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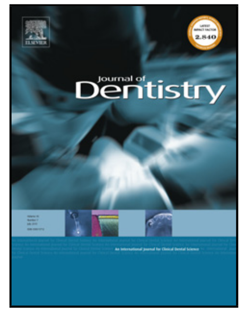

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Cost-effectiveness of managing cavitated primary molar caries lesions: A randomized trial in Germany

Short title: Cost-effectiveness of caries management

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Abstract

Objectives: The Hall Technique (HT), Non-Restorative Cavity Control (NRCC) and conventional carious tissue removal and restoration (CR) are strategies for managing cavitated caries lesions in primary molars. A randomized controlled three-arm parallel group trial in a university clinic in Germany was used to measure the cost-effectiveness of these strategies.

Methods: 142 children (HT: 40; NRCC: 44; CR: 58) were followed over a mean 2.5 years. A German healthcare perspective was chosen. The primary outcome was estimated molar survival; secondary outcomes were not needing extraction, not having pain or needing endodontic treatment/extraction, or not needing any re-intervention at all. Initial, maintenance and endodontic/restorative/extraction re-treatment costs were derived from fee items of the statutory insurance. Cumulative cost-effectiveness and cost-effectiveness acceptability were estimated from bootstrapped samples.

Results: HT molars survived longer (estimated mean; 95% CI: 29.7; 26.6-30.5 months) than NRCC (25.3; 21.2-28.7 months) and CR molars (24.1; 22.0-26.2 months). HT was also less costly (66; 62-71 Euro) than NRCC (296; 274-318 Euro) and CR (83; 73-92 Euro). HT was more cost-effective than NRCC and CR in >96% of samples, and had acceptable cost-effectiveness regardless of a payer's willingness-to-pay. This superior cost-effectiveness was confirmed for secondary health outcomes. Cost-advantages were even more pronounced when costs were calculated per year of tooth retention (mean annual costs were HT: 29, NRCC: 154, CR: 61 Euro).

Conclusions: HT was more cost-effective than CR or NRCC for managing cavitated caries lesions in primary molars, yielding better dental health outcomes at lower costs.

Clinical significance: If choosing between these three strategies for managing cavitated caries lesions in primary molars, dentists should prefer HT over NRCC or CR. This would also save costs for the healthcare payer.

Keywords: caries; dental; effectiveness; health economics; pediatric dentistry; primary teeth; restorative dentistry

Introduction

For managing cavitated carious lesions in primary molars, numerous strategies are available. Conventional, i.e. non-selective carious tissue removal, and restoration (CR) of the cavity using amalgam, glass ionomer cement, resin composite or polyacrylic acid-modified composites used to be the standard treatment [1], although associated with high risk of pulpal complications and restoration failure [2]. If instead, selective carious tissue removal is performed, with some carious tissue being left over the pulp to avoid pulp exposure, success is improved, whilst similar restoration techniques result still in limited survival [3]. The Hall Technique (HT) has been established as an alternative management option, with lower associated risks of pulpal and restorative complications. For HT, carious tissue is sealed within the cavity beneath a stainless-steel crown, without any tissue removal or tooth preparation, preceded only by tooth separation using orthodontic separators, where required, to allow the crown to be fitted where the teeth approximate closely. The sealed bacteria are deprived of carbohydrate and diet; the lesion is inactivated [4-6]. Non-Restorative Cavity Control (NRCC) involves controlling the activity of the lesion by removing overhanging enamel and dentin if needed, followed by repeated and regular biofilm removal and fluoride application [7]. NRCC requires high adherence of patients and/or parents to continuously manage the lesion [8].

Evidence from randomized control trials supports the use of HT over CR for managing cavitated carious lesions in primary molars [6]. A recent randomized trial in Germany [9, 10] compared all three strategies, and found HT to be superior to avoid both major complications (tooth removal, pulpotomy etc.) and minor complications (restoration renewal or repair etc.). There is, so far, no data on the cost-effectiveness of these strategies.

Cost-effectiveness depends on the initial treatment costs, but also costs occurring during follow-up for regular “maintenance” (as for NRCC, where regular re-instruction and re-fluoridation are performed in a dental practice) and costs for re-treatments (required to remedy complications, and including re-restoration, endodontic treatment, i.e. mainly pulpotomy for primary teeth, or tooth removal). Cost-effectiveness also reflects effectiveness, for example measured as tooth survival, avoided pain or avoided complications and re-treatments. In the present study, we compared the cost-effectiveness of HT, NRCC and CR for managing cavitated carious lesions in primary molars based on data from a randomized controlled trial.

Materials and Methods

Reporting of this study follows the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [11]. The trial had been registered (No. NCT01797458) and ethically approved (Research Ethics Committee of Greifswald University/Germany, BB 39/11). Note that this economic evaluation had not been explicitly planned a priori.

Target population and subgroups

The target population were children aged 3–8 years with at least one cavitated occlusal-proximal caries lesion (ICDAS 3-5) in a primary molar, who attend the Department for Preventive and Paediatric Dentistry of Greifswald University. Molars presenting with clinical or radiographic signs or symptoms of pulpal or periradicular pathology (including pain) were not included. Subgroups of child's gender, age, and treated tooth were accounted for during analysis.

Setting and location

Analyses were performed in the context of the German healthcare system. Whilst treatments were provided in secondary (university) care, reimbursement and costs are identical to the primary care settings based on fee items of German item catalogues.

Comparators and horizon

Two alternative caries management approaches, NRCC and the HT were compared against conventional restorations (CR). The null hypothesis was no difference in the primary outcome parameter "success" (absence of minor or major failures, including secondary caries, lesion progression, loss of restoration, reversible pulpitis, irreversible pulpitis, need for extraction) at 2.5 years among any of the three arms. Participants were assigned to one of the arms using a computer-generated random number list with allocation. Only one molar per child was included in the study. Further study methodology details have been reported [9, 10]. Overall, 169 children (mean; SD age 5.6; 1.5 years) participated in the trial. However, only 142 children (HT= 40/52, NRCC = 44/52, and CR = 58/65) of the 169 baseline participants had data for the last follow-up (mean, SD follow-up time was 26.0; 11.2 months).

The horizon of the present analysis was this follow-up period. As imbalanced drop-out during follow-up may impact on survival, we used Kaplan Meier estimates to evaluate our primary outcome, survival time, accounting for censoring. Note, however, that these estimates are only valid within the follow-up period; the true survival time may be longer.

Follow-up examinations were performed by two trained examiners (----deleted for review purpose----). Children in the HT and CR arms were recalled twice per year, while those in the NRCC arm were asked to attend once every three months to assess lesion's status, to reinforce oral hygiene, and if needed to assist the caries arrest process including fluoride varnish application.

Currency, price date and discount rate

Costs were calculated in Euro 2017. Future costs (i.e. those experienced during follow-up) were discounted at 3% per annum [12]. Discounting accounts for the lost opportunities when spending money now instead of later on.

Health outcomes and effectiveness

Our primary outcome was survival time of molars, i.e. the time until molars needed extraction. Exfoliated molars were assumed to be censored (survived). Our secondary outcomes were (1) the proportion of survived per all treated molars, (2) the proportion of molars not causing pain, needing endodontic or surgical (extraction) treatment during follow-up, and (3) the proportion of molars not needing any kind of re-intervention (note that for NRCC, re-instruction and re-fluoridation were assumed to be planned part of the initial therapy and not counted here).

Estimation of costs

A mixed public-private-payer's perspective was chosen. Dental treatments in Germany are largely reimbursed by the statutory insurance, with the majority of German patients (89%) being enrollees [13]. For these, most costs, especially in pediatric dentistry, are covered by the statutory insurance, and only very few costs are covered either by the patient or his private additional insurance.

Dental treatment costs within the statutory insurance are estimated using the statutory fee item catalogue, Bewertungsmaßstab (BEMA), or Gebührenordnung für Ärzte (GOÄ). GOÄ costs are related to BEMA, as described in the appendix, where details on the cost calculation are provided. Given that travelling times or times off school (or, for accompanying parents, off work) were not recorded, we could not account for opportunity costs. All costs were calculated per molar and, with only one molar treated per child, patient.

Analytical methods

Bootstrapping was performed to construct a sampling distribution of mean costs and effectiveness. Kaplan-Meier estimates for mean (95% CI) survival times of different strategies were generated and bootstrapped. In addition, mean (95% CI) proportions of teeth not experiencing extraction, not having pain or requiring endodontic/surgical therapy, and not experiencing any complications were estimated. Mean (95% CI) cumulative total costs and subdivided endodontic/extraction and restorative costs were estimated.

Costs and effectiveness were used to construct a cost-effectiveness plane to depict cost-effectiveness. Strategies were ranked according to their costs, and more expensive strategies compared with less expensive ones using incremental-cost-effectiveness ratios (ICER). ICERs express the cost difference per gained or lost effectiveness; positive ICERs indicate additional costs per additional effectiveness, while negative ICERs indicate additional costs per effectiveness loss. Strategies which were costlier and less effective (i.e. with a negative ICER) were dominated, strategies which were more costly but also more effective were undominated.

Using estimates for costs (c, in Euro) and effectiveness (e, in years), the net benefit of each strategy combination was calculated using the formula

$$\text{net benefit} = \lambda \times \Delta e - \Delta c,$$

with λ denoting the ceiling threshold of willingness to pay, i.e. the additional costs a decision maker is willing to bear for gaining an additional unit of effectiveness [14]. If $\lambda > \Delta c/\Delta e$, an alternative intervention is considered more cost-effective than the comparator despite possibly being more costly [15]. We used the net-benefit approach to calculate the probability of a strategy being cost-effective for payers with different willingness-to-pay ceiling thresholds.

In addition to exploring cost-effectiveness with different cost components and effectiveness outcomes, a sensitivity analyses was performed, where we varied the costs of NRCC, assuming the reinstruction costs to be distributed among all present teeth. Additionally, cumulative costs were submitted to a multivariable statistical analysis via Generalized Linear Models to jointly assess possible predictors of costs. Statistical analysis was performed using SPSS 22 (IBM, Armonk, USA) and open source Python (Python Software Foundation 2017) libraries, such as NumPy, pandas, lifelines, and Matplotlib.

Results

HT molars survived longer (estimated mean; 95% CI: 29.7; 26.6-30.5 months) than NRCC (25.3; 21.2-28.7 months) and CR molars (24.1; 22.0-26.2 months). Given the low number of events, the proportion of molars not lost and not experiencing pain or requiring endodontic/extraction treatment was not significantly different between groups. HT showed significantly fewer re-interventions than NRCC and CR (Table 1).

Overall, HT was also less costly (66; 62-71 Euro) than NRCC (296; 274-318 Euro) and CR (83; 73-92 Euro). Initial costs were similar for HT and CR, while NRCC showed lower initial costs (first visit); however, these costs occurred regularly during follow-up for NRCC (increasing cumulative costs). Restorative re-treatment costs were also significantly lower in HT than alternatives, while costs for endodontic/extraction re-treatment were not significantly different (Table 1). The cost-advantage of HT was even lower when accounting for the longer follow-up by annualizing them, with HT generating a mean of 29 Euro per year, while NRCC (154 Euro per year) and CR (61 Euro per year) were more costly.

HT was more cost-effective than NRCC and CR in >96% simulations (Fig. 1), and had acceptable cost-effectiveness regardless of a payer's willingness-to-pay (Fig. 2). This superior cost-effectiveness was confirmed for secondary health outcomes, too (Table 2). It also held when assuming that NRCC generated lower costs during repeated reinstruction and re-fluoridation visits (NRCC had mean cumulative costs of 135 Euro, i.e. remained far more expensive than HT and CR, without higher effectiveness). Also, when accounting for possible confounding by age, dental arch, molar and follow-up period, costs remained significantly lower in HT than NRCC and CR (p=0.039; Table 3).

Discussion

Where prevention has failed, strategies for managing carious lesions in children are important to avoid pain and infection and increase the survival rate of affected teeth [1]. This reduces the risk of medical complications associated with dental caries [16], loss of time at school, loss of arch space associated with early tooth extraction and number of reparative interventions and associated treatment induced anxiety. Traditional restorative dental care involving non-selective carious tissue removal and fillings is the most common approach for treating cavitated carious lesions in primary teeth. However, this standard approach to managing lesions has limited effectiveness in controlling the disease process. Growing evidence suggests that alternative, less invasive approaches like HT or the NRCC might be effective for managing carious lesions in primary teeth [6, 8].

In order to see the economic benefit of these approaches, we performed a cost-effectiveness analysis on an existing randomised control trial, which compared the relative costs and clinical outcomes of these three different approaches (HT, NRCC, CR) for managing cavitated carious primary molars. The main finding of our analyses was that molars treated with HT survived longer (nearly no teeth were lost during the trial) and required significantly fewer re-interventions than NRCC and CR. Consequently, HT was less costly than the other two interventions, despite having the highest initial treatment costs.

A number of clinical aspects are relevant. For the NRCC, there is not a standardized frequency of follow-up appointments. In this study participants were invited to attend 3-monthly recalls. It is obvious that the "initial" treatment costs of NRCC, therefore, occur regularly during follow-up. The cumulative impact of these costs was substantial, with NRCC being the most expensive intervention in this trial, however without superior effectiveness. Costs may be much lower if NRCC follow-up was to be provided in kindergartens or schools, or by dental therapists or other, less costly providers. This is notable, as cost-effectiveness for dental interventions may be very different when provided in surgery versus in other settings [17]. However, even if we halved the regular costs (by assuming re-instruction costs to be divided among all present teeth), this did not improve its cost-effectiveness ranking. It seems that the lower effectiveness of NRCC is a strong influence and detrimental to its cost-effectiveness.

Also, we sub-divided different costs, e.g. for endodontic/extraction and restorative treatments. We found that for both NRCC and HT, re-treatment costs were mainly restorative. For primary teeth, a restoration should ideally function until the tooth sheds naturally. Stainless steel crowns (SSCs) seem to be able to allow such long-term retention, and are recommended as restoration of choice for treating multiple-surface carious lesions in primary molars [1, 18]. HT combines this beneficial restoration type (reducing restorative complications) with the lower endodontic risks (by sealing the lesion instead of excavating it and hence avoiding pulp exposure). As avoiding (costly) re-treatments will be even more relevant over longer follow-up periods, we assume the overall cost-effectiveness of HT over the primary tooth life (until exfoliation) to be even higher. It can also be expected that the cost-effectiveness of HT would be even more pronounced if one accounts for opportunity cost (those generated by children being off school, or parents being off work for the time of the appointments), compared against both NRCC (which inherently has high opportunity costs, as repeated visits are needed) and CR (with high opportunity costs given the many restorative re-treatments being needed).

A number of methodological aspects should be discussed. First, we chose the German healthcare system as our healthcare perspective, using fee items to quantify treatment costs. This was justified, as these are the truly occurring costs to the payer (which was the statutory insurance). Second, the horizon of our study was the study's follow-up period, i.e. 2.5 years. A period of about 6 years seems more relevant if one wants to see the treated primary molars to exfoliate, i.e. to yield final success. However, our study horizon was sufficient to consider both initial and re-treatment costs into our estimates. Third, our study tried to account for the uncertainty in estimates (of costs and effectiveness) and heterogeneity (i.e. the impact of possible confounders on costs and cost-effectiveness). We found both aspects to have limited importance for cost-effectiveness. For example, HT was always most cost-effective, regardless of which outcome was chosen or which willingness-to-pay threshold was assumed. Also, no confounding variable was found to be associated with cumulative costs, only the treatment strategy was significantly decisive for costs. Last, our perspective was that of a payer. Within German healthcare, these pay based on fixed fee items. It is obvious that the costs for providers will be different and also less standardized, depending on setting-specific aspects (surgery costs, staff costs, material costs). Also, societal costs will differ: When accounting for indirect and opportunity costs (like travel or time costs, that is the monetary value of time spent at the dentist instead of at work for parents, for example), treatments which require fewer (and shorter) visits will be advantageous. HT needed fewer re-treatments, which would improve cost-effectiveness further. In practice, however, CR may be performed immediately (in the same visit as the examination), while HT may need a second visit, allowing tooth separation in the meantime. In this case, CR may be more advantageous (at least regarding initial indirect/opportunity costs). Further studies should aim to assess this in more detail.

This trial and the analysed data have some limitations. The study was performed in a secondary care setting, which limits the external validity of the findings. Nevertheless, NRCC and HT are technically simple procedures to perform in terms of clinicians' dexterous skills and can be easily trained (although the skills and success of clinicians being responsible for instigating behaviour change in their patients in more difficult to gauge). Furthermore, the German public insurance reimburses dentists for nearly all treatments performed on children, independently of the care setting and using identical fee items. The cost-effectiveness is likely to be similar in primary German healthcare. However, our findings cannot be transferred to other healthcare systems, where cost-estimates and treatment options are different. We also did not account for trial and implementation costs. However, these are likely to be limited, given HT and NRCC being easy to apply, without additional equipment or a great amount of training. Nevertheless, future studies should consider these costs.

In conclusion, and within the limitations of this trial and the conducted analyses, HT was more cost-effective than CR or NRCC for managing cavitated carious lesions in primary molars, yielding better health outcomes at lower costs. If choosing between these three strategies for managing cavitated caries lesions in primary molars, dentists should prefer HT over NRCC or CR. This would also save costs for the healthcare payer.

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Tables

Table 1: Effectiveness and costs of different treatment strategies. HT: Hall Technique, NRCC: Non-Restorative Cavity Control, CR: Conventional Restorative treatment. Different superscript letters indicate statistically significant differences.

Parameter	HT	NRCC	CR
Survival time (months)	29.7 (26.6-30.5) [a]	25.3 (21.2-28.7) [ab]	24.1 (22.0-26.2) [b]
Proportion survived (%)	98 (91-100) [a]	93 (84-100) [a]	95 (88-100) [a]
Proportion without pain or endodontic complications or extraction (%)	98 (91-100) [a]	90 (81-99) [a]	91 (85-97) [a]
Proportion without any re-interventions (%)	93 (84-100) [a]	70 (57-83) [b]	67 (55-79) [b]
Total cumulative costs (Euro)	66 (62-71) [a]	296 (274-318) [b]	83 (73-92) [c]
Initial costs (Euro)	62.70	33.64	61.65
Costs for restorative re-treatments (Euro)	3 (0-7) [a]	14 (6-21) [b]	17 (9-24) [b]
Costs for endodontic re-treatments/ extraction (Euro)	1 (0-2) [a]	8 (1-15) [a]	4 (0-9) [a]
Annual total costs (Euro)	29 (23-34) [a]	154 (139-169) [b]	61 (46-76) [c]

Table 2: Mean incremental cost-effectiveness ratios (ICER) for NRCC (Non-Restorative Cavity Control) and CR (conventional carious tissue removal and restoration) compared with HT (Hall Technique). In these analyses, (negative) ICERs represent additional costs (in Euro) per lost effectiveness (in months or %).

Outcome	Compared with HT	ICER
Survival time (months)	NRCC	-52
	CR	-3.0
Proportion survived (%)	NRCC	-38
	CR	-2.8
Proportion without pain or endodontic complications or extraction (%)	NRCC	-29
	CR	-2.4
Proportion without any re-interventions (%)	NRCC	-10
	CR	-1.1

Table 2: Association between patient- and tooth-level variables and costs. Multivariable generalized linear modelling was performed. Mean differences (95% CI) in Euro and level of significance (p-value) are given. Significant associations are highlighted in bold. N: number of teeth.

Parameter	**N**	**Mean difference (95% CI)**	**p-value**
Patients‘ age at initial treatment (years)	-	0 (-5/5)	0.940
Follow-up period (months)	-	1 (-1/2)	0.070
Gender			
female	58	2 (-14/17)	0.836
male	84	Ref.	
Jaw			
Maxilla	79	0 (-15/15)	0.977
Mandibular	63	Ref.	
Molar			
First	96	-1 (-17/16)	0.903
Second	46		
Treatment			
HT	40	**-21 (-41/-1)**	**0.039**
NRCC	44	**212 (194/230)**	
CR	58	**Ref.**	

NRCC: Non-Restorative Cavity Control; CR: conventional carious tissue removal and restoration; HT: Hall Technique

Figures

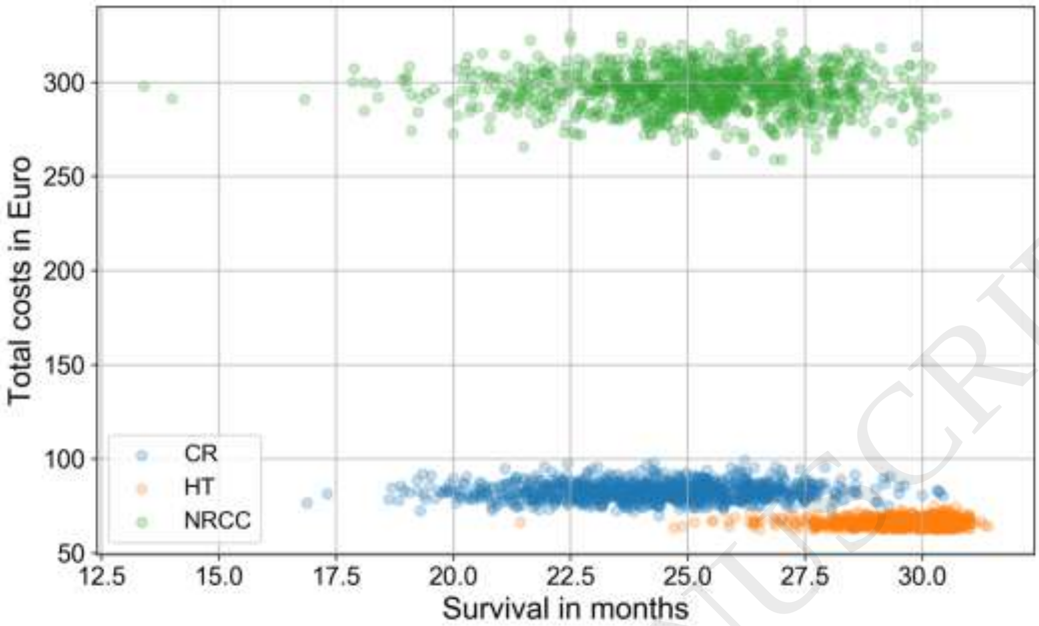

Figure 1: Cost-effectiveness plane. The costs (Euro) and effectiveness (survival in months) of the three strategies (HT: Hall Technique, orange; NRCC: Non-Restorative Cavity Control, green; CR: Conventional Restorative treatment, blue) were plotted based on bootstrapped sample estimates.

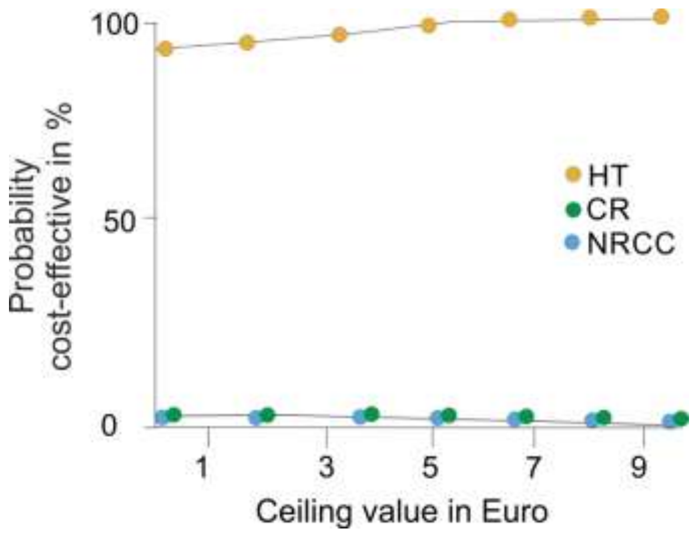

Figure 2: The cost-effectiveness acceptability curve indicates how with increasing willingness-to-pay, the probability of cost-effectiveness of different strategies increases. HT had the highest probability of being cost-effectiveness regardless of a hypothesized payer's willingness-to-pay threshold.

Appendix

For initial and re-treatments, costs were derived from fee items of the public health insurance item catalogue in Germany. This comprises dental and medical (for prescription) catalogue (BEMA and GOÄ), as described in the main text. BEMA and GOÄ use a point-based system to derive monetary fees. For BEMA, we used the 2017 point value of 1.045 Euro for all items except those for individual prophylaxis (IP), where 1.16 Euro in mean can be claimed. For GOÄ, 80 GOÄ points equal one BEMA point.

A range of treatment fee items were used for different initial and re-treatments, as indicated in Table S1. For HT, the placement of a stainless-steel crown after tooth separation using orthodontic separators was charged. For NRCC, regular re-instruction and fluoridation were charged; in a sensitivity analyses, the re-instruction costs were distributed among the present teeth to account for this reinstruction being a patient level measure. For CR, anesthesia, moisture control, cavity lining and a direct two-surfaced restoration were charged; note that not all items were charged in every case. Retreatments involved re-cementation or new placement of stainless-steel crowns, pulpotomy or extraction in combination with local anesthesia or, in 2 cases, under NO-sedation. Sedation was charged using a fixed fee; this fee may well differ in different settings. For all strategies, costs for clinical and radiographic assessment were not accounted for, as we assumed these to be similar initially, and distributed among the present teeth during follow-up.