

# Scientific Article

## Extent of Tooth Decay in the Mouth and Increased Need for Replacement of Dental Restorations: The New England Children's Amalgam Trial

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**Abstract:** **Purpose:** The purpose of this study was to assess the relationship between baseline caries experience and the restoration replacement rate in children. **Methods:** The 5-year New England Children's Amalgam Trial recruited 534 6- to 10-year-old children with 2 or more carious posterior teeth. The association between decay and longevity of restorations was assessed. Restorations with no follow-up ( $n=391$ ) were excluded from analysis. **Results:** The average follow-up was  $3.0\pm 1.6$  years in 489 children. Restorations with follow-up ( $n=3,604$ ) were placed in mouths with a median of 15 dfs/DFS and 8 dft/DFT. The need for replacement increased significantly ( $P\leq .001$ ) with increasing numbers of dfs/DFS and dft/DFT. After 5 years of follow-up, at least 15% of restorations in a mouth with  $\geq 14$  dfs/DFS needed replacement, compared to 9% for 2 to 5 dfs/DFS. Comparing dft/DFT after 5 years of follow-up, there was a 23% replacement rate for  $\geq 12$  dft/DFT compared to 10% for 2 to 3 dft/DFT. Decay in the mouth had a greater association with the need for replacement due to new caries compared to replacement due to recurrent caries. **Conclusion:** Children with more decay at the time of restoration placement were at higher risk for replacement of restorations. (*Pediatr Dent* 2008;30:388-92) Received March 28, 2007 | Last Revision August 13, 2007 | Revision Accepted August 28, 2007

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There are many factors to consider in assessing a child's risk for caries, including oral hygiene, presence of cariogenic bacteria, fluoride exposure, diet, salivary flow rate, parental education, socioeconomic status, and maternal/sibling caries prevalence.<sup>1-4</sup> The strongest predictor of caries risk in children, however, is past caries experience.<sup>1-5</sup> Children with a history of many cavities are much more likely to present with future cavities.

Dental restorations treat the signs and symptoms of the disease, but do not stop the disease process.<sup>1,5</sup> Restorations repair the structure of the tooth, but cannot prevent further caries in the same tooth. Dental restorations themselves have a finite life span and fail for a variety of reasons, including loss, fracture, recurrent caries, and new caries on the same tooth that requires removal of the existing restoration.

It is common knowledge among dentists that restorations are themselves susceptible to failure due to disease.<sup>1</sup> No studies have been conducted, however, to quantify this consensus. Although there is a substantial volume of dental

literature that has examined the reasons for replacement of restorations, including caries,<sup>2-4,6</sup> no studies have examined the exact relationship between decay in the mouth and the need for replacement of dental restorations.

Severity of disease can be measured by the number of decayed and filled primary and permanent surfaces (dfs/DFS) and teeth (dft/DFT) present in the mouth at the time of restoration placement. It would seem likely that the susceptibility of restorations to failure due to disease contributes to their need for replacement, and that children at high risk for caries (as predicted by previous caries) are then at higher risk for the replacement of existing restorations due to further caries on the same tooth. There are no prior studies confirming this hypothesis, however, nor any data to provide information to dentists and patients about the likelihood of replacement. Such data are necessary to document the additional burden of replacement in both time and money for both patients and providers.<sup>7</sup> Furthermore, such data may provide additional motivation for good oral health practices to prevent the need for further replacement procedures, in addition to preventing further decay.

The purpose of this analysis was to investigate the association between the rate of restoration replacement and the number of decayed and filled surfaces/teeth in both primary and permanent dentition combined, at the time of restoration placement, using data collected prospectively as part of the New England Children's Amalgam Trial (NECAT).

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## Methods

**Study design and participants.** A detailed discussion of the design of NECAT has been previously published.<sup>8,9</sup> The study was approved by the Institutional Review Boards of the New England Research Institutes, Watertown, Mass, the Forsyth Institute, Boston, Mass, and all dental clinics (Mt. Blue Health Center, Farmington, Me; Codman Square Health Center, Dorchester Mass; South Boston Community Health Center, S. Boston, Mass; Windsor Street Health Center, Cambridge, Mass; the Children's Hospital Boston, Mass; and the Forsyth Institute, Boston, Mass). English-speaking children who were 6 to 10 years old at baseline were eligible if they had no known prior or existing amalgam restorations, 2 or more posterior teeth with dental caries requiring restorations on occlusal surfaces, and no clinical evidence of existing psychological, behavioral, neurological, immunosuppressive, or renal disorders. Children were recruited from 2 geographic areas:

1. an urban area with fluoridated public drinking water (Boston, Mass); and
2. a rural area (Farmington, Me) where the majority of participants used well water, for which estimates of naturally occurring fluoride or usage of dietary fluoride supplements are unavailable.<sup>10</sup>

A total of 5,116 children were screened for eligibility. The screening process and baseline visits included a dental examination by a NECAT dentist, radiographs, and standard preventive dental care (eg, cleaning, application of fluoride and sealants). Family and sociodemographic data were collected by in-person interviews with parents/guardians at initial study visits. Eligibility was confirmed for 598 children, and parental consent and child assent was obtained for 534.

**Dental treatment and clinical procedures.** A complete dental examination was scheduled every 6 months during the 5-year trial. Participating children were provided preventive and restorative dental care. Restorations were continually placed over the course of the trial as needed, according to assigned treatment. Children were randomized to receive either amalgam (N=267) or composite/compomer (N=267) restorations at baseline and during the course of the trial. For children assigned to the composite/compomer group, compomer was placed in primary dentition, while composite was placed in permanent dentition. For children in the amalgam group, composite/compomer was used in anterior dentition if required by standard clinical practice guidelines.

One dentist treated 97% of the Boston-area participants, and 2 additional dentists treated the remaining 7 children at one Boston site. Three dentists treated rural Maine participants during the course of the trial. Thus, in Boston, the dentist diagnosing restoration failure was almost always the same dentist who diagnosed the need for restoration, and often so in Maine as well. Clinical variability was minimized by centralized training of all dental personnel and the use of standard

pediatric dental procedures as specified in the NECAT protocol and procedures manual. There was no evidence from statistical models that restoration longevity varied by operator or trial site (data not shown). The same technique was employed when placing all restorations, with rubber dam used most of the time (72% of restorations in 424 children). Restoration longevity did not vary significantly by rubber dam use (data not shown). Following the complete removal of decay, the tooth was acid etched with 30% phosphoric acid for 20 seconds and washed thoroughly. A bonding agent (Optibond; Kerr Corp, Orange, Calif) as applied and light cured for 30 seconds. The restoration was then placed following the manufacturer's indications. For the amalgam group, the material was Dispersalloy (Dentsply/Caulk, Mildford, Del). The compomer material was Dyract (Dentsply/Caulk), and the composite was Z100 (3M ESPE, St. Paul, Minn).

Restorations could cover multiple surfaces and were placed in both primary and permanent teeth throughout the trial. If a restoration required replacement, the reason for replacement was categorized as one of the following: (1) new caries; (2) recurrent caries; (3) fracture; (4) restoration loss; or (5) other reason. The criterion of "new caries" was used when the carious surface was different from the one previously restored on the same tooth. Restorations replaced for "other" reasons were most often repairs, when the tooth presented less than ideal marginal adaptation and/or stained margins.<sup>11</sup> Exact dates of dental visits, replacements, repairs, and extractions were recorded.

**Statistical analysis.** All restorations placed during the study (ie, all amalgam/composite/compomer restorations on all primary, permanent, posterior, and anterior teeth) due to new or recurrent caries were included for analysis. Replacements due to fracture or loss (eg, after a sport injury) were excluded, however, as those replacements were not likely to be related to decay in the mouth.

Each restoration contributed follow-up from the date of initial placement to the date of replacement (for any reason), extraction, exfoliation, or the child's last dental visit (whether at year 5 or before withdrawal from the trial), whichever occurred first. Because restorations were placed at the baseline dental visit, as well as during follow-up visits over the 5-year trial, the start of follow-up time varied by restoration. We estimated the date of exfoliation by averaging the dates of the last dental visit with the primary tooth and the first dental visit with the corresponding permanent tooth. Since dental exams were performed every 6 months and documented the status of each tooth, the date of exfoliation is accurate to within 3 months. Restorations placed with no subsequent follow-up (ie, at the last dental visit before withdrawal, tooth exfoliation, or at the end of the trial; N=391) were excluded from all analyses and descriptive statistics.

The outcome used for this study was survival time of the restoration (ie, time until replacement, if replaced) or available follow-up time of the restoration (if not replaced). There

were 2 predictors of interest in this analysis: (1) the number of decayed and filled surfaces (dfs/DFS), and (2) the number of decayed and filled teeth (dft/DFT). These predictors were measured as decay ever present in the mouth up until the time of placement of the outcome restoration, including the outcome restoration itself and restorations no longer present in the mouth (due to exfoliation of primary teeth). Thus, these predictors are cumulative measures of decay.

To evaluate whether the rate of replacement varied by number of dfs/DFS or dft/DFT (as continuous variables) in the mouth at the time of restoration placement, a random effects accelerated failure time model with proportional hazards was used, adjusting for age, gender, socioeconomic status, dental material (amalgam/composite/compomer), and tooth type (primary vs permanent, posterior vs anterior). The random effect in this survival model was the child, to account for the potential correlation between restorations in the same mouth. To test whether the association between decay and the need for replacement varied by restoration material, the interaction between dental material and dfs/DFS or dft/DFT was considered in models restricted to posterior teeth, as amalgam was not placed in anterior teeth. Another secondary analysis was performed—fitting separate models for replacements due to new vs recurrent caries—to assess whether decay was more likely associated with replacement rates for one reason compared to the other.

**Results**

At baseline, the average age of participants was 7.9±1.3 (SD) years old. The mean number of total cavities at baseline was 9.5±6.6 decayed tooth surfaces and 5.4±2.9 decayed teeth. Of these, 7.8±6.4 surfaces and 4.1±2.7 teeth were in primary teeth, and 1.7±2.2 surfaces and 1.3±1.5 teeth were in permanent teeth. The sample was gender-balanced and racially diverse.

Over the 5-year trial, 3,604 restorations with follow-up were placed in 489 children (1,471 amalgam, 1,229 compomer, and 904 composite). Of the restorations, 61% were in primary teeth and 39% were in permanent teeth, with 92% in posterior teeth and 8% in anterior teeth. Forty-one percent of restorations covered a single surface, with 48% covering 2 surfaces, 8% covering 3 surfaces, 2% covering 4 surfaces, and 1% covering 5 surfaces. Restorations were placed in mouths with a median of 15 dfs/DFS and 8 dft/DFT.

The average length of restoration follow-up was 3.0±1.6 years, with a range of 0.03 to 6.3 years. Although this was a 5-year study with dental visits every 6 months, children sometimes scheduled visits at longer intervals, resulting in greater than 5 years of follow-up.

Over the entire study, 212 (6%) of restorations were replaced (3% due to new caries on adjacent surfaces+3% due to recurrent caries). Of these, 69 were in primary teeth and 143 in permanent teeth (which had longer follow-up due to exfoliation of primary teeth). Of the restorations replaced, 85 of the initial restorations were single-surface, 99 were 2-surface,

and 28 had 3 or more surfaces. Restoration longevity did not vary significantly by number of surfaces or primary/permanent dentition, after controlling for decay in the mouth (data not shown).

Of those restorations with 5 years of follow-up (N=711), 100 (14%) were replaced (6% due to new caries+8% due to recurrent caries). Of these restorations, 19 were in primary teeth and 81 in permanent teeth, 39 were single-surface, 52 were 2-surface, and 9 had 3 or more surfaces. Figure 1 shows the replacement rates of restorations with 5-year follow-up by categories of dft/DFT. It is clear that the need for replacement increased with decay in the mouth. For example, after 5 years of follow-up, there was a 23% replacement rate for 12+ dft/DFT compared to a 10% replacement rate with 2 to 3 dft/DFT.

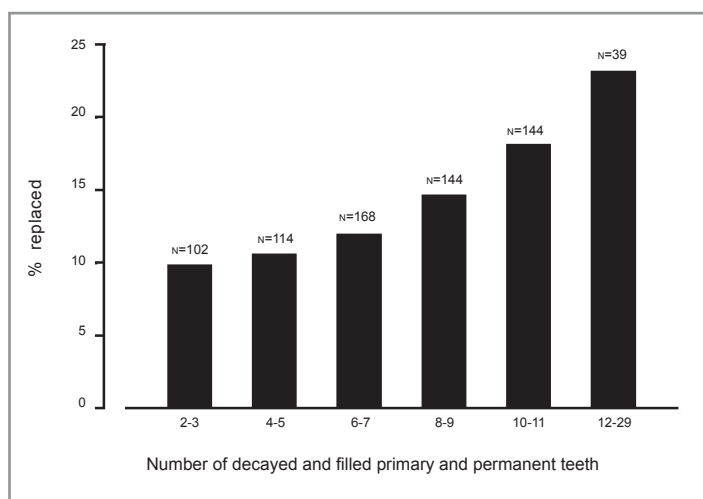


Figure 1. Restoration replacement rates by number of decayed and filled teeth at the time of restoration placement, within 5 years of observation in the New England Children’s Amalgam Trial (N=711 restorations).\*

\*The sample size (N) refers to the total no. of restorations with 5 years of follow-up.

Random effects survival analysis showed a significant effect of the amount of decay on the need for replacement ( $P<.001$  for dft/DFT and  $P=.001$  for dfs/DFS). In terms of predicting the need for replacement, the number of decayed/filled teeth, rather than surfaces, was the better measure, as this marker was more significantly related to replacement rates. Figure 2 shows survival curves for all restorations by categories of dft/DFT. Replacement rates were generally higher for increasing numbers of dft/DFT. The need for replacement also increased with age ( $P<.001$ ) and was higher in posterior teeth compared to anterior teeth ( $P=.004$ ). The need for replacement was significantly higher for composite and compomer restorations than amalgam restorations ( $P=.048$ ). The interaction between dental material and dft/DFT was not significant ( $P=.44$ ), however, nor was there any evidence of a trend, indicating no differences in the effect of decay on restorations of varying materials.

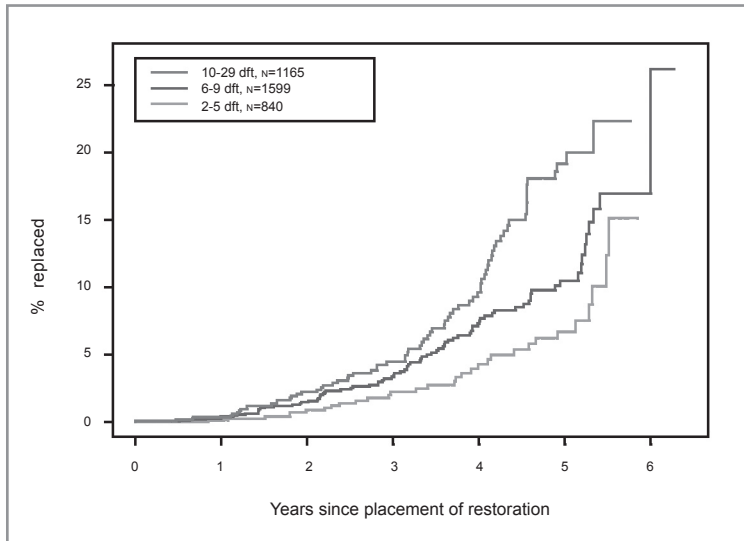


Figure 2. Restoration replacement rates in all teeth, by categories of decayed and filled teeth (primary and permanent teeth combined), in the New England Children's Amalgam Trial (N=3,604).\*

\* $P < .001$ , calculated from a random effects accelerated failure time model with proportional hazards, adjusted for age, gender, socioeconomic status, dental material (amalgam/composite/compomer), and tooth type (primary vs permanent, posterior vs anterior).

In random effects survival analysis models, the amount of decay had a strong association with the need for replacement due to new caries ( $P = .002$ ), but a weaker association with the need for replacement due to recurrent caries ( $P = .08$ ). Although the replacement rates due to both new and recurrent caries generally increase with number of dft/DFT, decay in the mouth clearly had a greater association with replacement due to new caries compared to recurrent caries.

## Discussion

This paper presents, for the first time, analyses to investigate the increased need for replacement of dental restorations due to decay in the mouth. Although this association has been common knowledge among dental practitioners,<sup>1</sup> there have been no prior studies to substantiate this consensus, nor any data to provide information to dentists and patients about the likelihood of replacement. There is a substantial volume of dental literature that has examined many reasons for replacement of restorations, including caries. No studies, however, have examined the exact relationship between decay in the mouth and the need for replacement of dental restorations. The NECAT data allowed us to properly investigate this association by recruiting a cohort of children with a high rate of initial restorations and providing regular dental care during the course of the trial.

This analysis demonstrated an increase in the replacement rates with increasing dft/DFT in the mouth at the time of restoration placement, thus supporting the hypothesis that the need for replacement is increased due to decay in the mouth. Variation in replacement rates by the number of dft/DFT was evident as early as 1 year after restoration replacement, with

the need for replacement within 5 years over twice as likely for restorations in children with at least 12 dft/DFT compared to those with 2 to 3 dft/DFT. As each individual restoration in a child with high levels of decay will more likely need replacement (compared to individual restorations in a child with less decay), taking into account all the restorations present in the child's mouth yields a considerable increase in the need for dental restoration replacement work. Thus, the burden of replacing restorations in a child grows more than linearly with the number of restorations in the child's mouth, and is considerably higher in children with higher levels of decay.

Although the cumulative number of dft/DFT is correlated with the number of restorations placed at each treatment visit, inclusion of the number of restorations placed at the same visit did not appreciably alter the results of the statistical model (data not shown), nor was this variable statistically significant. Therefore, the association between the cumulative number of dft/DFT at the time of placement and the survival of that restoration is unlikely to be due to the possible compromises resulting from multiple restoration placement or age-related poor patient cooperation.

Furthermore, the association between dft/DFT and the subsequent need for restoration replacement did not depend on the type of restorative material (among amalgam, composite, and compomer). Thus, the extent of dft/DFT in the mouth is unlikely to be an important factor to consider when deciding what type of restorative material is most suitable for a patient. On the other hand, composite/compomer materials had significantly higher rates of replacement, independent of decay—a finding that is consistent with results from some previous studies of restoration longevity.<sup>12-15</sup>

Decay in the mouth clearly had a greater effect on the need for replacement due to new caries compared to replacement due to recurrent caries. New caries lesions are likely to develop in a surface other than the one that has been restored if the specific reasons for the original restorations (eg, poor oral hygiene, diet, or bacteria) continue to lead to disease development.<sup>1-4</sup> The new lesion on the same tooth as the restoration may then require the replacement of the original restoration. The same is true for recurrent caries around the restoration, though to a lesser extent. Recurrent caries may be more strongly related to other factors, such as dental material,<sup>12-15</sup> operator,<sup>16</sup> or conditions of placement.<sup>17,18</sup>

Although there are many factors that affect the need for replacement of a restoration,<sup>19</sup> an association between dft/DFT and replacement rate persisted while controlling for other factors, including the child's age. Thus, it is unlikely that the observed association was due to problems with patient cooperation at younger ages. In fact, in our study, the need for replacement significantly increased with age. This may be

related to diets of older children/adolescents who are likely to be more autonomous in dietary decisions and choose more cariogenic foods and beverages. Because the youngest children studied were 6 years old, this increase in the need for replacement with age does not contradict the increased need for replacement observed in children younger than 6 years old in prior studies.<sup>6</sup> Additionally, the limited baseline age range in this study confounded the effect of primary vs permanent dentition, precluding a comparison of their survival rates.

It should be noted that restorative dentistry itself, regardless of the nature and quality, may contribute to an increase in the future risk of recurrent caries. Considering the ethical responsibility to treat tooth decay, this confounding factor may be inevitable in analyses such as ours. Although our population was not a representative sample of all children, this research is most applicable to children who are older than 6 years of age with multiple dental treatment needs and at high risk for caries. Patients should be informed that dental restorations are susceptible to failure and that this failure may be preventable in the same way that tooth decay is preventable, with modifications in oral hygiene and diet.

**Conclusions**

Based on this study’s results, the following conclusions can be made:

1. Children with high rates of caries are at higher risk for replacement of restorations.
2. Patients should be informed that dental restorations are susceptible to failure due to factors related to tooth decay, such as bacteria, diet, and poor oral hygiene.

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