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A retrospective study of root canal therapy in non-vital primary molars

ABSTRACT

Aim *This study was performed to assess the clinical and radiographic success rates of a formocresol and zinc oxide eugenol (ZOE) primary molar root canal therapy (RCT) technique. The effects of this treatment on the permanent successors and on exfoliation times were also investigated.*

Material and methods *Study design: the retrospective study included 161 patients with 211 primary molars treated by RCT by a single operator in a private paediatric dental office in the Toronto area. Data were coded and entered into a Microsoft Excel database and analysis undertaken using SPSS software. Predominantly non-parametric tests were used to evaluate statistical differences ($p < 0.05$).*

Results *A clinical success rate of 90% (190/211) and a radiographic success rate of 77.3% (136/176) were obtained. Following RCT in a primary molar, enamel defects were found in 6.8% (7/103) of premolars, all of which occurred in first premolars, and in patients treated at a mean age of 54.1 months ($p < 0.005$). Treated molars exfoliated on average 7.6 months sooner than contralateral teeth ($p < 0.005$).*

Conclusion *This formocresol and ZOE RCT is a viable treatment for necrotic primary molars and yielded very high clinical and acceptable radiographic success rates.*

Keywords *Exfoliation times; Formocresol; Primary molar; Root canal therapy; Zinc oxide eugenol.*

Introduction

Root canal therapy (RCT) in primary molars has long been advocated when the criteria for a classical pulpotomy cannot be met [Gould, 1972]. Various materials have been used as endodontic obturating agents in primary teeth. The most common are: unfortified ZOE, used either alone or applied with formocresol, iodoform and camphorated parachlorophenol pastes (Kri paste or Endoflas FS) as well as iodoform and calcium hydroxide mixtures (Vitapex®) [Barr et al., 1991; Coll and Sadrian, 1996; Fuks et al., 2002; Holan and Fuks, 1993; Mortazavi and Mesbahi, 2004; Moskovitz et al., 2005; Rifkin, 1980].

The antimicrobial properties of endodontic medicaments contained in obturation materials have been tested *in vitro*. In all studies, formocresol was found to have superior antimicrobial activity against microorganisms found in the canals of abscessed primary molars and the only antimicrobial to produce negative cultures against enterococci faecalis [Cox et al., 1978; Pear, 1942; Tchaou et al., 1995; Tchaou et al., 1996; Wesley et al., 1970]. Camphorated parachlorophenol mixtures showed similar but consistently less antimicrobial activity compared to formocresol [Wolfsohn, 1958]. Significantly less antimicrobial activity was found with eugenol or pure ZOE, iodoform and calcium hydroxide mixtures [Cox et al., 1978; Pear, 1942; Tchaou et al., 1995; Tchaou et al., 1996].

Despite the weak antibacterial activity of the above-listed alternative pulp medicaments from *in vitro* studies, many clinical studies have reported high clinical success rates (78% to 100%) with root filling materials containing these medicaments [Garcia-Godoy, 1987; Holan and Fuks, 1993; Mortazavi and Mesbahi, 2004; Moskovitz et al., 2005; Nadkarni and Damie, 2000; Rifkin, 1980]. Possible explanations for this disparity may be related to a difference in space (root canal vs. petri dish), medicament dosing, surface tension, (follow-up) time, dentin permeability, lateral canals, pH, moisture or microbial flora [Wesley et al., 1970]. Alternatively, the high clinical success rates may be attributed to variations in study design and/or reported findings.

Clinically, the success of primary molar RCT is multifactorial but it is clear that in comparison with other obturation materials formocresol has exceptional antimicrobial properties.

The aim of this retrospective study was to examine the long-term clinical and radiographic outcomes of a primary molar RCT using formocresol and ZOE. In addition, it also evaluated the effect of primary molar RCT on permanent successors and exfoliation times.

Methods

This retrospective study was approved by the University of Toronto Health Sciences Research Ethics Board. Inclusion criteria for the study and possible benefits to the subjects were described in the protocol submission to the Research Ethics Board. Informed

consent processes and confidentiality procedures were also reviewed and approved.

The subjects selected for this study were treated using a primary molar RCT by a single operator (P.A.) at a private paediatric dental office in the Toronto area between the years 1996 and 2010.

The inclusion criteria included healthy children requiring at least one RCT on a primary molar with a minimum follow-up period of 6 months. All RCT's were completed in one appointment except in the event of a non-draining swelling and/or cellulitis, where a two-appointment procedure was performed.

The clinical indications for RCT in restorable and strategically important teeth [Barr et al., 1992; Bawazir and Salama, 2006; Holan and Fuks, 1993] included teeth with one or more of the following:

I) A non-vital pulp or radicular pulp which exhibited excessive bleeding and was unable to be controlled;
II) A history of spontaneous / prolonged pain;
III) Abnormal mobility;
IV) Evidence of a draining fistula or parulis.

The radiographic indications for RCT included [Barr et al., 1992; Bawazir and Salama, 2006]:

I) A furcation or periapical bone resorption not invading the developing follicle, with minor or no root resorption (internal or periapical root resorption of < 1 mm),
II) No pathology of the succedaneous tooth (breach of its follicle).

Radiographic assessments were made by examining bitewing and/or periapical radiographs. Treatment was performed under rubber dam isolation after local anesthesia. Pulpal access was made after all coronal caries was removed. A trial length for files was obtained by measuring the tooth on the preoperative radiograph and subtracting 1–2 mm. Root canal pulpal filaments were removed with NiTi K-files, which were usually size #25 or #30 (ranged from #20 to #45). Care was taken to avoid enlarging the pulpal canals. Canals were irrigated with 3% hydrogen peroxide [Garcia-Godoy, 1987; Holan and Fuks, 1993], then dried with paper points.

The canals were obturated with a mixture of: one drop of full strength Buckley's formocresol, one drop of eugenol and pure unfortified zinc oxide (Henry Schein®) mixed to a creamy consistency. This was delivered into the root canal system by using lentulo spiral burs with pre-measured markers (Henry Schein®).

All teeth were restored with an unfortified ZOE base and stainless steel crowns (3M ESPE, St. Paul, MN, USA), which were cemented using glass ionomer cement (KETAC-CEM) (3M ESPE, St. Paul, MN, USA).

Whenever possible a post treatment periapical radiograph was taken. In the event that an immediate postoperative radiograph was not taken on the day of final treatment (usually due to lack of patient cooperation), the patient was asked to return for follow-up a few days later. At this appointment, a postoperative radiograph was taken. In rare cases when patients did not return to the clinic as instructed, a periapical radiograph was taken at the next recall appointment.

Oral antibiotics (amoxicillin, 50 mg/kg tid, or in the event of a penicillin allergy, clindamycin, 20 mg/kg tid, 10 day course) were prescribed to all patients who presented with a fever and/or a non-draining abscess and/or cellulitis, which was indicative of a non-contained or spreading infection.

Outcomes deemed to indicate clinical successes included:

I) Absence of reported pain (spontaneous or stimulated).
II) Absence of soft tissue abscess, parulis or facial cellulitis.
III) Absence of pathologic tooth mobility.
IV) Absence of extraction of treated tooth.

Outcomes deemed to indicate radiographic success included:

I) Absence of new furcation or periapical radiolucency.
II) Absence of pathologic external or internal root resorption (either new or worsening of existing).
III) Improvement or stasis of a pathologic radiolucency when present preoperatively.
IV) Succedaneous tooth and follicle not affected by treated primary molar.
V) Root filling did not alter the path of eruption of the succedaneous tooth.

The survival time or lifespan of treated teeth was determined by recording the time of exfoliation or extraction. In the event that a tooth was lost between recall exams, the first date at which the tooth was observed to be lost was recorded as the terminal survival date (log-rank test). Radiographic standardisation and sample size calculations were completed using Cohen's Kappa test with SPSS statistical analysis (IBM SPSS Inc., Armonk, New York, USA). A single investigator (KS) evaluated all clinical and radiographic data following a standardisation exercise with two other staff paediatric dentists.

Results

One hundred and sixty-one subjects (males = 98, females = 64) with a mean age at the time of treatment of 72 months (range = 33 to 148 months) were included in the study. These subjects comprised 211 treated primary molars: 69 maxillary first molars, 16 maxillary second molars, 73 mandibular first molars and 53 mandibular second molars. There were no significant differences in the sample representation by gender or by molar type according to the Breslow (generalised Wilcoxon) test ($p = .786$ and $p = .497$, respectively). Logistic regression analysis showed no correlation between age at time of treatment and clinical outcome

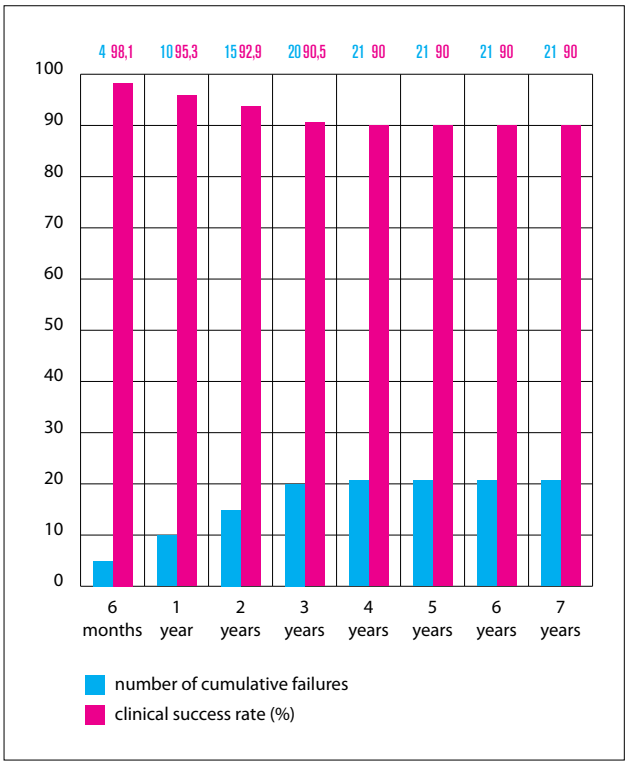

FIG. 1 Clinical Success Rates with Cumulative Failures over Time (N = 211).

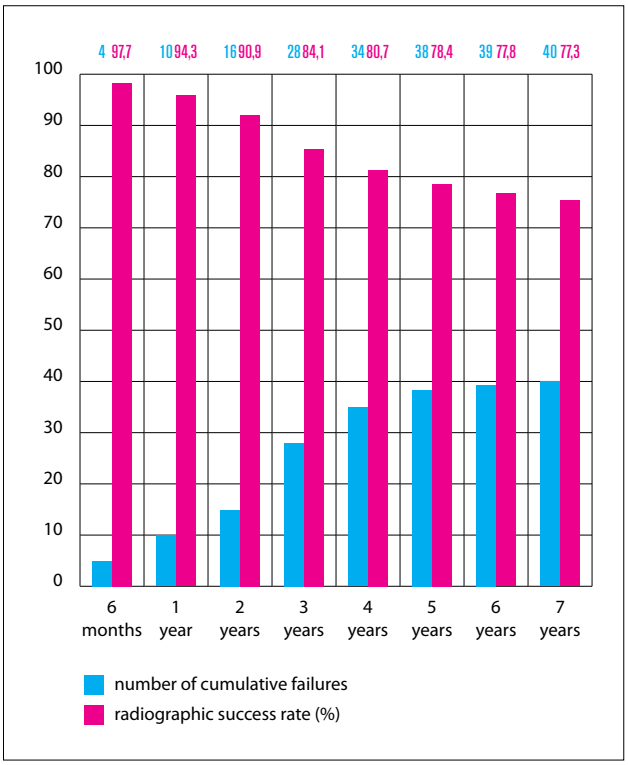

FIG. 2 Radiographic Success Rates with Cumulative Failures over Time (N = 176).

or radiographic outcome (p = 0.300 and p = 0.760, respectively).

It was determined that a sample size of 91 teeth was required to achieve 80% power and a 5% statistical significant level. No significant difference was found between number of appointments for treatment and clinical or radiographic outcome (N = 200 teeth one appointment, N = 11 teeth two appointments, Pearson chi-square: p = 0.922 and p = 0.536, respectively). Antibiotics were prescribed in 50% of patients. In order to standardise the principal investigator's radiographic analysis, a standardisation exercise was completed. Highly significant inter-rater reliability was observed with a kappa score of 0.81. The intra-rater reliability kappa core was 0.84.

Subjects' preoperative clinical signs and symptoms were recorded as the following: 46.0% no clinical symptoms, 26.5% soft tissue abscess, 6.2% pain with fever, 1.4% pain no fever, 2.4% parulis, 17.5% had more than one of the aforementioned symptoms. Facial cellulitis was observed in six patients however it was always present with either pain or an associated soft tissue abscess. The mean follow-up period was 36 months (range = 6 to 111 months).

Overall, 190 of the 211 primary molars treated by RCT exhibited no clinical signs or symptoms over their respective follow-up periods, accounting for a clinical success rate of 90.0% (Fig. 1).

Only 176 treated teeth had appropriate preoperative and postoperative radiographs, accounting for the

	Preoperative N (%)	Postoperative N (%)
Furcation Radiolucency	128/176 (72.7)	79/176 (44.9)
Periapical Radiolucency	79/176 (39.8)	24/176 (13.6)
Radiolucency near Follicle of Succedaneous Tooth	39/176 (22.2)	26/176 (14.8)
Widened PDL or Loss of Lamina Dura	23/176 (13.0)	12/176 (6.8)
External Root Resorption	9/176 (5.1)	17/176 (9.7)
Internal Root Resorption	12/176 (6.8)	8/176 (4.5)
Within Normal Limits	29/176 (16.5)	70/176 (39.8)
Altered Eruption Succedaneous Tooth	n/a	2/176 (1.1)

TABLE 1 Preoperative and Postoperative Radiographic Findings (more than one type of radiographic finding may have been observed in individual teeth).

difference in sample size from clinical outcomes. Overall, 136 of 176 (77.3%) primary molars treated by RCT were considered radiographically successful (Fig. 2).

The preoperative and postoperative radiographic findings were compared (Table 1). The eruption path of two succedaneous teeth appeared to have been altered by unresorbed ZOE. These were considered radiographic failures. Antibiotic use had a negative correlation with radiographic success according to Spearman's rank correlation coefficient ($p < .05$). No significant correlation was found when antibiotic use and clinical outcome were compared (Spearman's rank correlation coefficient ($p > .05$).

Of the 211 teeth treated, only 108 teeth were observed until exfoliation or extraction and their succedaneous teeth were only followed clinically in 103 cases. Enamel defects were observed on seven of the premolars that succeeded treated teeth (7/103 or 6.8%). Enamel defects were only observed on first premolars and ranged from hypocalcified or hypoplastic enamel lesions to pre-eruptive carious lesions. Six out of seven of these treated primary molars were considered clinical and/or radiographic failures. Contralateral premolars, with untreated (preceding) primary molars, were examined and no enamel defects were recorded.

When age at time of treatment was considered, those who developed enamel defects in their succedaneous teeth had a mean age of 54.1 months at the initiation of RCT, while those that did not develop enamel defects (96/103) had a mean age of 77.2 months. This difference was significant ($p \leq 0.001$, independent student's T-test). When the data was further separated to exclude second primary molars and include only first primary molars, with (7/72) and without (65/72) enamel defects in their succedaneous teeth, the group without enamel defects had a mean age of 80.0 months (vs. 54.1 months for the group with enamel defects) ($p < 0.005$, independent student's T-test, equal variances assumed).

In order to study the effect that RCT had on the timing of exfoliation, treated teeth were compared to contralateral teeth that were either unrestored or restored (without pulp therapy, n= 79). This analysis showed a significantly longer survival time for non-pulp treated contralateral teeth (46.2 months) relative to RCT treated teeth (38.6 months) ($p < 0.005$, paired student's T-test).

When this same sample of 79 teeth was divided according to clinical outcome and assessed for differences in survival time it was found that only teeth deemed as clinical failures (9/79) had a significantly shorter survival time relative to their non-pulp treated contralateral teeth (23.4 months vs. 60.2 months, $p = 0.048$, paired student's T-test, equal variances assumed). The same analysis was performed for radiographic outcome but no significant difference in survival time was found.

Discussion

In this study a retrospective chart review was used to evaluate the clinical and radiographic outcomes of a formocresol and ZOE RCT technique in 211 non-vital primary molars. In addition this study evaluated the rate of enamel defects of the succedaneous teeth following RCT and the effect of RCT on the timing of exfoliation of treated teeth. All aims and objectives of this study were met.

A retrospective study design has the advantage of allowing a dramatically larger sample size and thus detecting smaller differences in outcome. The final sample size of this study was 211 primary molars for clinical evaluation and 176 primary molars for radiographic evaluation from 161 healthy subjects. The current investigation has the largest sample size reported for formocresol and ZOE RCT – three to seven times that of previous reports [Barr et al., 1991; Bawazir and Salama, 2006; Coll and Sadrian, 1996; Mortazavi and Mesbahi, 2004]. Retrospective studies also allow for longer follow-up periods, however for RCT studies these range from as little as six months [Bawazir and Salama 2006] or a year [Mortazavi and Mesbahi 2004] to 40 or more months [Barr et al., 1991; Coll and Sadrian, 1996].

To compare the present clinical success rate of 90% directly to other studies is difficult, and perhaps inappropriate, given the variability in study designs (sample size, inclusion criteria, follow-up period, definitions of successful outcome, choice of restoration) and reported findings.

Clinical outcomes for specifically formocresol and ZOE primary molar RCT studies range from 74.5% to 93.6% [Barr et al., 1991; Bawazir and Salama, 2006; Coll and Sadrian, 1996; Mortazavi and Mesbahi, 2004]. Some techniques apply formocresol via paper point first then obturate with ZOE [Bawazir and Salama, 2006; Coll and Sadrian, 1996], while another seals formocresol-dabbed cotton pledgets in pulp chambers for 1-2 weeks and then obturates with ZOE [Mortazavi and Mesbahi, 2004]. Our technique involves obturation with a mixture of formocresol within the ZOE and is the same as Barr et. al. described [1991]. The theory behind sealing formocresol within the pulp space is to provide continued antimicrobial activity since mechanical debridement of the ramification and deltas between root canals of primary molars is often quite difficult [Goerig and Camp, 1983; Zurcher 1925].

In the present investigation, the clinical inclusion criteria were broader (degree of pathosis) and the definitions of clinical success were equivalent relative to published studies for RCT [Bawazir and Salama, 2006; Coll and Sadrian, 1996; Fuks et al., 2002; Holan and Fuks, 1993; Mortazavi and Mesbahi, 2004; Nadkarni and Damie, 2000; Yacobi et al., 1991; Payne et al., 1993]. As a result, the clinical outcome of 90%

for formocresol and ZOE RCT is a comparably highly acceptable outcome. The radiographic success rate of this investigation is within the average for comparable formocresol and ZOE RCT studies, which range from 72.0% to 90.9% [Barr et al., 1991; Bawazir and Salama, 2006; Coll and Sadrian, 1996; Mortazavi and Mesbahi, 2004].

Preoperative and postoperative radiographic findings were compared for two reasons. The first reason was to emphasise the broad inclusion criteria of this study. The high rate of negative preoperative radiographic findings in the present investigation was indicative of the degree of pathoses present in both the pulpal and periapical tissues and is a detail that has not been discussed in other similar papers. Variable inclusion criteria in primary tooth RCT studies are a significant outcome bias, which are often overlooked in the interpretation of reported outcomes. The second reason to analyse preoperative and postoperative radiographic findings was to determine the rate of healing in the surrounding structures of treated teeth following RCT. The AAPD guidelines state that the objective of RCT in primary teeth is that the radiographic infectious process should resolve in 6 months, as evidenced by bone deposition [AAPD, 15/16]. However, it is well established that radiographic healing in permanent teeth with apical periodontitis is a slow process. In fact, less than half of permanent teeth with apical periodontitis are healed one year after RCT, approximately 95% are healed after 6 years and the remaining 5% require an even longer period to heal completely [Dugas et al., 2002; Fristad et al., 2004; Molven et al., 2002; Orstavik 1996].

There are no studies that extensively assess the rate of healing following RCT in primary teeth. However one may postulate that endodontic healing should occur over time in primary teeth as it does in permanent teeth. In the present investigation, stasis of a preoperative radiographic pathology was considered to be a successful treatment. Other studies have previously defined stasis (as well as improvement) of preoperative radiographic findings as a successful outcome [Barr et al., 1991; Fuks et al., 2002; Moskovitz et al., 2005; Nakorchai et al., 2010; Prabhakar et al., 2006].

Lack of resolution of radiographic lesions over the period of the study is troubling despite an absence of clinical signs or symptoms. Nevertheless, this definition of success can be viewed similarly to recent pulpotomy studies, in which development of internal root resorption or pulp canal obliteration is viewed as a successful outcome [Doyle et al., 2010].

Since patients who experienced systemic spread of infection (fever) and were prescribed antibiotics were more likely to have negative radiographic outcomes, a careful radiographic diagnosis should be applied in determining if the associated tooth is suitable for RCT treatment.

Interestingly, enamel defects were only observed on first premolars and ranged from hypocalcified or hypoplastic enamel lesions to pre-eruptive carious lesions. Six out of seven of these treated primary molars were considered clinical and/or radiographic failures. Age at time of RCT proved to be a significant factor in determining which patients might develop enamel defects in their succedaneous teeth. A survey of the literature indicates there are no previous studies that evaluate the effect of age at the time of irreversible pulpitis and RCT in primary molars and the incidence of enamel defects in succedaneous teeth.

A possible explanation for these observations may be related to the age at which the enamel of premolars calcifies. First premolars calcify between 18 months and 6 years of age while second premolars calcify between 24 months and 7 years of age [AAPD, 2011]. Therefore a younger child would be more vulnerable to errors in enamel calcification.

Other factors that may contribute to enamel defects on first premolars could be that first primary molars erupt, on average, one year earlier than second primary molars [AAPD, 2011]. As a result, first primary molars are exposed to cariogenic bacteria for a longer period of time and are more vulnerable to caries. In this investigation 67% of treated teeth were first primary molars. Yet another possible reason that only first and not second premolars were found to have enamel hypoplasia may be due to the anatomical differences between first and second primary molars. First primary molars may be more likely to undergo pulpal degeneration due to the fact that the pulp occupies a larger proportional space and that the coronal enamel and dentin is much thinner relative to second primary molars [Zurcher, 1925].

Although this study does not rule out the possibility that formocresol and ZOE RCT was responsible for the enamel defects in succedaneous teeth, it is the belief of the authors that the process of the chronic infection spreading into the periapical structures with eventual necrosis of a primary molar is more likely to have caused the enamel defects than the RCT itself. Therefore the enamel defect on the succedaneous tooth would have occurred prior to the initial diagnostic appointment. Future studies may investigate this further by recording enamel defects on premolars following a history of extracted abscessed primary molars. Given the evidence presented thus far, one may propose that a patient's age should be considered in planning the treatment (RCT vs. extraction) of a necrotic primary molar, as any prolonging of inflammation near a developing permanent tooth may impact its calcification process.

On average, treated teeth exfoliated 7.6 months earlier than their contralateral teeth. The shortening of the lifespan of the treated teeth did not require space maintenance therapy. However, when treated teeth were deemed clinical failures, they were more likely

to exfoliate earlier than clinically successful teeth, on average 36.8 months earlier.

The RCT technique in this investigation was carried out on all teeth by a single operator (PA). A study design with a single operator offers the advantage of a consistent and reproducible technique. However a potential disadvantage of this study design would be that the outcome is due in part to a superior operator rather than a superior technique.

Other potential limitations of this study are related to its retrospective nature. All data relied upon the accuracy of the clinical records and the radiographs that were available in charts. A control group could not be added to the study sample and follow-up periods were pre-determined. Patients did not always have routine follow-up. Ideally patients would have had routine clinical and radiographic follow-up of treated teeth and their contralateral teeth until exfoliation, as well as a consistent clinical assessment of their succedaneous teeth.

Furthermore, chart and radiographic analysis relied solely upon the principal investigator (KS). Despite these high kappa scores, the standard in this field of research is to have more than one investigator evaluating clinical and radiographic data in order to reduce potential for bias [Barr et al., 1991; Bawazir and Salama, 2006; Coll and Sadrian, 1996; Yacobi et al., 1991].

Conclusions

1. RCT in primary molars using one drop of full strength Buckley's formocresol, one drop of eugenol and pure zinc oxide powder as root filler demonstrated a high clinical (90.0%) and an acceptable radiographic success rate (77.3%).
2. Enamel defects in first premolars were rarely observed (6.8%) but when present, they were more likely to occur in a child that was treated by RCT at a younger age (mean 54.1 months).
3. Primary tooth RCT may shorten the lifespan of a primary tooth compared to a contralateral tooth, particularly if the tooth has a negative clinical outcome. However, the shortening of the lifespan did not require space maintenance therapy.

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