INPLASY

Efficacy of the Hall technique versus conventional restorations for managing carious primary molars in children: a meta-analysis

INPLASY202680053
doi: 10.37766/inplasy2026.8.0053
Received: 13 August 2026
Published: 13 August 2026

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ADMINISTRATIVE INFORMATION

Support - This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202680053

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 August 2026 and was last updated on 13 August 2026.

INTRODUCTION

Review question / Objective To compare success, major and minor failure rates of HT and CR for carious primary molars in children ≤12 years old.

Condition being studied Dental caries in primary molars is one of the most prevalent chronic diseases in childhood, affecting approximately 532 million children globally. Untreated carious lesions in primary molars can cause localised pain, compromised chewing ability, and may adversely affect the eruption of permanent successors, normal jaw development, and long-term oral health–related quality of life. In young children, extensive or multisurface caries in primary molars poses particular challenges for restorative management, as conventional treatments often require local anaesthesia and high-speed drilling, which induce anxiety and fear, while also exhibiting suboptimal long-term success rates with increasing failure over time.

METHODS

Participant or population Children aged ≤12 years diagnosed with cavitated caries in primary molars requiring restorative treatment. Patients with systemic diseases, autism, bleeding disorders or special oral healthcare needs were excluded.

Intervention The experimental group received the Hall technique (HT), defined as cementation of a preformed metal crown directly onto a carious primary molar without local anaesthesia, tooth preparation or mechanical caries removal. Interventions involving modified Hall protocols or combined auxiliary treatments (fluoride, atraumatic restorative treatment) were excluded.

Comparator The control group received conventional restorations (CR), including composite resins, glass ionomer cement, compomers and amalgams. Studies involving

conventional stainless-steel crowns, silver diamine fluoride or no treatment control were excluded.

Study designs to be included Parallel-group randomised controlled trials (RCTs), regardless of blinding or allocation concealment, published in English or Chinese. Studies involving retrospective cohorts, case series, cross-sectional studies or noncomparative trials were excluded.

Eligibility criteria Additional inclusion and exclusion criteria not defined in the PICOS sections include:

Studies must clearly report at least one predefined endpoint: composite clinical success rate, major failure rate and minor failure rate, with standardised diagnostic definitions provided in the original manuscripts.

Duplicate publications were excluded (studies with the longest follow-up were retained).

Manuscripts with unextractable incomplete outcome data were excluded.

Overlapping patient cohorts reported across multiple articles were excluded; for studies reporting identical patient populations, the version with the longest follow-up duration or the most comprehensive data was prioritised.

The search was limited to English- and Chinese-language publications, with no other restrictions applied.

Information sources Systematic searches were conducted on 1 March 2026 across the following six electronic databases: PubMed, Web of Science, Cochrane Library, Embase, Scopus and China National Knowledge Infrastructure (CNKI), covering the period from database inception to 1 March 2026. The search was limited to English- and Chinese-language publications, with no other restrictions applied. No additional records were retrieved via reference list tracking.

Main outcome(s) The primary outcome is composite clinical success rate, defined using composite criteria (e.g. restoration intact, absence of pain and pulpal symptoms, no radiographic pathology). The effect measure is odds ratio (OR) with 95% confidence interval (CI), pooled using a random-effects model. Outcome data were extracted at various follow-up durations reported in the original trials, ranging from 12 to 60 months. For subgroup analysis, follow-up intervals were standardised into three nonoverlapping categories: ≤12 months, 13 to <36 months, and ≥36 months. Heterogeneity was assessed using the Q test and I^2 statistic.

Quality assessment / Risk of bias analysis The methodological quality of the 13 included RCTs was assessed using the Cochrane RoB 1.0 seven-domain tool, visualised in the traffic-light summary plot (Figure 2). Most trials exhibited low risk of selection and detection bias, with scattered unclear risk judgements in blinding of clinical staff and allocation concealment; no manuscript presented uniformly high risk across all evaluation domains, indicating acceptable overall methodological quality of the pooled trial cohort.

Strategy of data synthesis Meta-analysis was performed using Stata software (version 17.0). The odds ratio (OR) with its 95% confidence interval (CI) was selected as the pooled binary effect measure. A random-effects model was used for all pooled analyses.

Heterogeneity assessment: Heterogeneity across studies was assessed using the Q test and I^2 statistic. Stratified I^2 thresholds were adopted for categorisation: I^2 75% = high heterogeneity.

Subgroup analysis: Subgroup analysis was exclusively conducted for clinical success rate (≥10 included studies) with standardised, nonoverlapping follow-up intervals defined as ≤12 months, 13 to <36 months and ≥36 months. For major and minor failure rates (only seven eligible studies each), subgroup analysis was not performed due to insufficient statistical power.

Sensitivity analysis: Sensitivity analysis adopted the leave-one-out sequential removal method to test the stability of pooled OR values.

Publication bias assessment: Publication bias assessment combined two approaches: (1) visual qualitative inspection of funnel plots and (2) quantitative Egger's linear regression test for the clinical success outcome (13 trials, sufficient sample size for formal testing). For major/minor failure endpoints (7 trials each), Egger's test was deemed statistically underpowered and therefore omitted.

All forest plots were ordered alphabetically by first author within each subgroup for consistent readability. A two-tailed significance level of $\alpha = 0.05$ was adopted for all statistical tests.

Subgroup analysis Subgroup analysis was exclusively conducted for the clinical success rate

outcome (≥10 included studies), with standardised, nonoverlapping follow-up intervals defined as follows:

≤12 months follow-up

13 to <36 months follow-up

≥36 months follow-up

These standardised intervals were used to eliminate ambiguous grouping of trials with exactly 36 months of follow-up. For major failure rate and minor failure rate (only seven eligible studies each), subgroup analysis was not performed due to insufficient statistical power.

Additional subgroup analyses that could not be performed:

Original trial data lacked uniform stratified reporting by child age, gender, geographic region or caries lesion surface count (single vs multisurface). Consequently, supplementary subgroup analyses for these modifiers could not be conducted, resulting in residual confounding of the pooled effect estimates. Subgroup stratification by filling material (composites, GIC, compomers, amalgams) was also not feasible due to insufficient trial numbers per material subgroup.

Sensitivity analysis Sensitivity analysis adopted the leave-one-out sequential removal method to test the stability of pooled odds ratio (OR) values. This method involves sequentially excluding each individual trial from the meta-analysis and recalculating the pooled effect estimate to determine whether any single study disproportionately influences the overall result.

Results of sensitivity analyses:

Clinical success rate: Sequential exclusion of individual trials yielded pooled OR values ranging from 5.11 to 6.87, with no single trial capable of reversing the overall significant treatment effect, thereby verifying the robustness of the primary outcome results (Supplementary Figure 2).

Major failure rate: After excluding any single trial, the pooled major failure OR fluctuated between 0.09 and 0.18, with all 95% CIs consistently below 1.0, confirming the stability of the protective effect of HT against severe treatment failure (Supplementary Figure 3).

Minor failure rate: Sequential leave-one-out sensitivity testing produced pooled OR values ranging from 0.10 to 0.17 upon single-trial removal; all pooled effect estimates remained statistically significant, indicating high robustness of secondary minor failure outcomes (Supplementary Figure 4).

Country(ies) involved China.

Keywords Deciduous teeth; paediatric dentistry; stainless steel crown; dental caries/therapy.

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