatt 2008	Commentary/Analysis	Personal Commentary/Analysis on Innes NP, Evans DJ, Stirrups DR. The Hall technique: a randomized controlled clinical trial of a novel method of managing carious primary molars in general dental practice: acceptability of the technique and outcomes at 23 months. BMC Oral Health 2007, 7:18
Santamaria et al. 2014	Part of an included reference	The research/publication forms part of an included publication: Santamaría RM, Innes NPT, Machiulskiene V, Schmoeckel J, Alkilzy M, Splieth CH. Alternative caries management options for primary molars: 2.5-Year outcomes of a randomised clinical trial. Caries Research. 2017 Jan 1 [cited 2022 Apr 30];51(6):605–14. doi: 10.1159/000477855.
Schwendicke et al. 2019	Part of an included reference	Cost-effectiveness analysis on an included trial: Innes N, Stewart M, Souster G, Evans D. The Hall Technique; retrospective case-note follow-up of 5-year RCT. British Dental Journal. 2015 Oct 23;219(8):395–400. doi: 10.1038/sj.bdj.2015.816.
Schwendicke et al. 2018	Part of an included reference	Cost-effectiveness analysis on an included trial: Santamaría RM, Innes NPT, Machiulskiene V, Schmoeckel J, Alkilzy M, Splieth CH. Alternative caries management options for primary molars: 2.5-Year outcomes of a randomised clinical trial. Caries Research. 2017 Jan 1;51(6):605–14. doi: 10.1159/000477855.
Schwendicke et al. 2016	Wrong Outcome	Cost-effectiveness analysis; Survival data not compatible for our analysis.
Simpson et al. 2020	Commentary/Analysis	Personal Commentary/Analysis on Schwendicke F, Krois J, Robertson M, Splieth C, Santamaria R, Innes N. Cost-effectiveness of the Hall Technique in a randomized trial. Journal of Dental Research. 2019 Jan 14;98(1):61–7. doi: 10.1177/0022034518799742.
Lakshmi et al. 2018	Wrong Outcome	Acceptability analysis of two different techniques; Survival data not available for our analysis.
Yengopal 2015	Commentary/Analysis	Personal Commentary/Analysis on Santamaría RM, Innes NPT, Machiulskiene V, Schmoeckel J, Alkilzy M, Splieth CH. Alternative caries management options for primary molars: 2.5-year outcomes of a rando- mised clinical trial. Caries Res. 2017;51(6):605-614. https://doi.org/10.1159/000477855.

Source: The author.

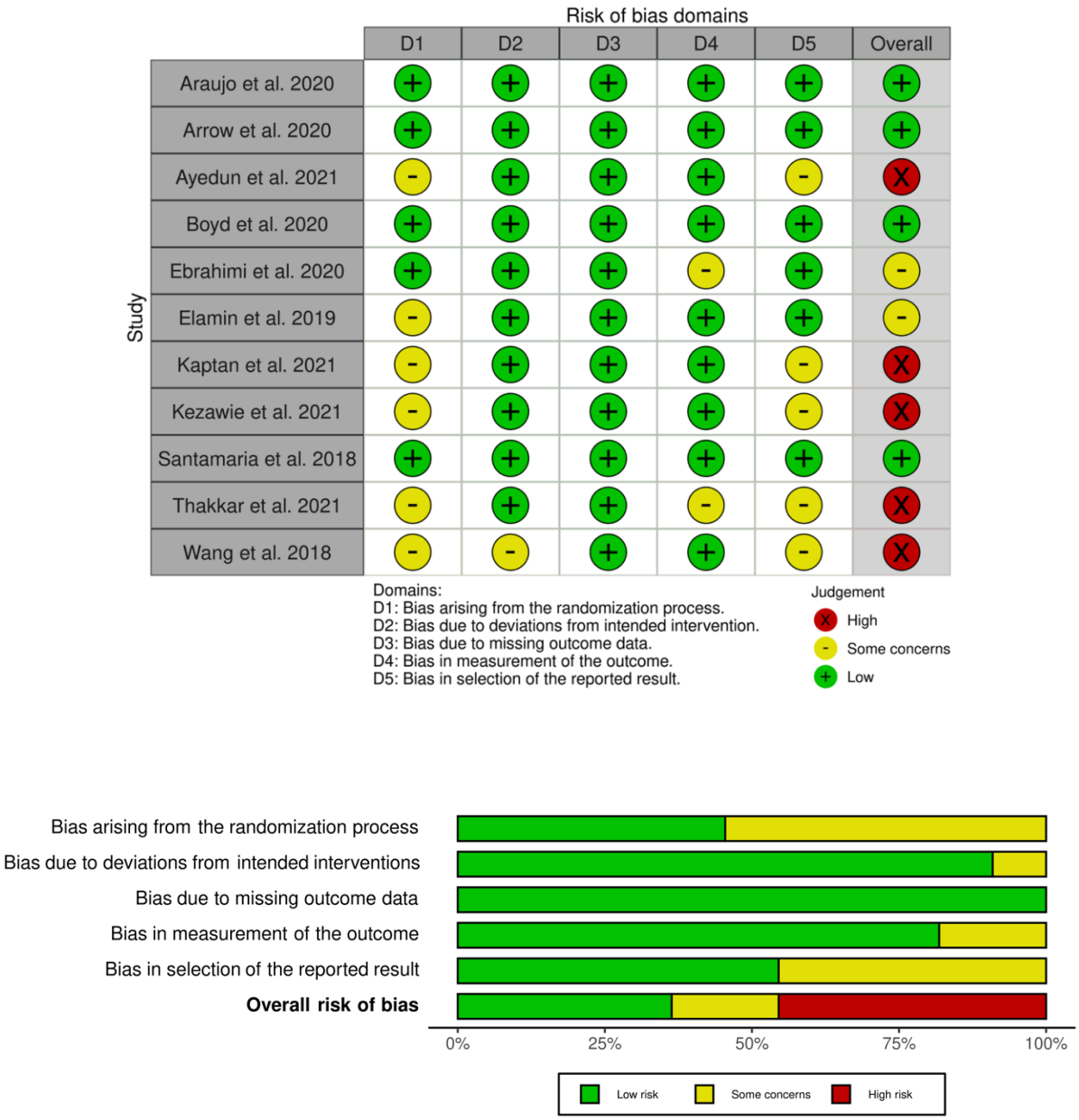
5.3 RISK OF BIAS ASSESSMENT

A visual representation of the risk of bias assessment of the included studies is presented in Figure 5.2 for the RCTs and Figure 5.3 for the NRSIs. The RoB 2 tool was used for all 11 included RCTs, there was high risk of overall bias in 46% of the studies, 36% of the studies had low risk, and the remaining 18% had some concerns.

Bias was present in most studies due to lack of information about allocation concealment or randomization process, failure to blind operators/children/parents and outcome assessor, considerable dropout rates, differing baseline characteristics between treatment groups, lack of protocol registration with a pre-specified analysis plan, outcome assessment was performed by the practitioner, and deviations from the intended intervention.

Concerning the grading, six trials raised some concerns about the randomization process (D1), ten were risk-free in terms of deviations from the intended intervention (D2), none of the trials presented risk in terms of missing outcome data (D3), regarding measurement of the outcome nine studies did not present any risk (D4), and finally five studies brought up some concerns about selective outcome reporting (D5).

Figure 5.2 - Risk of bias assessment of the included studies in the Randomized Clinical Trials group

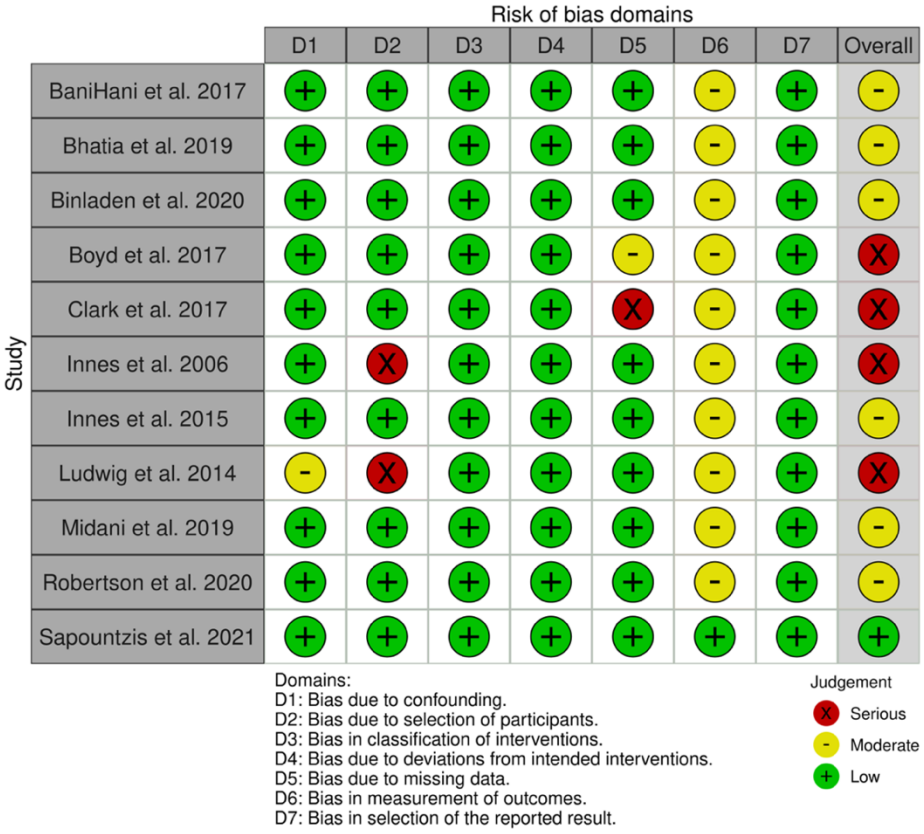


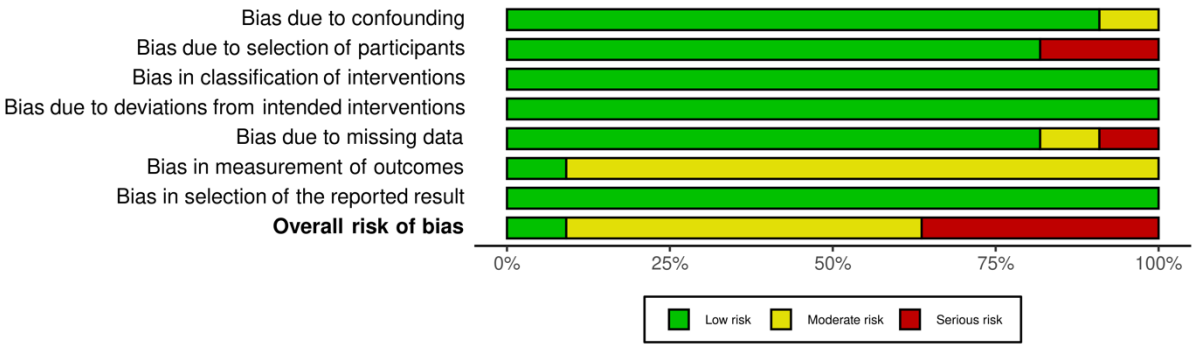
Source: The author.

For the eleven NRSIs, the ROBINS-I tool was used and 55% of studies had moderate risk of overall bias, 36% of studies had severe risk, and only 9% had low risk. Bias in the studies was detected because the follow-up was performed at different times, information on the analysis was limited, retrospective analysis of data, both groups' treatments were performed at different times and the participants' age was significantly different, the dropouts difference between groups was not balanced,

blinding of the outcome assessors was not found or was impossible since it was performed by the same practitioners, Risk due to confounders was limited to one study as moderate (D1), two studies showed a serious risk regarding participant selection (D2) by presenting problems in the selection and differences in the start/follow-up of the intervention, all studies were risk-free in both classification (D3) and deviations from the planned intervention (D4), serious and moderate risk existed in two studies respectively for missing data (D5), the domain that evaluated the measurement of outcomes was the one that presented moderate risk in 10 of the 11 studies (D6), and lastly no study presented risk in terms of selection of outcome reporting (D7).

Figure 5.3 - Risk of bias assessment of the included studies in the Non-Randomized Studies of Interventions group





Source: The author.

5.4 DATA SYNTHESIS

For the quantitative analyses, randomized clinical trials and non-randomized studies of interventions were evaluated separately. Tables 5.3 and 5.4 present the overall pooled results of survival of preformed metal crowns applied according to the Hall Technique on deciduous molars at different time points corresponding to all included studies. Since the studies measured survival at different time points, and taking into account the variability of the reported follow-up data, our study used a two-group approach for the analysis, less than or equal to (≤) 18 months and greater than or equal to (≥) 18 months.

Table 5.3 - Overview of survival results (%) by timepoints of preformed metal crowns applied according to the Hall Technique on decayed primary molars in randomized clinical trials

Study	Country	Survival Timepoints									
		1m	3m	6m	9m	12m	15m	18m	24m	30m	36m
Araujo et al. 2020	Brazil	100%		98%		98%		93%	93%	93%	93%
Arrow et al. 2020	Australia					98%					
Ayedun et al. 2021	Nigeria		100%	100%	100%	100%					
Boyd et al. 2020	New Zealand					89%			85%		
Ebrahimi et al. 2020	Iran			98%		94%					
Elamin et al. 2019	Sudan								94%		
Kaptan et al. 2021	Turkey			96%		93%					
Kezawie et al. 2021	Syria			100%		100%		100%			
Santamaria et al. 2018	Germany					98%				92%	
Thakkar et al. 2021	India						97%				
Wang et al. 2018	China			98%		96%					

Source: The author.

Table 5.4 - Overview of survival results (%) by timepoints of preformed metal crowns applied according to the Hall Technique on decayed primary molars in non-randomized studies of interventions

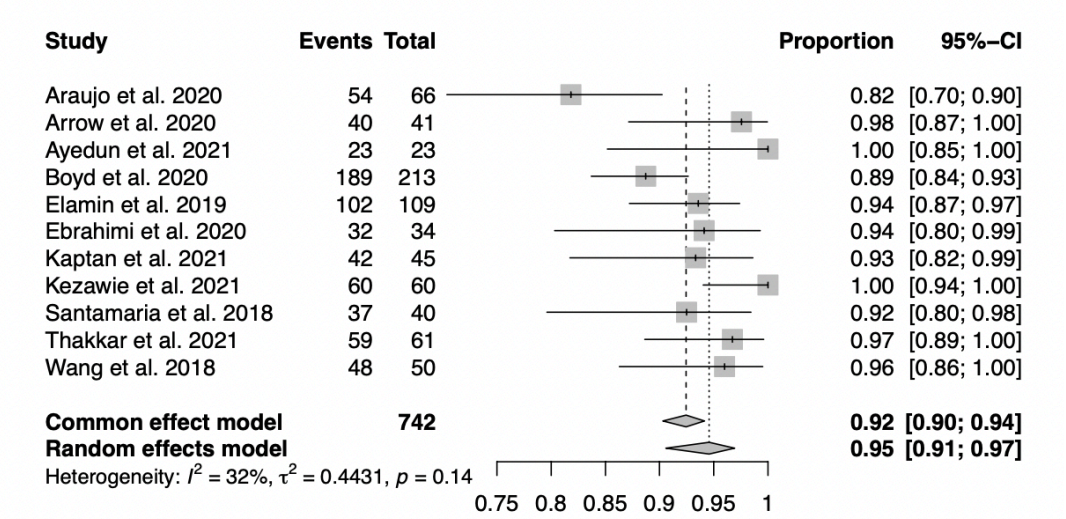
Study	Country	6m	9m	12m	15m	17m	18m	20m	22m	24m	36m	60m
BaniHani et al. 2017	England		96%									
Bhatia et al. 2019	India	100%										
Binladen et al. 2020	United Arab Emirates	100%		99%			99%			98%		
Boyd et al. 2017	New Zealand									94%		
Clark et al. 2017	USA		99%					97%				
Innes et al. 2006	Scotland										73%	68%
Innes et al. 2015	Scotland									97%		91%
Ludwig et al. 2014	USA				97%							
Midani et al. 2019	Germany								92%			
Robertson et al. 2020	England									100%		
Sapountzis et al. 2021	Australia					99%						

Source: The author.

5.4.1 Randomised clinical trials

We performed a meta-analysis of 11 RCTs to evaluate the success rate of PMCs applied according to the Hall Technique on decayed primary molars. The overall analysis yielded a pooled proportion of 95% (95% CI 91-97) corresponding to the mean success rate (Figure 5.4). Heterogeneity was considered moderate (I^2 = 32%), yet not statistically significant (p = 0.14).

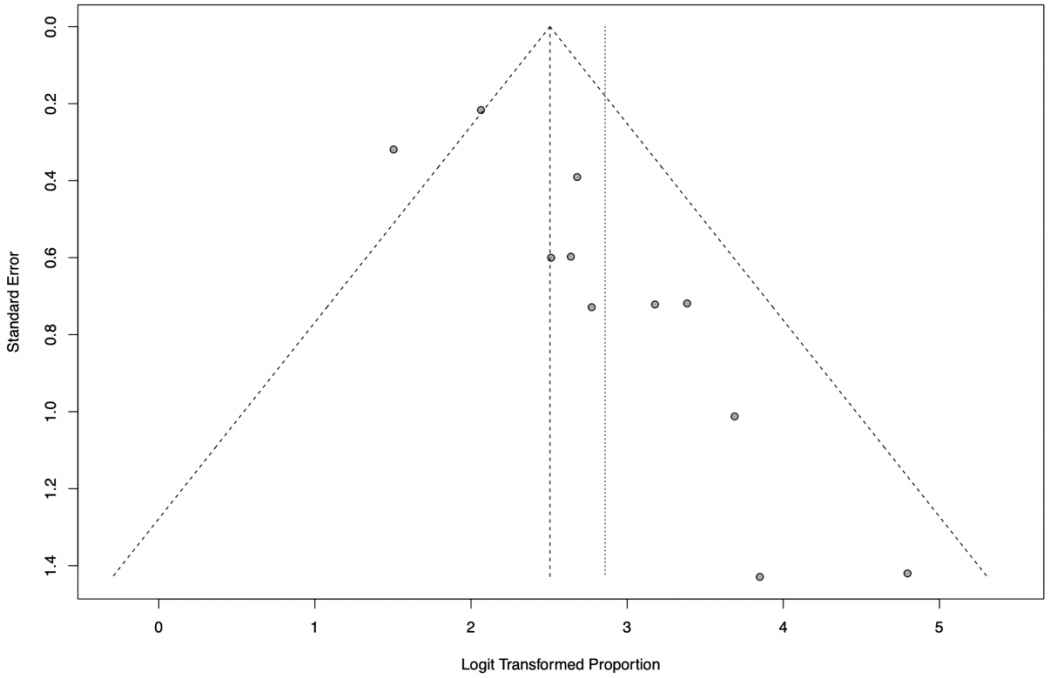
Figure 5.4 - Primary Forest Plot of the main included studies in the RCT group



Source: The author.

Visual inspection of the funnel plot figure suggests asymmetry (Figure 5.5), however, publication bias analysis (peters test) revealed lack of asymmetry in the funnel plot (p= 0.3258).

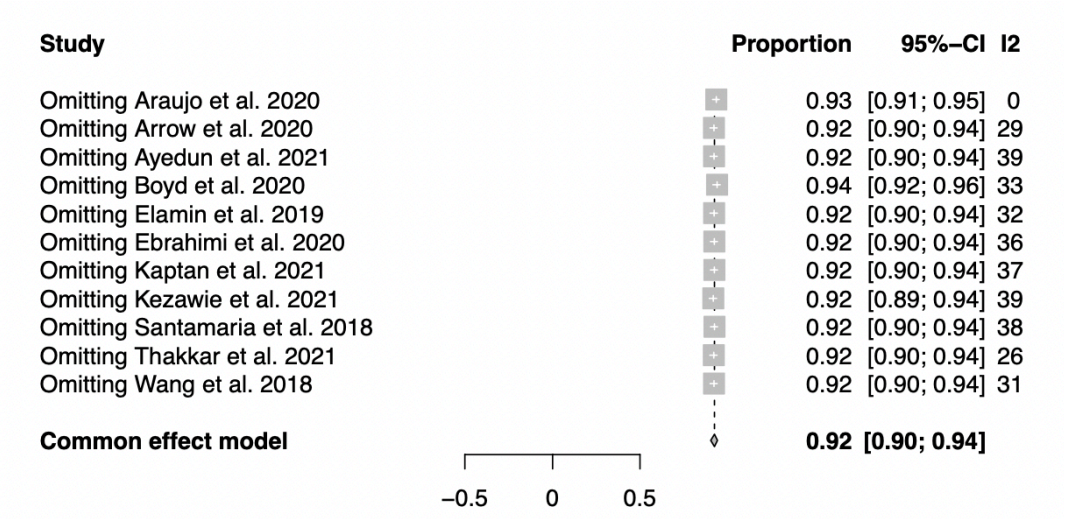
Figure 5.5 - Primary Funnel Plot of the main included studies in the RCT group



Source: The author.

Since there was moderate heterogeneity, a sensitivity analysis was performed to investigate the influence of each individual study on the overall heterogeneity by excluding each one separately (Figure 5.6), revealing the influence of one study (79) which, when omitted, I^2 decreased to 0% ($p = 0.53$) and the pooled proportion remained unchanged.

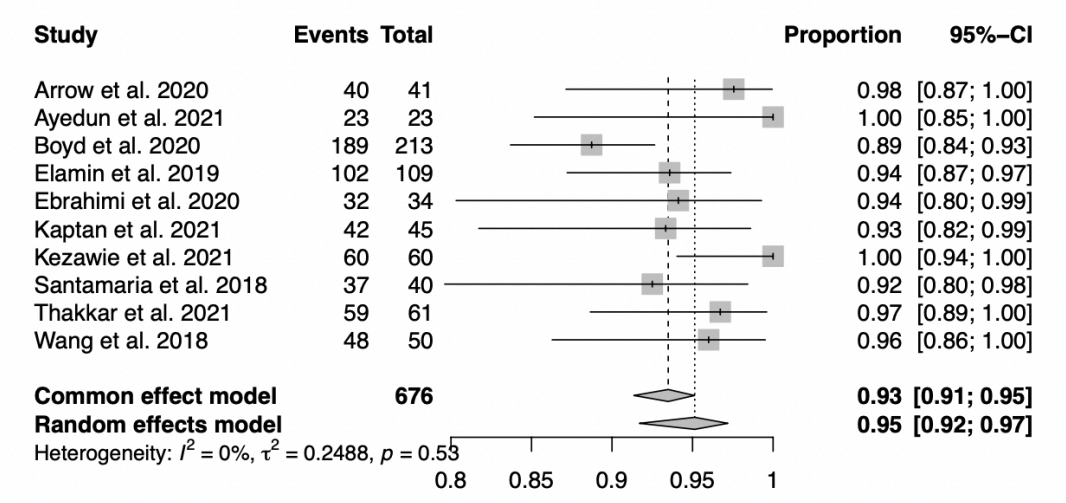
Figure 5.6 - Sensitivity analysis of the main included studies in the RCT group



Source: The author.

Consequently, a new meta-analysis was performed omitting the latter study, resulting in a pooled proportion for the success rate of 95% (95% CI:92-97) (Figure 5.7). Heterogeneity was not detected (I^2 = 0%) and was not statistically significant (p = 0.53).

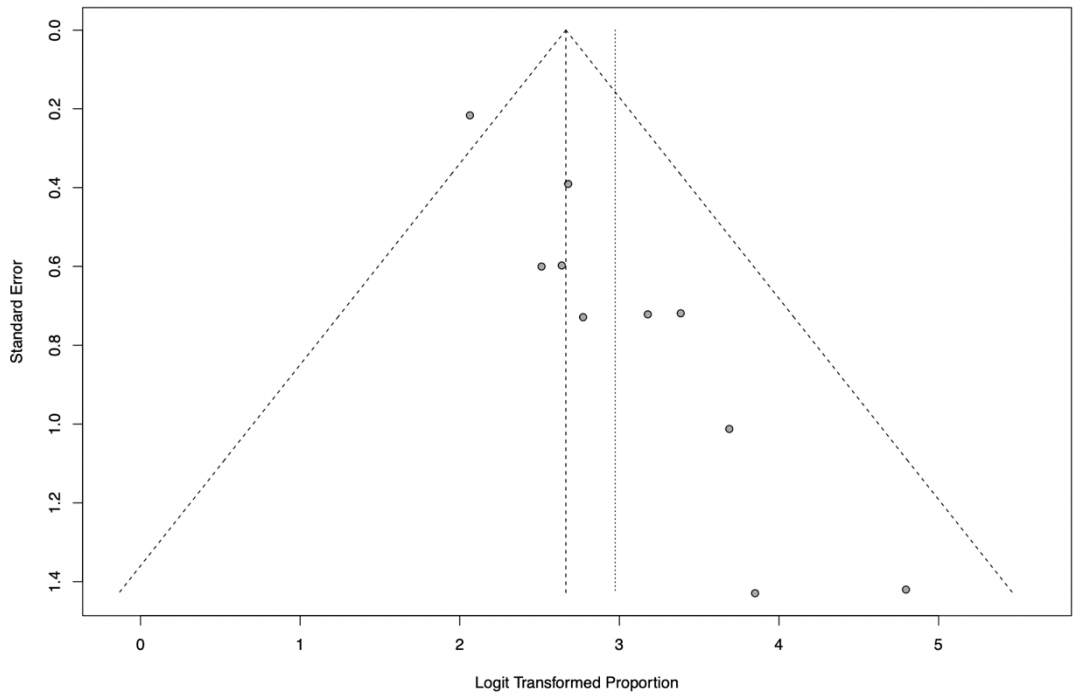
Figure 5.7 - Secondary Forest Plot of the included studies after the sensitivity analysis in the RCT group



Source: The author.

However, both visual inspection of the funnel plot figure (Figure 5.8), and publication bias analysis (peters test) revealed the presence of asymmetry in the funnel plot (p = 0.0453).

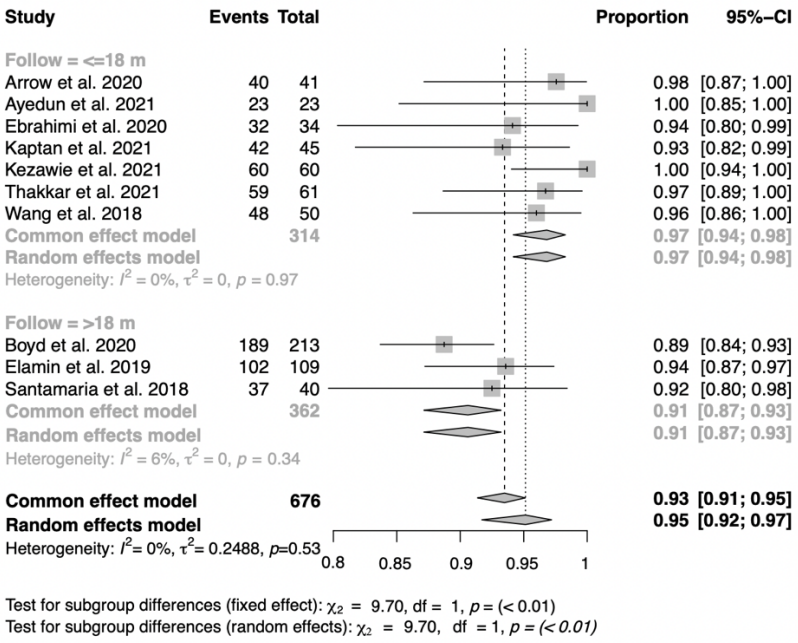
Figure 5.8 - Secondary Funnel Plot of the included studies after the sensitivity analysis in the RCT group



Source: The author.

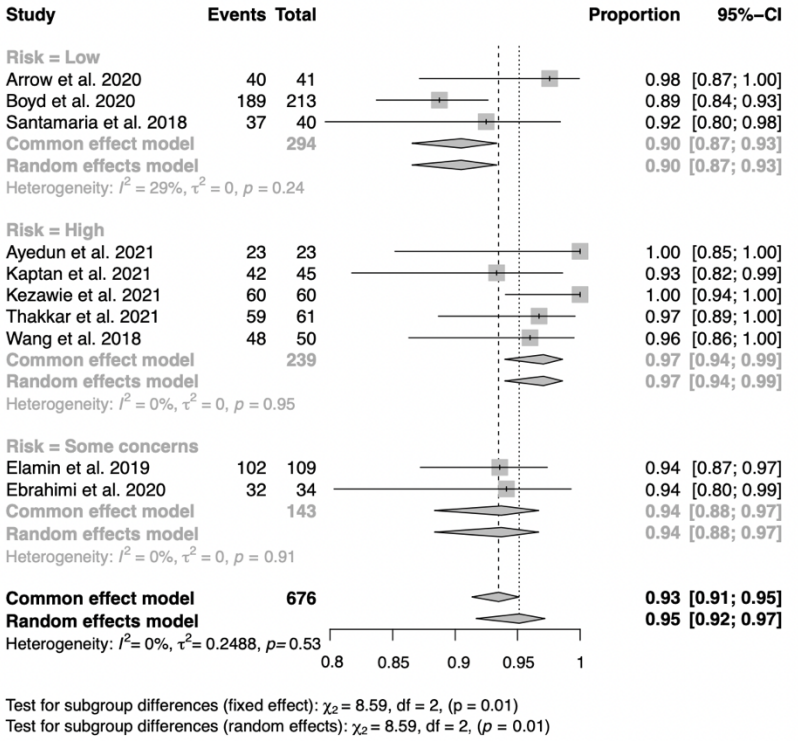
Subgroup analyses were performed and where statistically significant for follow-up (p = 0.0018) (Figure 5.9) and the inter-group pooled proportion was 97% for those with a follow-up ≤ 18 months and 91% for ≥ 18 months; risk of bias (p = 0.0136) (Figure 5.10) with the inter-group pooled proportion of 90% for those with low risk of bias, 97% at high risk and 94% for those with some concerns; or setting (p = 0.0289) (Figure 5.11) the inter-group pooled proportion was 96% in academic, 89% public, 94% private and 96% in medical settings.

Figure 5.9 - Forest Plot of the Subgroup analysis according to Follow-up



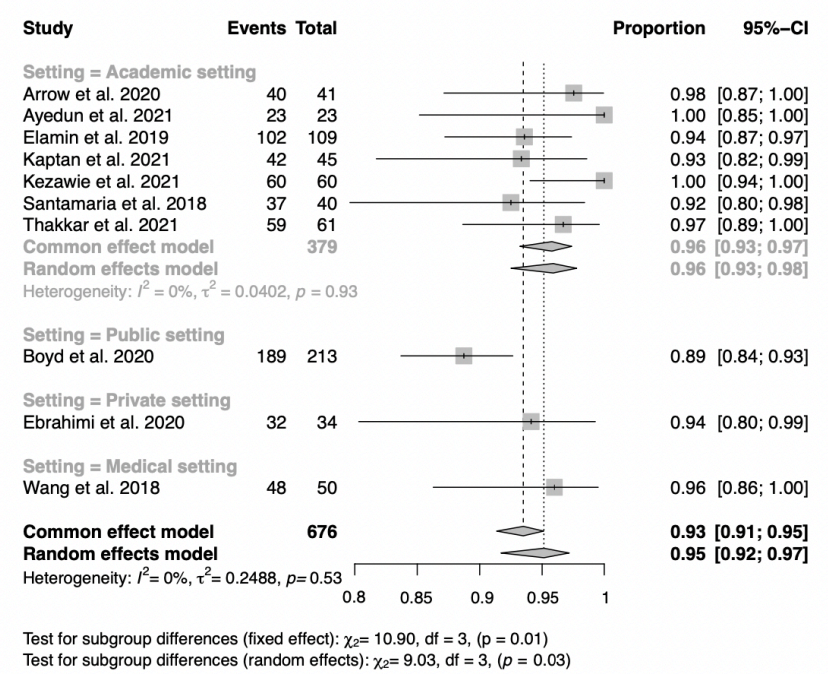
Source: The author.

Figure 5.10 - Forest Plot of the Subgroup analysis according to Risk of bias



Source: The author.

Figure 5.11 - Forest Plot of the Subgroup analysis according to Setting

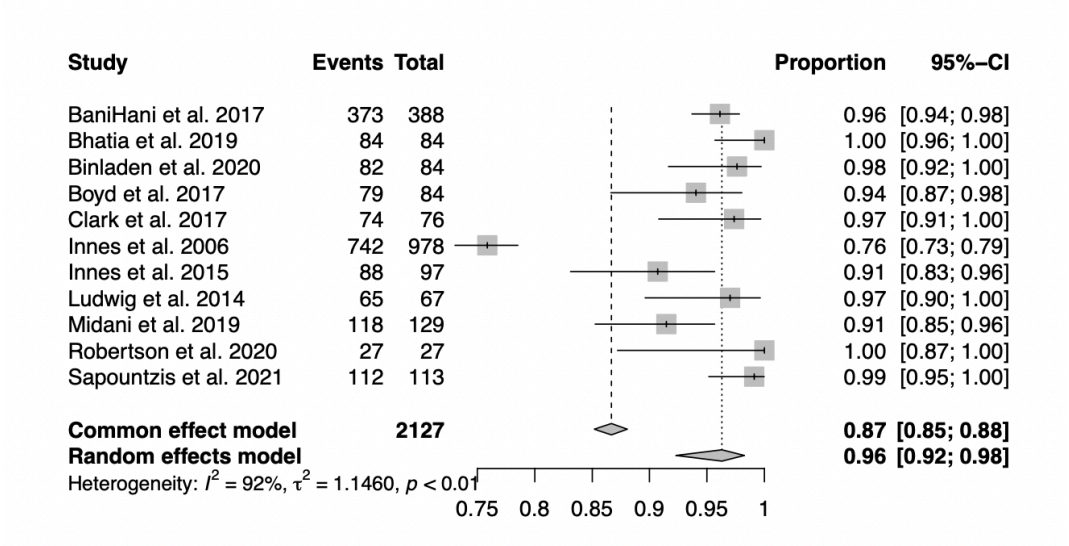


Source: The author.

5.4.2 Non-randomized studies of interventions

A meta-analysis was performed for 11 NRSIs to assess the success rate of the Hall technique in primary molars. A 96% (95% CI: 92-98) pooled proportion of success rate (Figure 5.12) was found. There was a high degree of heterogeneity (I^2 = 92%) that was statistically significant (p <0.01).

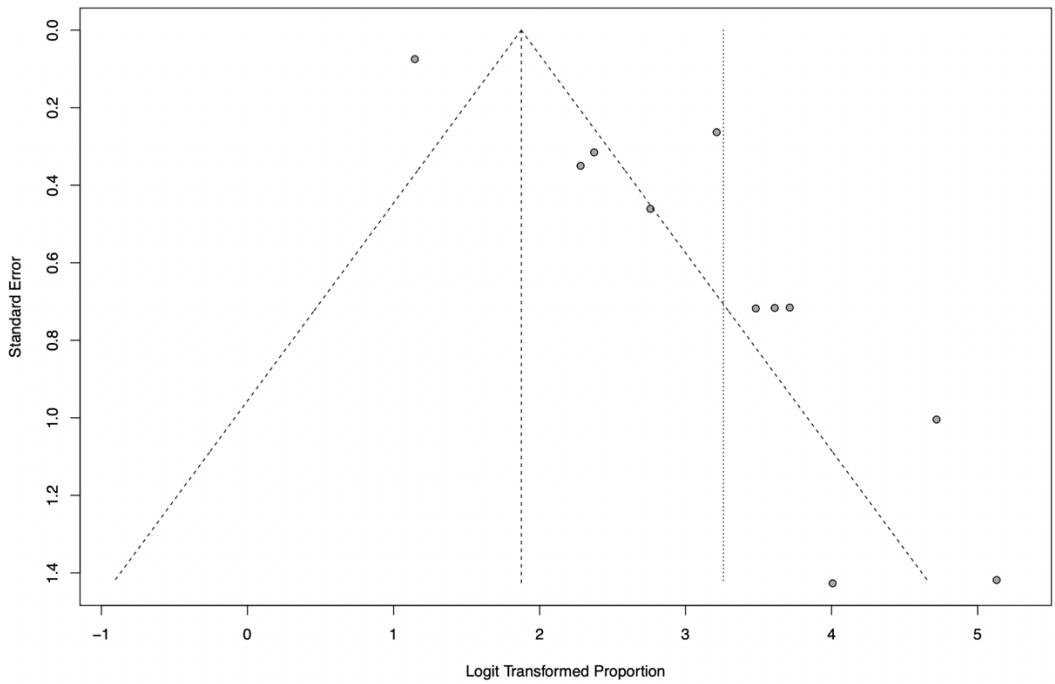
Figure 5.12 - Primary Forest Plot of the main included studies in the NRSI group



Source: The author.

Asymmetry in the funnel plot (p= 0.0138) was observed through publication bias analysis and visual inspection of the funnel plot figure (Figure 5.13).

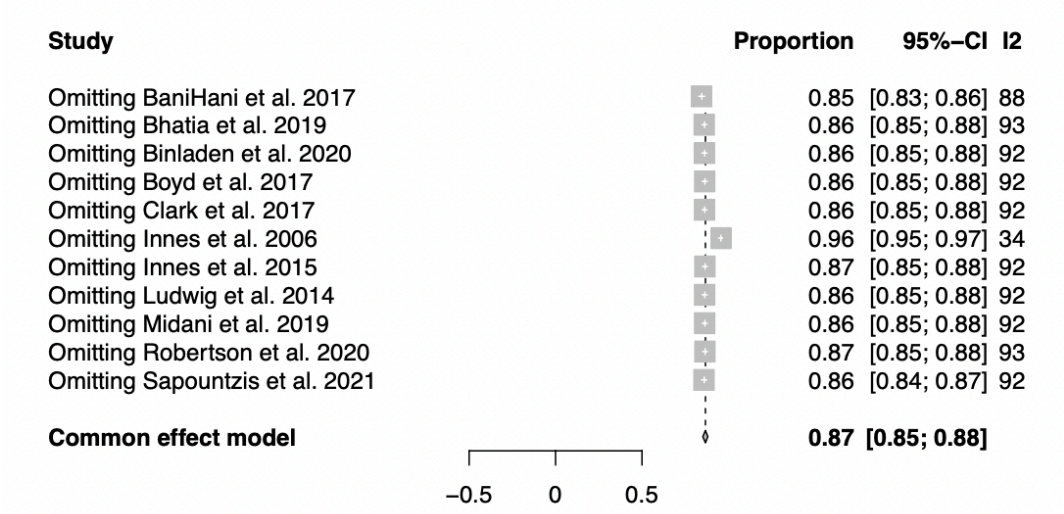
Figure 5.13 - Primary Funnel Plot of the main included studies in the NRSI group



Source: The author.

Sensitivity analysis was performed (Figure 5.14) due to high heterogeneity, detecting the influence of one study (66), and by omitting it, I^2 decreased to 34% (p = 0.14) and pooled proportion remained very similar.

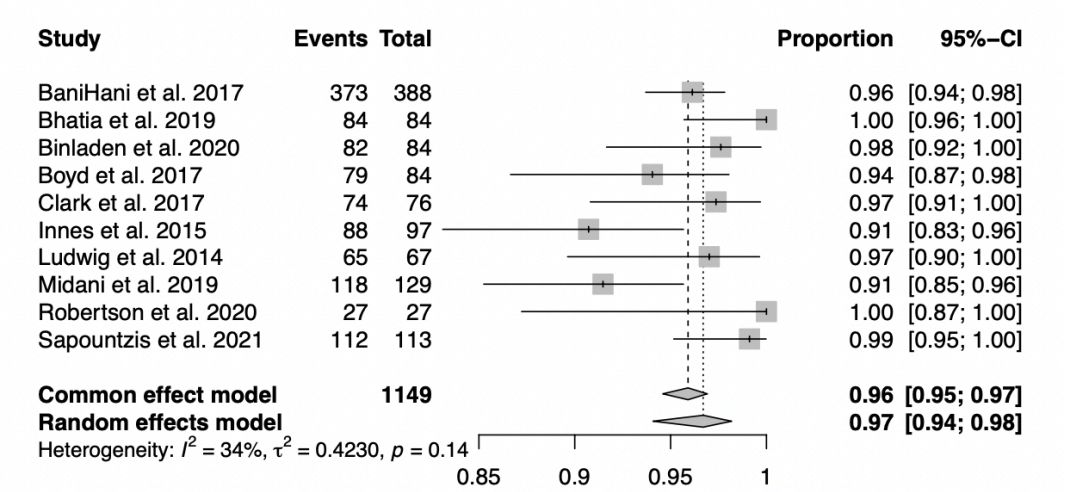
Figure 5.14 - Sensitivity analysis of the main included studies in the NRSI group



Source: The author.

A new meta-analysis was performed omitting the study cited above, resulting in a pooled proportion for success rate of 97% (95% CI 94-98) (Figure 5.15). Moderate heterogeneity (I^2 = 34%) not statistically significant (p = 0.14) was detected.

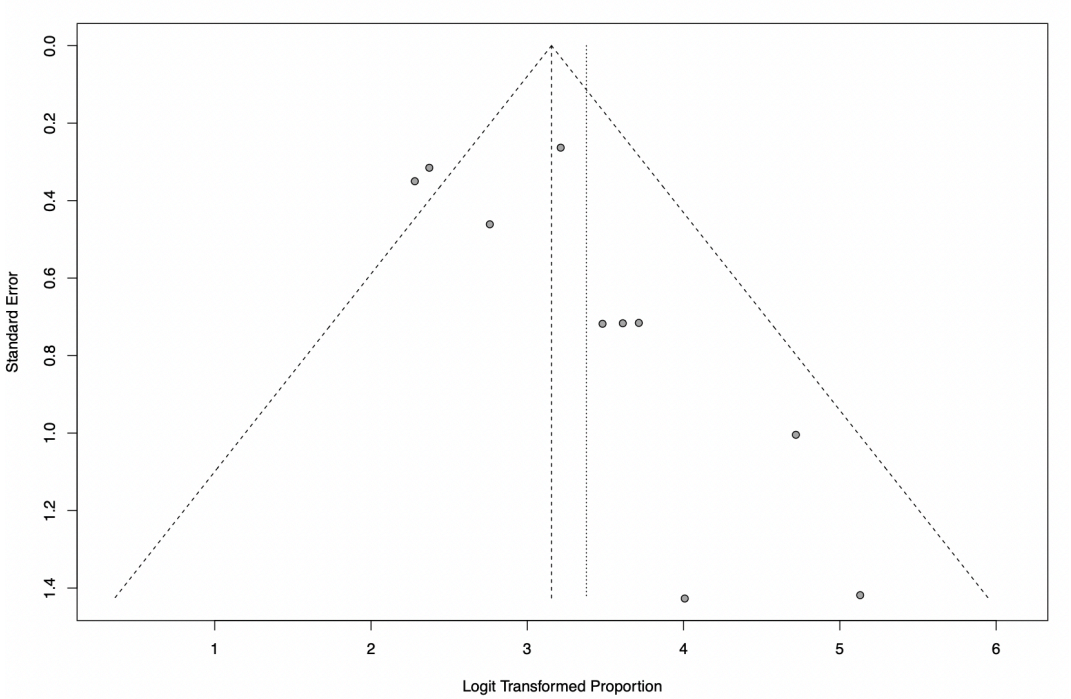
Figure 5.15 - Secondary Forest Plot of the included studies after the sensitivity analysis in the NRSI group



Source: The author.

No asymmetry was detected in the funnel plot (p = 0.7172) using publication bias analysis, however, visual inspection of the funnel plot figure revealed funnel plot asymmetry (Figure 5.16).

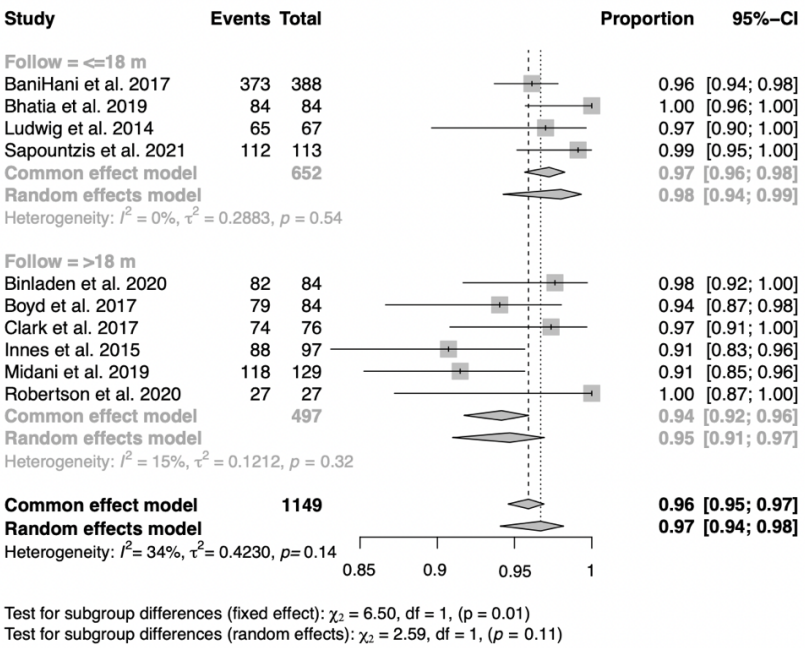
Figure 5.16 - Secondary Funnel Plot of the included studies after the sensitivity analysis in the NRSI group



Source: The author.

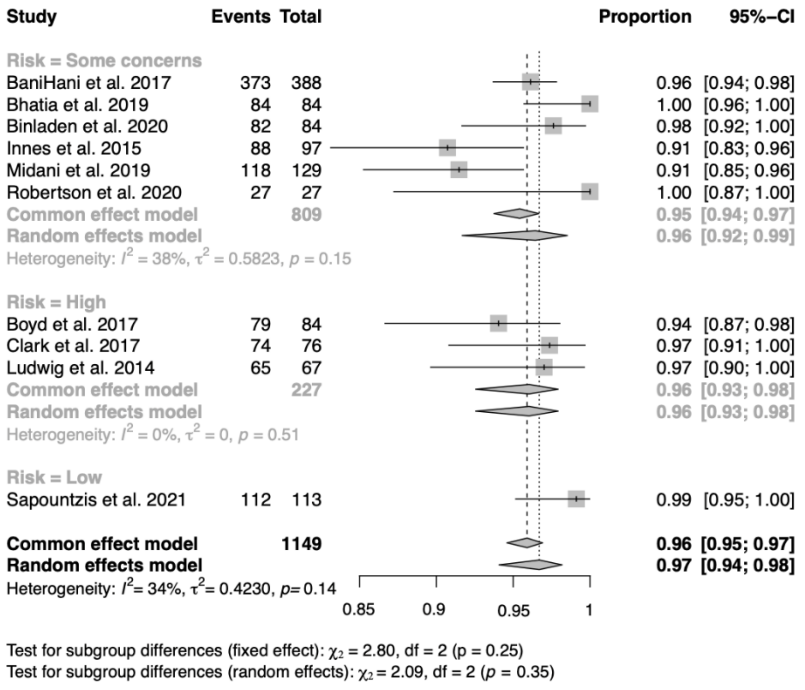
Subgroup analysis found no evidence of a statistically significant influence on the success of the Hall Technique for: follow-up (p = 0.1077) (Figure 5.17) and the pooled proportion success rate was 98% for those with follow-up ≤ 18 months (n=634) and 95% for those with follow-up ≥ 18 months (n=468); risk of bias (p = 0.3515) (Figure 5.18) and the pooled proportion success rate was 96% for those with some concerns (n=772) and high risk (n=218), and 99% for those with low risk (n=112); and setting (p = 0.2689) (Figure 5.19) and the pooled proportion success rate was 97% in the academic setting, 98% in the public setting, and 94% in the private setting.

Figure 5.17 - Forest Plot of the Subgroup analysis according to Follow-up



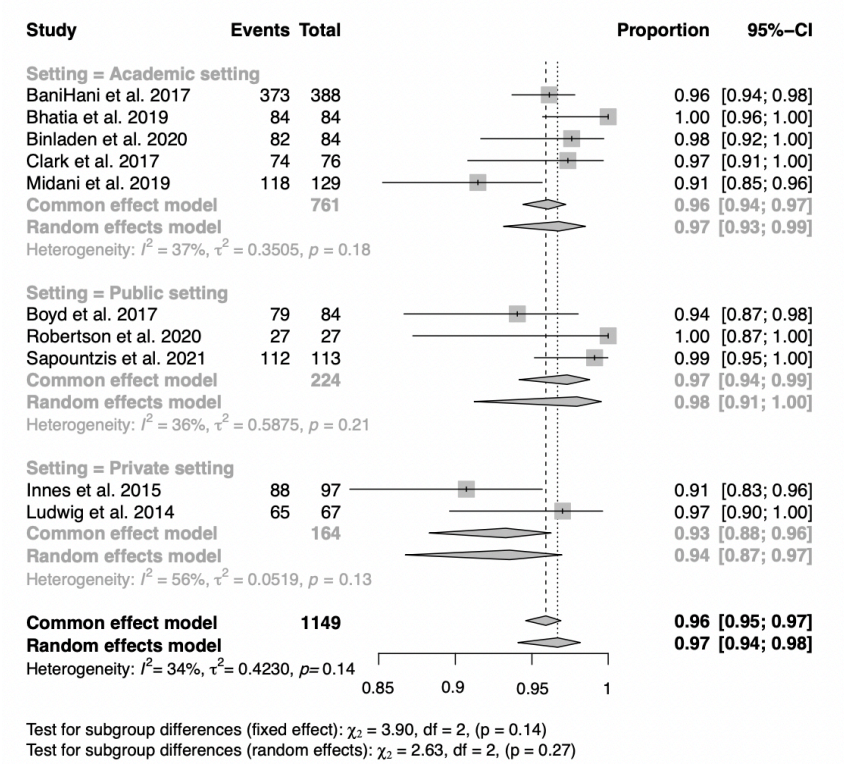
Source: The author.

Figure 5.18 - Forest Plot of the Subgroup analysis according to Risk of bias



Source: The author.

Figure 5.19 - Forest Plot of the Subgroup analysis according to Setting



Source: The author.

5.5 CERTAINTY OF EVIDENCE ASSESSMENT

The certainty of evidence and corresponding explanation of each factor rating is detailed in Box 5.1. RCTs were downgraded mainly due to study limitations as the overall risk of bias was considered serious due to problems in the randomization process, deviations from the intended intervention, outcome measurement, and selective outcome reporting, followed by publication bias detected by funnel plot visual inspection. Among the NRSIs, risk of bias was perceived as high due to limited information on the analysis, retrospective data analysis and treatments performed at different times, high number of dropouts, large difference in dropouts between groups, and blinding. Additionally, there was considerable inconsistency because considerable heterogeneity was found between studies, along with publication bias present in the

peters statistical analysis and visual inspection. Solely in the case of NSRIs, we were able to increase the quality of the evidence with the assessment of 3 additional categories (magnitude of effect, confounding factors, and dose-response gradient) due to a positive response.

Box 5.1 - Certainty of evidence analysis of all included studies according to the GRADE approach

№ of studies	Certainty assessment						Certainty
	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	
11	Randomized trials	serious[a]	not serious[b]	not serious[c]	not serious	publication bias strongly suspected[d]	⊕⊕◯◯ Low
11	Non-randomized studies of interventions	serious[e]	serious[f]	not serious[c]	not serious	publication bias strongly suspected very strong association[d]	⊕⊕⊕◯ Moderate

Source: The author.

a. Downgraded because in six of the eleven studies, information on allocation concealment was missing (bias arising from the randomization process), blinding was not possible in most of the studies (bias due to deviations from the intended interventions), in two studies, the assessor was the same therapist (bias in measurement of the outcome) and five did not have a registered protocol providing a pre-specified analysis plan (bias in selection of the reported result).

b. Low heterogeneity among studies (I^2 32%, p=0.04).

c. Treatment delivered in different settings, but under the same treatment protocol.

d. Downgraded because Funnel plot reveals asymmetry among studies.

e. Downgraded because in one of the studies information about analysis was limited, so it is not clear about their efforts to control confounding factors (bias due to confounding), a retrospective analysis of practice records was done and the treatments were performed at different times (bias in selection of participants into the study), a high number of dropouts were present in one study, while in another there was a high difference of patients excluded in the analysis between groups (bias due to missing data), in the case of blinding either the information was not reported or was reported as not possible (bias in measurement of outcomes).

f. Downgraded because Considerable heterogeneity was found among studies (I^2 92%, p<0.01).

6 DISCUSSION

This systematic review is the first to evaluate different types of intervention studies to explore the survival of preformed crowns applied following the Hall Technique when restoring deciduous molars and investigate the factors that might influence survival. The overall pooled ratio of the success rate was 95% in randomized clinical trials, and 97% in non-randomized studies of interventions, showing significantly high rates in both cases.

Upon methodological quality assessment, the majority of the randomized clinical trials exhibited some concerns to high risk of bias, and highlighted critical aspects in their structure, such as the absence of information on allocation concealment; lack of blinding of participants, operator or outcome assessor (generally unfeasible due to the use of different restorative materials), and even scenarios in which the operator is also the outcome assessor; as well as lack of protocol registration. For non-randomized studies of intervention, most of the studies showed a moderate to serious risk of bias, and during the methodological quality analysis, confounding and participant selection problems were found due to insufficient information on the analysis performed, retrospective analysis of data along with differences in baseline time, follow-up and participants' age; missing data and problems in measurement of the outcomes due to non-blinding of the outcome assessor.

In this sense a protocol registration is mandatory prior to participant enrollment to ensure transparency for the process (100), and a reporting guideline would be used when writing the report, helping to avoid missing information.

Additionally, although blinding is an important component to avoid bias in intervention studies, implementing it is often not possible due to the different types of restorative material used in the trials, so it should not be considered a major problem within the study, however this should be used and judged with caution and responsibility (101,102). Nonetheless, in the case of randomised trials, the randomisation process and allocation concealment need to be adequately justified to ensure that there are no significant differences between intervention groups and that participant enrollment was not manipulated. Finally, for the evidence to be robust, the

discrepancy in the available data needs to be minimal, ensuring careful handling and, where necessary, analyses to confirm that estimate of effect is not biased.

Such methodological differences between the studies, which despite being randomised studies considered as high quality evidence, denote problems in their internal validity exposing potential problems of overestimation the effects. This might explain the differences in the overall success rate found in our analysis according to the risk of bias, which were 90% [CI: 0.87, 0.93] for those of low risk, 94% [CI: 0.88, 0.97] for those of some concerns and 97% [CI: 0.94, 0.99] for those of high risk.

A sensitivity analysis was performed in both groups to assess the influence of each individual study on the overall effect size of each meta-analysis. In total, two studies were shown to influence the overall results due to high heterogeneity found between included studies. This was expected as, in the case of Araujo et al. (79), is the only randomized controlled trial conducted in a school setting with no access to dental facilities compared to the rest of the studies (n=10) which all were conducted in a primary care setting with available equipment and clinical environment. Unlike the other retrospective cohorts (n=10) that were designed under a scientific outline, the Innes et al. (66) study is the first retrospective study to report Hall Technique survival data collected from the records of a general practitioner's private practice on treatments performed over a 13-year period.

In the subgroup analysis of the randomized clinical trial studies, a pooled success rate of 97% [CI: 0.94, 0.98] was found for studies with follow-up ≤ 18 months and a significant lower rate of 91% [CI: 0.87, 0.93] for studies with follow-up ≥ 18 months. This can be explained by the time interval for the crown survival assessment between groups, being a maximum of 1.5 years for the first group and twice as long (3 years) for the other, added to the exposure of factors such as lesion depth, cavity size, crown adaptation problems, luting cement used and even patients' habits, quadrupling the number of failures in the group with longer follow-up time. Although these differences in survival were found, Hall Technique continue to outperform other restorative treatments, as no plastic restorative material is able to surpass the reported annual success rates (9,103).

This technique has been shown to be a very effective long-lasting restoration, and in our study, success rates varied minimally depending on the work setting, being 89% [CI 0.84, 0.93] in public settings, 94% [CI 0.80, 0.99] in private settings and 96% [CI 0.86, 1.00] in academic and medical settings. This can be interpreted as the

possibility of implementing this technique in different settings, significantly extending the reach of dental care to more children.

Lastly, the certainty of evidence of the included studies was considered low for randomized studies and moderate for non-randomized studies of intervention. The reasons for downgrading in the case of randomized trials were mainly due to bias issues, such as lack of information on allocation concealment (bias arising from the randomization process), the impossibility of blinding in most studies (bias due to deviations from the intended interventions), having the same therapist as the outcome assessor (bias in outcome measurement), and lack of a registered protocol providing a pre-specified analysis plan (bias in the selection of the reported outcome). Although the indirectness was considered not serious, we should emphasize that the treatments were delivered in different settings, yet under same treatment protocol, which may imply differences in the effect estimates.

It was perceived in the NRSIs that the information in the studies on the analysis was limited, the treatments were performed at different times (bias in the selection of study participants), there was a high number of dropouts, and even a high difference of patients excluded in the analysis between the groups (bias due to lack of data), in the case of blinding either the information was not reported or was reported as not possible (bias in the measurement of the results). Besides, a considerable heterogeneity between studies pointing to problems with inconsistency.

Our study has some limitations. First, we planned to perform a meta-regression to assess whether there was an association with HT success; however, the studies did not report the necessary data, which made the analysis not feasible. On the other hand, it was impossible for us to perform an assessment with a common time point across studies because the primary studies did not report an exact time point in the reported survival rate; the time points were highly variable.

Our results showed that the overall success rate of the Hall Technique is higher than 95% over a follow-up period of 1 to 89 months. The available evidence (27,28,30,31) corroborates that HT outperforms any other type of restorative treatment in terms of failure, retreatment, pain and discomfort in the long term. Moreover, this minimally intervention strategy, which arrests the caries lesion, preserves the dentin-pulp complex undamaged and protects the tooth structure until exfoliation, is the most cost-effective option (24–26,104). However, despite this undeniable fact, the technique

is not widely used and it is therefore important to understand the reasons behind its' implementation.

It has been observed that dentists prefer not to use this treatment in their daily practice due to the perceived complexity of the technique (105), lack of confidence in the placement of the crowns (106), not considering HT as an effective treatment to restore deciduous molars (107) and complete lack of knowledge or preparation to implement the technique, as well as lack of access to the appropriate material (108) as barriers for using HT. These information highlights the urgent need to promote and encourage the understanding how we could overcome the barriers and facilitate the use of this technique. It is necessary to provide continuing education programs and establish clinical policies to overcome the lack of knowledge and clinical experience for the dental community, allowing prompt, painless and effective treatment of caries in children and improving the quality of health care.

7 CONCLUSIONS

The present review found a high survival rate in both types of interventional studies (RCTs and NRSIs).

The primary studies had a moderate to high risk of bias and demonstrated moderate to low certainty of evidence.

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APPENDIX A – Search strategy used for all databases adapted from the Medline/PubMed main search strategy

Database	Search query: November/2022
PubMed/Medline	(("tooth, deciduous"[MeSH Terms] OR “deciduous dentition”[Text Word] OR “deciduous teeth”[Text Word] OR “baby teeth”[Text Word] OR “primary molar”[Text Word] OR “deciduous molar”[Text Word] OR “primary teeth”[Text Word] OR “ primary tooth” [Text Word]) AND (“preformed metal crown”[Text Word] OR “stainless steel crown” [Text Word] OR “metal crown”[Text Word] OR “hall technique” [Text Word]) AND (longevity[MeSH Terms] OR survival[Text Word] OR success[Text Word] OR effectiveness OR efficacy))
Embase	('tooth, deciduous'/exp OR 'tooth, deciduous' OR 'deciduous dentition'/exp OR 'deciduous dentition' OR 'deciduous teeth'/exp OR 'deciduous teeth' OR 'baby teeth'/exp OR 'baby teeth' OR 'primary molar' OR 'deciduous molar' OR 'primary teeth'/exp OR 'primary teeth' OR 'primary tooth'/exp OR 'primary tooth') AND ('preformed metal crown' OR 'stainless steel crown'/exp OR 'stainless steel crown' OR 'metal crown' OR 'hall technique') AND ('longevity'/exp OR longevity OR 'survival'/exp OR survival OR 'success'/exp OR success OR effectiveness OR 'efficacy'/exp OR efficacy)
Scopus	(TITLE-ABS-KEY ("tooth, deciduous" OR "deciduous dentition" OR "deciduous teeth" OR "baby teeth" OR "primary molar" OR "deciduous molar" OR "primary teeth" OR " primary tooth")) AND (TITLE-ABS-KEY ("preformed metal crown" OR "stainless steel crown" OR "metal crown" OR "hall technique")) AND (TITLE-ABS-KEY (longevity OR survival OR success OR effectiveness OR efficacy))
Web of Science (all databases, all collections)	TS= (tooth, deciduous OR deciduous dentition OR deciduous teeth OR baby teeth OR primary molar OR deciduous molar OR primary teeth OR primary tooth) AND TS=(preformed metal crown OR stainless steel crown OR metal crown OR hall technique) AND TS=(longevity OR survival OR success OR effectiveness OR efficacy)
Livivo	("tooth, deciduous" OR “deciduous dentition” OR “deciduous teeth” OR “baby teeth” OR “primary molar” OR “deciduous molar” OR “primary teeth” OR “ primary tooth”) AND (“preformed metal crown” OR “stainless steel crown” OR “metal crown” OR “hall technique”) AND (longevity OR survival OR success OR effectiveness OR efficacy)
ProQuest	noft("tooth, deciduous" OR “deciduous dentition” OR “deciduous teeth” OR “baby teeth” OR “primary molar” OR “deciduous molar” OR “primary teeth” OR “ primary tooth”) AND noft(“preformed metal crown” OR “stainless steel crown” OR “metal crown” OR “hall technique”) AND noft(longevity OR survival OR success OR effectiveness OR efficacy)

APPENDIX B - Detailed information on the attempt to contact the authors to request missing or unclear information

Study	Authors' contact attempt	Reply obtained	Information obtained
Arrow et al. 2020	Email sent according to established terms	Answered	Number of children who received HT; PMC manufacturer; GIC manufacturer; Success and failure criteria; Hall Crowns applied; Crown failure; Participants' gender
Ayedun et al. 2021	Email sent according to established terms	Answered	Trial registration; Operators number & training; Participants' gender.
Bhatia et al. 2019	Email sent according to established terms	Not Answered	Unavailable
Clark et al. 2017	Email sent according to established terms	Answered	No available information on the research
Ebrahimi et al. 2020	Email sent according to established terms	Answered	Trials Registration; Operators information; Success and failure criteria; PMC manufacturer; GIC manufacturer; Funding
Elamin et al. 2019	Email sent according to established terms	Not Answered	Unavailable
Kaptan et al. 2021	Email sent according to established terms	Not Answered	Unavailable
Kezawie et al. 2021	Email sent according to established terms	Answered	Participants' gender; Conflict of interest; Funding; Allocation concealment; Operator qualification; Trial Registration
Sapountzis et al. 2021	Email sent according to established terms	Not Answered	Unavailable
Wang et al. 2018	Email sent according to established terms	Not Answered	Unavailable

ANNEX A – PRISMA checklist

Section and Topic	Item #	Checklist item	Location whereitem is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	13 / 15
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	23 – 27
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	29
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	32 – 33
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	32
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	32 / 83
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	32
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	33 – 34
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	33 – 34
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	33 – 34
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	34 – 35

To be continued

continuation

Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	35
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	35
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	35
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	35
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	35
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	35
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	35
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	34 – 35
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	35 – 36
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	39
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	41/44
Study characteristics	17	Cite each included study and present its characteristics.	41
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	45 - 48
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	49 - 50
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	48
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	51 - 62
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	52 / 54 / 57 / 60
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	52 – 53 / 58

To be continued

conclusion

Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	45 - 48
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	62 - 63
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	65 - 68
	23b	Discuss any limitations of the evidence included in the review.	65 - 68
	23c	Discuss any limitations of the review processes used.	65 - 68
	23d	Discuss implications of the results for practice, policy, and future research.	65 - 68
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	31
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	31
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	31
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

ANNEX B – PROSPERO registration record

NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Survival of preformed metal crowns using hall technique approach for restoring primary molars - systematic review and meta-analysis

Daniela Raggio, Claudia López, Gabriela Seabra da Silva, Tamara Tedesco, Thais Gimenez, Mariana M Braga, Mariana P Araújo, Nicola P T Innes, Jayakumar Jayaraman

Citation

Daniela Raggio, Claudia López, Gabriela Seabra da Silva, Tamara Tedesco, Thais Gimenez, Mariana M Braga, Mariana P Araújo, Nicola P T Innes, Jayakumar Jayaraman. Survival of preformed metal crowns using hall technique approach for restoring primary molars - systematic review and meta-analysis. PROSPERO 2021 CRD42021204415 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021204415

Review question

The aim of this systematic review and meta-analysis will be to address the survival of preformed metal crowns on deciduous molars using the Hall technique

Searches

A literature search will be performed through the PubMed/MEDLINE, EMBASE, Scopus, Web of Science and Livivo databases to identify relevant published articles that assessed the survival of preformed metal crowns using the Hall technique.

Furthermore, the grey literature (OpenSigle/Opengrey) will be examined to identify potentially eligible studies that may meet the inclusion criteria, in order to verify all relevant elements not identified during the database searches.

There will also be a hand search of the reference list of selected studies and other systematic reviews on the topic to retrieve possible eligible documents that may be omitted during the database search.

No restrictions will be placed on language or year of publication.

Types of study to be included

We will include randomized clinical trials and/or prospective/retrospective non-randomized studies to assess the survival of preformed metal crowns using Hall technique on deciduous molars.

Condition or domain being studied

The high prevalence of dental caries and inadequate treatment of caries lesions in primary teeth are major global public health problems. By the time children reach school age, both the cost of dental treatment and the high prevalence of caries lesions raise concerns about efficient prevention and successful restorative treatment of caries lesions

Participants/population

Inclusion criteria: Children with decayed dentin-level cavities in primary molars that were deemed to be in need of being restored (i.e. cavitated or non-cavitated carious lesions extending into dentine and affecting at least one occlusal/proximal surface), and in which pre-formed metal crowns were placed following Hall technique's approach for their treatment.

Exclusion criteria: Children without good general health, with a history of pulp involvement, periapical lesions or non-physiological mobility associated to the decayed primary molar to be treated, whose deciduous molars have received a preformed metal crown following the Hall Technique and do not have any type of survival information recorded, and those who have not had at least 12 months of post-treatment follow-up.

Intervention(s), exposure(s)

Preformed metal crowns using the Hall technique approach

Comparator(s)/control

Any other direct restorative treatment in primary molars (Atraumatic Restorative Treatment - ART, Glass ionomer cement, composite resin, amalgam, compomer).

Main outcome(s)

Survival of preformed metal crowns using Hall technique

* Measures of effect

Cumulative survival rate (Proportion and 95%CI)

Additional outcome(s)

Associated factors with the survival rate

* Measures of effect

Proportion and 95%CI

Data extraction (selection and coding)

In order to retrieve all relevant papers, two reviewers will screen the reference lists of included papers and related reviews. The same reviewers will independently assess the identified publications and will select studies for inclusion by title and abstracts based on the inclusion criteria. Any discrepancies in opinion will be resolved by a third reviewer. The same two reviewers will independently collect the data from eligible studies.

In order to carry out the qualitative analysis the following data will be collected: publication details (author and year), sample characteristics (country where the study was carried out, age of the participants, tooth type, number and surfaces involved, number and location of the metal crowns, the brand of the preformed metal crown, the type/brand of the GIC used, comparator group, setting), study methodology (design of the study, number and characteristics of the operators such as training and calibration), outcome data (follow up, dropout percentage and how the dropout was handled, criteria or index to evaluate the survival, and how the survival analysis was performed, survival rate).

Risk of bias (quality) assessment

The bias risk assessment will be performed through specific bias risk assessment forms related to the study design (Cochrane Handbook for Systematic Reviews of Interventions version 6.0). Bias risk assessment for randomised controlled trials will be performed using the Cochrane risk of bias tool for randomised trials (RoB tool); and for non-randomised trials, bias risk assessment will be performed using the Cochrane risk of bias tool for non-randomised studies - of Interventions (ROBINS-I tool).

Strategy for data synthesis

Data synthesis from the studies will be performed by two independent researchers (CLG and GSS), and discrepancies at any stage will be solved by consensus among the examiners, and a joint discussion will be held with a third examiner (DPR), considered an expert in the field. The statistical analysis will be performed by two researchers (TG, TKT).

All analysis will be performed using R packages “meta and metaphor”, version 3.6.1 (R Core Team, 2012, Vienna, AUT).

The characteristics of each study will be collected in a Microsoft Excel spreadsheet prepared specifically for this purpose. Initially, the narrative synthesis (qualitative synthesis) of the findings will be structured around the population studied (children with dentin-level cavities in deciduous molars), the intervention (pre-formed metal crowns using the Hall Technique) and the characteristics of the outcome (survival).

If sufficient trials are available and their populations and outcome measures are clinically similar for performing a quantitative synthesis, meta-analysis will be conducted using fixed or random-effects models, depending on heterogeneity results.

The following effect measures will be used: A single-arm (proportion) meta-analysis will be performed with

the cumulative survival rate and 95% CI.

The presence of heterogeneity will be evaluated according to the section 10-10 of the Cochrane Handbook for Systematic Reviews of Interventions 60 (Deeks J, Higgins J, 2019), by the ?² test (Q test). A P-value lower than 0.10 suggests heterogeneity. Values of I² will be classified as follows: no relevant heterogeneity (0% to 40%), moderate heterogeneity (30% to 60%), substantial heterogeneity (50% to 90%) and considerable heterogeneity (75% to 100%). If significant heterogeneity is found among the studies, we will explore the sources of heterogeneity using subgroup analysis and meta-regression.

The methodological quality will not be used for inclusion or exclusion in the meta-analysis, it will only be a qualitative analysis to guide future research.

Analysis of subgroups or subsets

Depending on the outcome of heterogeneity among studies, a subgroup analysis will be performed to identify factors associated with the survival of preformed metal crowns using the Hall technique, and if high heterogeneity exists among studies a meta-regression will be performed to analyze the impact of covariates on the outcome of the meta-analysis.

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Type and method of review

Intervention, Meta-analysis, Systematic review

Anticipated or actual start date

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Anticipated completion date

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Conflicts of interest

Language

English

Country

Brazil

Stage of review

Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Humans; Metals; Molar; Tooth, Deciduous

Date of registration in PROSPERO
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14 August 2020

Details of any existing review of the same topic by the same authors
Innes NPT, Ricketts D, Chong LY, Keightley AJ, Lamont T, Santamaria RM.

Preformed crowns for decayed primary molar teeth.

Cochrane Database Syst Rev. 2015.

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions
13 January 2021

PROSPERO
This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. The registrant confirms that the information supplied for this submission is accurate and complete. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.