A Retrospective Study of Root Canal Therapy in Non-Vital Primary Molars

By

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ABSTRACT

Purpose: This retrospective study was performed to assess the clinical and radiographic success rates of a non-vital 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.

Methods: The study included 161 patients with 211 primary molars treated by RCT by a single operator in a private pediatric dental office in the Toronto area.

Results: A clinical success rate of 90.0% and a radiographic success rate of 77.3% were obtained. Enamel defects were found in 6.8% of permanent successors and in patients who were significantly younger at the time of root canal therapy treatment (p = .001). Treated molars exfoliated on average 5.8 months sooner than contralateral teeth (p<0.001).

Conclusions:

Formocresol and ZOE RCT is a viable treatment for necrotic primary molars and yielded very high clinical success rates with moderate radiographic success rates.
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A. INTRODUCTION

Non-vital root canal therapy in primary molar teeth has long been advocated when the criteria for a classical pulpotomy cannot be met (Gerlach 1932, Gould 1972). The success of any root canal therapy is dependent upon the reduction or elimination of bacteria from within the root canal space. This is accomplished by adequate root canal debridement, antimicrobial irrigation, and obturation with a non-soluble antimicrobial material.

The ideal root canal filling material in primary teeth should be: antimicrobial, easy to manipulate, easily removed if necessary, resorbable, biologically safe, cost effective, radiopaque, and should not harm periapical tissues nor affect the development or eruption of succedaneous teeth. Although the use of various medicaments, including iodoform, calcium hydroxide, zinc oxide eugenol, and camphorated parachlorophenol, has been reported in the treatment of the putrescent pulp (Castagnola & Orlay 1952, Rabinowitch 1953, Meyer & Sayegh 1979, Full 1979, Rifkin 1980, Tagger & Sarnat 1984, Garcia-Godoy 1987, Holan & Fuks 1993, Coll et al. 1988, Primosch et al. 2007, Trairatvorakul et al. 2008), the current investigation proposes that for non-vital root canal therapy in primary molar teeth, formocresol is a superior antimicrobial medicament and that zinc oxide eugenol is a suitable obturation material and carrier for formocresol.

protocol, inclusion criteria of treated teeth, follow up times and conflicting definitions of a success, radiographically, clinically or both combined.

The aim of this retrospective study was to examine the long term clinical and radiographic outcomes of a non-vital primary molar root canal therapy using formocresol and zinc oxide eugenol. In addition, this study evaluated the effect of non-vital primary molar root canal therapy on permanent successors and exfoliation times.
B. REVIEW OF LITERATURE

1) Primary Molar Root Canal Anatomy

A. The Study of Primary Root Canal Anatomy

In order to appreciate the technique and rationale involved in primary molar root canal therapy, it is critical to have a comprehensive understanding of the anatomy of primary molar root canals. Conventionally, the most accurate way to study the root canal space of primary molar teeth was by the injection of a flowable material into these spaces (Barker et al. 1969).

Two of the most exhaustive descriptions of primary molar root anatomy were published by Zurcher (1925) and by Hibbard and Ireland (1957). In both studies, the canal spaces of extracted primary molar teeth were respectively injected with vulcanite or polymethyl methacrylate resin. Zurcher (1925) began their study with a very large initial sample size of 10,000 primary molar teeth, but due to voids and imperfections in their technique, only 10% of teeth were available for subsequent study. Hibbard and Ireland (1957) overcame these technical deficiencies by using a more modern resin material infused via a newly designed injector flask technique. These technical advancements almost completely eliminated voids. Since these two landmark studies were reported, various other techniques involving decalcification, dehydration and dye injection techniques have been used to similarly describe the root canal spaces of the human dentition (Barker et al. 1969, Barker et al. 1975, Robertson et al. 1980, Salama et al. 1992).
Today, a more contemporary way of studying dental root anatomy is with the use of cone beam computed tomography (CT). Although this more current technique has been used to describe canal spaces of the permanent dentition (Michetti et al. 2010, Fuakami et al. 2010), there appear to be no published reports on the use of cone beam CT to describe the root canal spaces of primary molar teeth.

B. The Anatomy of Primary Molars and their Root Canal Spaces

The roots of primary teeth are completely formed approximately 16 to 20 months following their eruption (Nowak & Casamassimo 2007). As a general rule, the basic number of root canals for a maxillary molar is three and for a mandibular primary molar two, with the morphologic patterns conforming to the external root form (Hibbard & Ireland 1957).

Unfortunately, the above description of simplistic anatomy is not usually what is observed in situ. The root canal systems found in primary molar teeth frequently contain many ramifications and deltas (Goerig & Camp 1983). Zurcher (1925) commented that, “The wide variations occurring in the root canals of the milk teeth result from the deposition of physiological secondary dentin”. Although Zurcher (1925) provided no evidence to substantiate this claim, many investigators have since shown that they were accurate in assuming that the shape of root canals of the primary teeth is influenced by the deposition of secondary and/or tertiary dentin (Ireland 1941, Bevelander & Benzer 1943, Kronfeld 1949, Hibbard & Ireland 1957, Kuttler 1959, Salama et al. 1992).
The deposition of secondary dentin occurs with eruption of primary and permanent teeth and especially with occlusal contact (Kuttler 1959). According to some authors the stimulation of physiologic root resorption is also a factor in secondary dentin formation (Ireland 1941, Bevelander & Benzer 1943, Hibbard & Ireland 1957).

The age at which physiologic root resorption commences in primary teeth has been variously described by several authors (Zurcher 1925, Kronfeld 1949, Goerig & Camp 1983). Goerig and Camp (1983) reported that physiologic resorption begins as soon as root development is complete, which for primary teeth is usually 18 months post-eruption (AAPD 2007). Via histological analysis, Kronfeld (1949) found that physiologic resorption for any primary tooth could begin as early as the fourth year. On the other hand, Zurcher (1925), via gross anatomical observation and vulcanite injection, reported that physiologic resorption began at the end of the fourth year for primary incisors and between seven and eight years of age for primary molars.

Furthering this complexity, pulpal and/or periodontal inflammation may also stimulate the formation of tertiary dentin and cause pathologic changes in the resorption process and this results in yet more transverse pulpal communications (Ireland 1941, Kuttler 1959, Barker et al. 1975, Rimondini & Baroni 1995).

With the deposition of secondary dentin, Hibbard and Ireland (1957) found that primary maxillary and mandibular first molars can have two to four root canals and that primary maxillary and mandibular second molars can have two to five root canals. Maxillary and
mandibular first primary molars are more variable than second primary molars since the latter generally have stouter roots.

Overall, the greatest degree of variation in canal number consistently occurred in the mesial or mesiobuccal roots. Two or more canals were found in approximately 80% of the mesial roots of primary mandibular molars and greater than 50% of mesiobuccal roots of primary maxillary molars. (Jorgensen 1956, Hibbard & Ireland 1957, Barker et al. 1975). The palatal roots of primary maxillary molars were invariably the longest and the stoutest. They also tended to fuse with the distobuccal roots in 29 to 75% of the teeth (Hibbard & Ireland 1957, Barker et al. 1975, Salama et al. 1992).

Reduced palatal root resorption was recorded in 56% of maxillary second primary molars, and similar to the maxillary first primary molars, the palatal roots were observed to be significantly curved and splayed (Prove et al. 1992). The mesiobuccal root of the primary maxillary first molar was more slender than in the second molar, and the second molar’s mesiobuccal root had more of an apical bend, departing first mesially, then recurving towards the vertical axis of the tooth midway along its length. The distobuccal root of the maxillary second molar exhibited this same divergence and recurvature when not fused with the palatal root (Hibbard & Ireland 1957).

All primary molars had divergent roots to allow space for their apically placed permanent successors. The mandibular primary second molar exhibited greater root divergence than the first molar, with the mesial root showing greater recurvature at the apical bend (Hibbard & Ireland 1957, Barker et al. 1975).
In young specimens of mandibular primary molars with incompletely formed apices, the roots may possess single and very broad root canals. Eventually, each of the roots may possess two partially or completely separate canals so that four canals may be encountered (Barker et al. 1975). However, only 25% of the distal roots in either primary mandibular molar contain more than one canal (Zurcher 1925, Hibbard & Ireland 1957). The distal root of the primary mandibular first molar may be 2 to 3mm shorter than the mesial root as the tooth bud of the first premolar is situated more under the distal root (Allen 1979). In addition, partial taurodontism, defined as a root stem greater than 2.5mm, can be seen in 7-9% of primary mandibular molars (Jorgensen 1956, Barker et al. 1975).

The complexity of the root canals of primary molars presents a quandary from the standpoint of clinical practice. The technique and materials chosen to perform root canal therapy in these teeth is critical given the fact that complete mechanical preparation and debridement of these root canal spaces is very difficult, if not impossible.

2) **Rationale for Root Canal Therapy in Primary Molars**

According to the American Academy of Pediatric Dentistry (AAPD) recommendations, endodontic treatment is indicated in primary teeth in which, following coronal pulp amputation, the radicular pulp exhibits hyperemia, or evidence of necrosis of the radicular pulp, with or without carious involvement (AAPD 2010).

Despite this long-standing recommendation, a 2005 survey revealed that only 85% of diplomats of the AAPD reported that they performed pulpectomy therapy. A comparable
percentage of American dental school directors reported the teaching of pulpectomy therapy to their undergraduate students (Dunston & Coll 2008).

Reluctance to carry out root canal treatment in primary molars may be based on the lack of consistent evidence-based treatment protocol and medicaments as well as the difficulty associated with cleaning and shaping the complex root canals of primary molars (Fuks & Eidelman 1991, Fuks 2000). Accordingly, preparation of the root canals in primary molars, unlike permanent teeth, is based on the use of chemical agents rather than mechanical debridement and by the use of an antimicrobial root canal filling material (Moskovitz et al. 2005).

Extraction and space maintenance was postulated to be a more predictable treatment option for some clinicians (Rabinowitch 1953, Gould 1972, Goerig & Camp 1983, Coll et al. 1985), particularly in the case of an uncooperative child (Tagger & Sarnat 1984, Dunston & Coll 2008). This therapy offers an immediate and definitive solution to the symptoms of an irreversibly infected or necrotic primary molar, but it is not without detrimental consequences. Subsequent space loss and complications with the eruption of the permanent successor frequently ensue. Use of space maintenance to prevent a loss in arch length, incurs additional cost, oral hygiene care, appliance maintenance and more frequent recall exams (Nakornchai et al. 2010). In a five year survey by Rajab et al. (2002), the reported overall success rate for both fixed and removable space maintainers, that included band and loops, lingual arches, Nance appliances, and partial dentures, was 30.7%.
The advantage of root canal therapy is that it preserves masticatory function and maintains space for the succedaneous permanent tooth. It also avoids the precocious eruption of the permanent successor, as it has been suggested that premature loss of a primary tooth could, depending on its stage of development, accelerate or delay eruption of the succedaneous tooth (Fanning 1983, Barr et al. 1991, Fuks et al. 2002, Moskovitz et al. 2010). Additional reasons for primary root canal therapy include preservation of a pulpally involved primary tooth in the absence of a succedaneous tooth, prevention of aberrant tongue habits, prevention of possible speech problems, maintenance of esthetics and prevention of possible psychological effects of premature tooth loss (Goerig & Camp 1983).

3) **Intracanal Microbial Flora of Infected Primary Molars**

Various *in vitro* studies have cultured the microorganisms obtained from necrotic primary teeth and reported that *Streptococcus salivarius*, *alpha hemolytic Streptococci* (including *Streptococcus mitis*), *beta hemolytic Streptococci*, *gamma hemolytic Streptococci*, *Staphylococcus albus* and *Enterococcus faecalis* are the most frequently occurring microorganisms in the pulp canals of infected primary molars (Cohen 1960, Engstrom 1964, March 1967, Tchaou et al. 1995). However, other microbes such as *Staphylococcus aureus*, *Lactobacillus casei*, *Candida albicans*, *Neisseria catarrhalis* and enteric *Bacilli* are also found (Cohen et al. 1960, Engstrom 1964, Marsh & Largent 1967, Tchaou 1995). Usually two to five microorganisms have been reported per infected primary molar (Cohen et al. 1960, Marsh & Largent 1967).
Hobson (1970) found that in a sample of extracted primary teeth with necrotic tissue, 70% of
dentinal tubules were penetrated by microorganisms. He proposed that root resorption could
lead to the release of harmful microorganisms and infect adjacent tissues. He concluded that
the use of an intracanal antimicrobial drug would be desirable in the treatment of non-vital
infected primary teeth.

The complex bacterial population observed in the root canals of infected primary molars
indicates that therapy should be directed towards the reduction and/or elimination of the
bacterial flora. This would involve both a thorough mechanical debridement of the endodontic
spaces as well as the intracanal placement of an effective antimicrobial agent to destroy any
remaining microorganisms (Fuks 2000).

4) Variations in Root Canal Therapy Technique

A. Irrigation

An important objective in root canal therapy is the removal of potentially-infected pulpal and
dentinal debris from the root canal system. In order to accomplish this objective, it is essential
to use an irrigant during the biomechanical preparation of the canal system (Harrison 1984). It
has been established that microorganisms, either remaining in the root canal space after
treatment or re-colonizing the filled canal system, are the main cause of endodontic failure
(Zehnder 2007). As a result, the use of chemical agents, including those contained in the
irrigation solutions, is of utmost importance in disinfecting the canals for root canal therapy of
primary molars.
Root canal irrigants should ideally have a broad antimicrobial spectrum, be capable of dissolving necrotic pulp tissue remnants and be non-toxic to the periradicular tissues (Harrison 1984, Zehnder 2007). Two factors that are important in the consideration of irrigation for root canal therapy of primary teeth are:

- The preservation of the developing follicle of the permanent tooth germ
- The abundance of lateral and accessory canals in primary molars

Historically, numerous compounds in aqueous solutions have been suggested as root canal irrigants (Harrison 1984) but in the literature for root canal therapy of primary teeth it has been reported that the most commonly used irrigants are sodium hypochlorite, hydrogen peroxide and saline (Rifkin 1980, Garcia-Godoy 1987, Dominguez Reyes & Solano Reina 1989, Holan & Fuks 1993, Coll et al. 1995, Nadkarni & Damie 2000, Rosendahl & Weinart-Grodd 2000, Fuks et al. 2002, Moskovitz et al. 2005, Ozalp et al. 2005, Nakornchai et al. 2010).

Sodium hypochlorite is an effective hemostatic agent, which helps to dissolve organic material. It is reportedly not toxic to pulpal tissues and does not interfere with pulpal healing (Fuks 2000, Nakornchai et al. 2005). A 5.25% sodium hypochlorite solution is hypertonic (approximately 2800mOsm/kg). The clinical efficacy of the solution is due to its ability to oxidize, hydrolyze and to some extent, osmotically draw fluids out of tissues (Pashley et al. 1985). It is inexpensive, has an extremely long shelf life, provides a lubricating effect for instrumentation along the canal walls, and increases the permeability of dentinal tubules for easier penetration by an intracanal medicament (Harrison 1984). However, it is also a potent tissue irritant to vital tissues (Rifkin 1980). It must be used judiciously and with great caution.
to prevent it from reaching the periapex where it can elicit a severe inflammatory reactions (Pashley et al. 1985, Fuks 2000, Mehdipour et al. 2007, AAPD guidelines 2010).

Hydrogen peroxide is also used as an irrigation solution in primary teeth (Garcia-Godoy 1987, Holan & Fuks 1993). It has the main advantage of effervescence, which occurs when it comes into contact with catalase, an enzyme present in cellular and blood products. The effervescence is believed to facilitate clearance of debris through the tortuous canals of primary molars. In addition, the nascent oxygen resulting from the chemical reaction with catalase is believed to be effective in destroying some strict anaerobes. As a result hydrogen peroxide is also mildly antimicrobial (Harrison 1984). Its main disadvantage however is that it does not possess the capacity to dissolve organic tissue (Harrison 1984, Zehnder 2007).

Sterile saline may also be used as an alternative solution, though some consider it an inert solution, lacking in antimicrobial properties (O’Riordan & Coll 1979, Zehnder 2007). Despite this, it is frequently used for irrigation (Mass & Zilberman 1989, Barr et al. 1991, Bawazir & Salama 2006).

A primary molar pulpectomy study by Ozalp et al. (2005), reported irrigating with a 5% sodium hypochlorite solution during root canal debridement followed by a final irrigation solution of 0.5% metronidazole. There was no explanation or reference given in the paper as to why the authors elected to use a final antibiotic rinse (Ozalp et al. 2005).
B. **Obturation**

I. **Instrumentation**

Various obturation techniques have been reported for primary teeth, including the use of a pressure syringe, a premixed syringe, a lentulo spiral and an endodontic plugger (Sigurdsson et al. 1992, Dandashi et al. 1993, Nurko et al. 2000, Fuks et al. 2002, Moskovitz et al. 2005, Bawazir & Salama 2006, Sari & Okte 2008). An ideal root canal obturation technique should provide complete filling of the canal without overfill (any radiopaque material extruded beyond apex) and with minimal or no voids (Guelmann et al. 2004).

The lentulo spiral has been reported to be the most effective instrument for carrying calcium hydroxide paste to the working length and to produce the highest quality obturation (Sigurdsson et al. 1992). Aylard and Johnson (1987), however, reported that the endodontic pressure syringe and the lentulo spiral were superior for filling straight canals while the lentulo spiral was superior for the obturation of curved canals. When considering the depth of fill properties, it was concluded that the lentulo spiral was the best overall ZOE filling tool (Aylard & Johnson 1987). Previous *in vitro* and *in vivo* studies of obturation methods in primary teeth showed the lentulo spiral to perform equal or better compared to other techniques (Sigurdsson et al. 1992, Dandashi et al. 1993, Bawazir & Salama 2006).

II. **Obturation Materials**

The ideal root canal filling material should be: antimicrobial, easy to manipulate, easily removed if necessary, resorbable (at the same rate as the primary root), biologically safe, cost
effective, radiopaque, adhesive to root canal walls, non-shrinking, non-soluble and should not harm periapical tissues nor affect the development or eruption of succedaneous teeth (Rifkin 1980, Holan & Fuks 1993, Fuks et al. 2002). None of the available obturating materials fulfill all of these criteria.

Various materials have been used as endodontic obturating agents in primary teeth. Among the most common are: unfortified zinc oxide eugenol (ZOE), used either alone or applied with formocresol, iodoform and camphorated parachlorophenol pastes (such as Kri paste or Endoflas FS) as well as iodoform and calcium hydroxide mixtures (such as Vitapex®) (Castagnola & Orlay 1952, Rifkin 1980, Coll et al. 1985, Coll et al. 1988, Barr et al. 1991, Holan & Fuks 1993, Coll & Sadrian 1996, Nurko et al. 1999, Fuks et al. 2002, Mortazavi & Mesbahi 2004, Primosch et al. 2007).

The antimicrobial properties of endodontic medicaments contained in obturation materials have been tested in vitro (Pear 1942, Cohen et al. 1960, Marsh & Largent 1967, Wesley et al. 1970, Brilliant et al. 1974, Cox et al. 1978, Tchaou et al. 1995, Tchaou et al. 1996). These studies have involved the culturing of bacteria obtained from the putrescent pulps of primary teeth in agar dishes. Thereafter various root filling materials were placed in punched out wells within the agar and the zones of inhibition for each filling material were measured. In all studies, formocresol was found to have superior antimicrobial activity against the microorganisms found in the canals of abscessed primary molars (Pear 1942, Cohen et al. 1960, Marsh & Largent 1967, Wesley et al. 1970, Brilliant et al. 1974, Cox et al. 1978, Tchaou et al. 1995, Tchaou et al. 1996).
Camphorated parachlorophenol mixtures (2.025% para-chlorophenol, 4.860% camphor, 1.215% menthol, 80.80% iodoform) showed similar but consistently less antimicrobial activity than formocresol. According to Castagnola and Orlay (1952) Kri 1 paste produced a 1.5 to 2.2 cm ring of inhibition against staphylococci, streptococci and mixed anaerobes grown on agar. Formocresol was also evaluated and found to produce a 2.0 to 2.6 cm ring of inhibition against the same microbes. According to Castagnola and Orlay (1952), the degree of bacterial inhibition produced by formocresol was described as a “rather strong” reaction, yet “approximately the same” as chlorophenol.

Significantly less antimicrobial activity was found with eugenol or ZOE (used alone), iodoform and calcium hydroxide mixtures (Pear 1942, Cox et al. 1978, Tchaou et al. 1995, Tchaou et al. 1996, Reddy & Ramakrishna 2007).

When antimicrobials were tested against enterococci faecalis, which are known to be the most difficult bacteria to destroy in root canals (Engstrom 1964), metacresylacetate (cresatin), camphorated chlorophenol, eugenol and phenol were essentially ineffective, while formocresol was the only medicament that routinely produced negative cultures (Brilliant et al. 1974). Wolfsohn (1958) also tested the antibacterial activity of various endodontic medicaments in vitro by applying them on discs that were subsequently placed on inoculated culture plates. Formocresol produced the largest zone of inhibition; camphorated parachlorophenol was almost as effective.

Despite the weak antibacterial activity from the above-listed alternative pulp medicaments from in vitro studies, many clinical studies have reported high clinical success rates with root
filling materials containing some of these medicaments (Castagnola & Orlay 1957, Rifkin 1982, Garcia-Godoy 1987, Mass & Zilberman 1989, Holan & Fuks 1993, Reddy & Fernandes 1996, Nurko & Garcia-Godoy 1999, Nadkarni & Damie 2000, Mortazavi & Mesbahi 2004, Moskovitz et al. 2005, Sari & Okte 2008). Possible explanations for this disparity may be related to a difference in space (root canal versus petri dish), medicament dosing, surface tension, time, dentin permeability, lateral canals, pH, moisture or microbial flora (Wesley et al. 1970). Alternatively, the high clinical success rates reported in the aforementioned studies, may be based on a lack of symptoms, which does not necessarily indicate that the inflammatory and/or infective process has been resolved.

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

III. Obturation of the Canals

In a study by Yacobi et al. (1991), primary teeth treated by ZOE root canal therapy were more likely to have successful results if canals were adequately filled compared to underfilled (p<0.001). Similarly, for root canal therapy in primary molars using ZOE, Bawazir and Salama (2006) reported a significantly lower radiographic success rate (56%) for teeth that were underfilled.

To the contrary, in a study by Holan and Fuks (1993), 89% (8/9) of primary molars filled flush to the apex with ZOE paste were successful. Overfilling the canals resulted in a success rate of 41% (7/17) while underfilling the canals resulted in an 83% (5/6) success rate (Holan & Fuks 1993).

Coll and Sadrian (1996) found that ZOE and formocresol root canal therapy success rates were significantly lower in primary teeth that had been overfilled. Success rate for underfilled canals was 86.5% (32/37) and for those filled to the apex was 88.9% (16/18). These were significantly greater (P = 0.011) than the success rate of overfilled canals, which was 57.7% (15/26).

Holan and Fuks (1993) also reported on the outcome of primary molar root canal therapy using Kri 1 paste, an obturation material containing 80% iodoform. They reported a 100% (7/7) success rate for primary molars that were obturated flush at the apex, an 86% (6/7) success rate for canals that were underfilled and a 79% (23/29) success rate for canals that were overfilled. These differences were not significant.
Endoflas is an alternative obturation material containing 41% iodoform and 57% zinc oxide. According to Fuks et al. (2002) and Moskovitz et al. (2005), primary molars treated by Endoflas-root canal therapy also showed a decreased success rate with overfilled root canals.

Fuks et al. (2002) reported that in Endoflas-filled primary incisors and molars, a success rate of 58% was reported when canals were overfilled and a success rate of 83% was reported when canals were adequately filled or underfilled (p>0.09). In this paper they refer to two non-existent tables to outline these results, thereby neglecting to display the actual data to support these findings (Fuks et al. 2002).

Moskovitz et al. (2005) reported the following outcomes for primary molars treated by Endoflas-root canal therapy: a 91% (31/34) success rate for underfilled canals, an 85% (17/20) success rate for flush-filled canals, and a 76% (58/76) success rate for canals that were overfilled.

Despite the fact that both Kri 1 paste and Endoflas are reportedly easily resorbed materials they still tend to produce decreased outcomes when extruded beyond the apex. The above-listed findings indicate the avoidance of overfilling canals for root canal therapy for primary teeth in order to maximize clinical success (Barker & Lockett 1971, Rifkin 1982, Holand & Fuks 1993, Fuks et al. 2002).

When applying this finding clinically, it is important to recognize that the radiographic apex does not necessarily coincide with the anatomical apex, due to the physiologic or pathologic resorption of the root of the primary tooth (Zurcher 1925, Allen 1979, Rimondini & Baroni
Therefore, the actual extent of root filling may exceed the extent evaluated on the radiograph, meaning that some cases evaluated as ‘flush fill’ could in fact be categorized as ‘overfill’ and those evaluated as ‘underfill’ may in fact be categorized as ‘flush fill’ (Moskovitz et al. 2005).

C. Final Restoration

The standard of care for the treatment of dental decay in primary teeth is to remove all decayed tissues, before restoring the tooth with a filling material. This process, however, can leave the tooth structurally weak, through the loss of decayed tissue, the unavoidable loss of sound tissue necessary to gain access to the decay and through the creation of resistance and retention form (Innes et al. 2007).

Stainless steel crowns are considered the restoration of choice for primary molars with multi-surface lesions, extensive caries and those where pulpal treatment has been performed (Kilpatrick 1993, Fayle et al. 2001, Threlfall et al. 2005, Nakornchai et al. 2010, AAPD Guidelines 2010). Any other direct restorative material, such as amalgam or composite resin, should only be used as an alternative one surface restoration following pulp therapy in a primary tooth if there is sufficient coronal tooth structure remaining and the primary tooth has a life span of two years or less (Holan et al. 2002, Guelmann et al. 2005).

Moskovitz et al. (2005) demonstrated a 96% success rate in pulpectomized teeth that were restored with stainless steel crowns while only 29% of teeth left with a temporary restoration exhibited a successful root canal therapy. In 2010, Moskovitz et al. reported that patients who
were left with temporary restoration following root canal therapy and failed to return on time for stainless steel crown restorations resulted in seven of 16 teeth being extracted. Properly adapted stainless steel crowns significantly reduce the possibility of microleakage (Fuks et al. 2002).

Roberts and Sherriff (1990) reported a retrospective study evaluating the fate of 1688 amalgam restorations and 716 stainless steel crowns over a 10 year period by the same operator. They described 5-year survival estimates for class I and class II restorations in primary molar amalgams to be 73.3% and 66.6%, respectively. For all pre-formed crowns (permanent and primary teeth), they found a 92% 5-year survival estimate.

Sixty-six pediatric dental patients were included in a split mouth design study comparing the lifespan of multi-surface amalgam restorations versus stainless steel crowns on primary molars (Einwag & Dunninger 1996). After one year the survival rate for multi-surface amalgams was just under 80%. After 4.5 years, the rate was well below 40%. In contrast, the survival rate for stainless steel crowns at 4.5 years was more than 90%. The authors found that the average lifespan for a stainless steel crown on a primary molar was 83% to 89% (range was stated since some primary molars were extracted for orthodontic reasons).

In the permanent dentition, the perils of coronal leakage following endodontic treatment were first described by Marshall and Messler in 1961. Ray & Trope (1995) and Kirkevang et al. (2000) found that the technical quality of coronal restorations had a significantly greater impact on periapical health than the technical quality of the root canal filling. Conversely,
Tronstad et al. (2000) found that the technical quality of endodontic treatment was significantly more important than the technical quality of the coronal restoration.

More recently several retrospective cohort studies supported the former findings about the importance of adequate coronal restorations. Acquilino and Caplan (2002) found that endodontically treated teeth that had amalgam or composite restorations were six times more likely to be lost than crowned teeth. Nagasiri et al. (2005) evaluated the outcome of 220 endodontically-treated permanent teeth without crown coverage. Overall success rates at one, two and five years were 96%, 88% and 36% respectively. These values represented restorative failures as all teeth that failed due to endodontic or periodontal reasons were excluded from the study. Remaining coronal tooth structure and type of restorative material had significant associations with tooth survival.

The results of these studies all substantiate the strong association between crown placement and the survival of endodontically-treated teeth. It should therefore be a consideration in treatment planning if long term tooth retention is the primary goal (Acquilino & Caplan 2002).

D. Single or Multiple Appointments

Rabinowitch (1953) reported on the success of 1363 vital and non-vital primary molars treated by root canal therapy using ZOE, formocresol and ammonia silver nitrate (a known antimicrobial agent since the 19th century (Chopra 2007)). He reported that an average of 5.5 visits were required for non-periapically involved teeth and an average of 7.7 visits were required for teeth with periapical involvement. Rabinowitch reported only seven known
failures out of the 1363 teeth treated, but it was not clear from his report if or how often the

treated teeth were followed up.

Velling (1961) suggested treating infected primary teeth by sealing a cotton pellet damped in
formalin creosote solution in the pulp chamber for three to five days. The final filling material
was ZOE into the pulp chamber. Velling reported five known failures of the 863 endodontically
treated teeth. Clinical and radiographic follow-up was reportedly completed when possible,
however figures for how many teeth were actually evaluated on recall were not included in
the study.

Rifkin (1980) reported a success rate of 89.7% (26/29) with a one to three appointment Kri
root canal therapy technique in primary molars and incisors over a period of 12 months.

Garcia-Godoy (1987) reported a two to four visit root canal procedure wherein a cotton pellet
moistened with Kri 3 liquid (25% para-chlorophenol) was sealed in the pulp chamber for three
to seven days or until no intracoronal exudate was found. The author reported a 95.6%
success rate after a follow up time period of 24 months.

In 1972, Gould was the first to report a one-visit ZOE root canal therapy method, using
camphorated monochlorphenol as the sterilizing agent and a thick mix of ZOE as the final root
canal filling material. He found that 35 of the 39 (or 90%) primary molars treated had a
successful outcome after a mean follow up time of 16 months.
O’Riordan and Coll (1979) and Coll et al. (1985) described one visit root canal therapy procedures for primary teeth. After mechanical preparation, they inserted paper points moistened with formocresol in the canals for five minutes and then obturated the root canals with ZOE as the final filling material. Coll et al. (1985) reported an 86.1% success rate after five or more years of follow up.

Other one-appointment root canal therapy techniques reported success rates ranging from 76% to 96.7% (Barr et al. 1991, Bawazir & Salama 2006, Primosch et al. 2007, Moskovitz et al. 2010).

With the inherent variances of primary tooth root canal therapy studies, it is difficult to determine the importance of a multi-visit technique versus a one-visit technique. There is however, unanimous evidence that root canals must be dried before they can be obturated (Gould 1972, O’Riordan & Coll 1979, Rifkin 1982, Coll et al. 1985, Garcia-Godoy 1987). Thus, if intracanal exudate cannot be controlled, then a multi-visit technique should be considered (Garcia-Godoy 1987).

E. Medicaments

I. Formocresol

Formocresol has been used in dentistry since Buckley introduced it in 1904. Buckley’s formula is a mixture of 19% formaldehyde, 35% cresol in a vehicle of 15% glycerin and water (Buckley 1908). Its antimicrobial action comes largely from formaldehyde, which fixes pulpal tissues by its vapors, acting ahead of cresol (Ranly et al. 1975, Full 1979, Mortazavi & Mesbah 2004).
Formaldehyde is a flammable and colourless gas at room temperature and pressure but is most commonly available commercially as a diluted aqueous solution, to a maximum concentration of 37%, referred to as formalin (WHO 1989). Buckley’s formocresol is bacteriostatic at a concentration of 0.020 and 0.025% formocresol and bactericidal at a concentration between 0.33 to 0.50% on cultures of *Streptococcus faecalis*, *Streptococcus salivarius* and *Staphylococcus aureus* (Verco 2000).

Buckley selected cresol as a solvent for formaldehyde because it is miscible with formalin, is a good disinfectant and chemically breaks down fatty compounds (Buckley 1905). Its latter ability to destroy cellular integrity presumably allows for deeper tissue fixation by the formaldehyde component of formocresol (Milnes 2006). Cresol has poor solubility and diffusibility due to its lipophilic nature and is metabolized to benzyl alcohol *in situ* (Mejare & Mejare 1978). The latter is a non-toxic metabolite (Kahl et al. 2008). Glycerin is used as an emulsifier to prevent polymerization of the formaldehyde to paraformaldehyde (‘s-Gravenmade 1975).

**II. Unfortified Zinc Oxide Eugenol (ZOE)**

Eugenol was the first essential oil proved to be a significant germicide and was first used in dentistry in 1876 by Chrisholm when he added zinc oxide to eugenol to make zinc oxide eugenol or ZOE (Meeker & Linke 1988). When in direct contact and at high doses eugenol can be cytotoxic. However in low doses and in indirect contact (as with a layer of dentin separating the pulp), eugenol has analgesic and anti-inflammatory properties (Markowitz et al. 1992). The use of ZOE to fill the root canals of primary teeth was first described by Sweet in 1930.

Gould (1972) was the first to report on a one-visit root canal therapy procedure for primary molars filled with ZOE. The prospective preliminary study involved only primary mandibular molars due to their relative ease of radiographic interpretation. Also, any tooth that had evidence of physiologic or pathologic root resorption was excluded from the study. With a sample size of 35 and a mean and median follow-up time of 16 months, the author reported 29 apparent successful treatments, one clinical failure, three radiographic failures and two questionable outcomes. The overall success rate was therefore 87.9% (29/33). The reported methodology consisted of filing and drying of canals, a five-minute application of a camphorated monochlorophenol-soaked cotton pellet in the pulp chamber, followed by the condensation of ZOE using endodontic pluggers. A caveat in the study was the fact that no specific criteria for success were stated. Furthermore the study group did not include primary maxillary teeth or primary teeth with physiological or pathological root resorption, which may not have been representative of the teeth that are treated in clinical situations (Gould 1972).

In a study evaluating the success rate of ZOE root canal therapy treatment of 34 irreversibly infected or necrotic primary molars, Holan and Fuks (1993) reported an overall success rate of 65% with a follow-up time of 6 to 84 months (no mean time given). Interestingly, the level of
root canal obturation was significant in determining the outcome for root canal therapy. While primary molars that were obturated flush to the apex resulted in an 89% success rate, those that were overfilled resulted in a 41% success rate (number of teeth in each group not given).

Yacobi et al. (1991) reported an 84% success rate with ZOE primary molar root canal therapy after a follow-up time of 12 months (n=49). However the authors designed the study with the intention that ZOE root canal therapy be used in lieu of aldehyde-containing pulpotomy techniques in the treatment of vital primary teeth. The study was therefore biased by including vital teeth that were merely “cariously infected”. This was unlike all other primary tooth root canal therapy studies which included irreversibly infected or necrotic teeth in their study groups (Gould 1972, Coll et al. 1985, Coll et al. 1988, Barr et al. 1991, Sadrian & Coll 1993, Holan & Fuks 1993, Mortazavi & Mesbahi 2004, Primosch et al. 2007). Furthermore when the same group of authors published a two-year report on the same study group, now a sample size of 103 primary molars, the outcome of successful treatment dropped to 67% (Payne et al. 1993).

Coll et al. (1988) reported on 27 primary incisor ZOE root canal therapy treatments followed for a mean of 45.5 months. They reported a 77.7% (21/27) success rate. Nadkarni and Damie (2000) reported an 89% success rate when 35 primary mandibular molars were treated by 2-appointment ZOE root canal therapy after a relatively short follow up time of nine months.
III. Unfortified ZOE and Formocresol

The reported successful outcomes for formocresol and zinc oxide root canal therapy procedures range from 74.5 to 99% (Rabinowitch 1953, Coll et al. 1985, Barr et al. 1991, Coll & Sadrian 1996, Mortazavi & Mesbahi 2004, Primosch et al. 2007). Although the materials used in the root canal therapy techniques of the aforementioned papers were the same, the manner in which they were used was not consistent. Further variations in these studies included:

- The number of appointments required to complete root canal therapy
- The inclusion criteria
- The sample size
- The duration of follow-up
- The definition of successful outcome
- The complete disclosure of results

These differences may explain the wide range of outcomes reported for root canal therapy using ZOE and formocresol as the root canal medicaments.

Rabinowitch (1953) reported a 99% success rate for a multi-visit root canal therapy technique using formocresol, ZOE and an ammoniacal silver nitrate solution in 1,363 primary molars. The only reported contraindication for root canal therapy was excessive root resorption. A minimum of four appointments (and a maximum of 17 reported appointments) were used for this technique:
• Appointment #1- A formocresol-moistened cotton pellet was placed in contact with the exposed pulp and sealed with ZOE.

• Appointment #2- All caries were removed, files were instrumented in canals just short of the apex and a formocresol solution (beechwood creosote, or cresol 50%, saturated formaldehyde solution 40%, absolute alcohol 20%) was sealed (presumably on a cotton pellet, though not described in the paper) in the tooth with zinc oxide.

• Appointment #3- The canals were once again instrumented just short of the apex and Howe’s ammoniacal silver nitrate solution was applied for one minute using a number 3 explorer or broach. Eugenol was then applied to the canals to ‘reduce’ the canal spaces and the tooth was sealed with ZOE for five to seven days.

• Appointment #4- Howe’s ammoniacal silver nitrate solution could be used again to mummify the canals and the canals were thereafter obturated with zinc oxide.

Rabinowitch (1953) reported that further treatments with formocresol and Howe’s ammoniacal silver nitrate solution were continued as necessary to eliminate infection. On average, 5.5 appointments were required for endodontically-treated teeth that had no pre-operative periapical involvement and an average of 7.7 appointments were required for endodontically-treated teeth with pre-operative periapical involvement. Silver nitrate was used for its anti-bacterial properties. Though not well understood in 1953, silver nitrate has since been shown to inhibit DNA replication in various gram-positive and gram-negative bacteria (Feng et al. 2000). In addition, silver ions interact with thiol groups, thus inactivating bacterial proteins (Feng et al. 2000).
Permanent restorations (amalgam restorations or stainless steel crowns) were reportedly usually placed about two to four weeks after the final appointment. The author reported seven failures but it was unclear how the author defined successful treatment. There was also no information given regarding the method of recall for these endodontically-treated teeth (Rabinowitch 1953).

In addition to the aforementioned voids in this study, this technique is not clinically applicable, as asking a patient return a minimum of four times to complete one root canal therapy treatment is impractical for both the patient as well as the clinician.

In a clinical report, O’Riordan and Coll (1979) introduced a one appointment primary tooth root canal therapy technique involving the placement of slightly moistened paper points with Buckley’s formocresol in each canal for five minutes followed by the condensation of a thick paste of ZOE into the root canals. This proposed technique was evaluated by Coll et al. (1985) who reported an 80.5% (33/41) success rate at the first recall exam (6 to 36 month post-treatment with a mean follow-up time of 21 months). On re-evaluation five years or more later, 86.1% (25/29) primary molars were considered successfully treated.

The inclusion criteria used for the Coll et al. (1985) study were narrow relative to other studies (Garcia-Godoy 1987, Mass & Zilberman 1989, Barr et al. 1991, Holan & Fuks 1993, Nadkarni & Damie 2000, Mortazavi & Mesbahi 2004). Contraindications to primary molar root canal therapy included:
1. Primary molars that were mobile vertically or displayed extensive furcation radiolucencies involving more than one half of the root.

2. Internal (root) resorption or other radiographic signs of pathologic root resorption involving more than the apical tip of the root.

3. A firm apical stop resistance point could not be obtained with a size 40 file or smaller.

These strict inclusion criteria undoubtedly had a positive effect on the reported successful outcome of this study. Other conclusions drawn by Coll et al. (1985) included: no significant difference in outcome between molar types and failures were most likely to occur in the first six months following treatment. Given the final sample size of 29 subjects the power of this study, though not reported, was low.

Coll and Sadrian (1996) used the same ZOE and formocresol root canal therapy technique as described in Coll et al. (1985) but increased their sample size to 54 primary molars and included 27 primary incisors. The success rate for primary molars was 74.5% (38/51) and 83.3% (25/30) for primary incisors after a mean follow-up time of 90.8 months (range = 20 to 177 months). This often cited paper (Nurko & Garcia-Godoy 1999, Nadkarni & Damie 2000, Primosch et al. 2005, Prabhakar et al. 2008, Sari & Okte 2008, Nakornchai et al. 2010, AAPD 2010) is usually quoted with an overall success rate of 77.7% despite the fact that primary molars have a lower success rate than primary incisors. The authors may have decided to list the results as such given the fact that their statistical analysis showed no significant difference between the outcome of molars and incisors (p = 0.53). However, the amalgamation of these outcomes seems particularly unfit given the small sample size and the fact that 30% of the
primary incisors treated by root canal therapy in this study were necrotic due to trauma, a very different type of inflammatory reaction than caries into the pulp.

The authors also proposed that primary teeth with greater than 1mm of root resorption had a 23.1% success rate, which was significantly lower than the teeth which had no evidence or less than one millimeter of root resorption preoperatively, however this was based on a sample of 13 primary teeth (3/13). Similarly, the authors proposed that primary teeth with greater than 1mm of root resorption were also more likely to be overfilled (P = 0.054). This conclusion was based on a sample size of 13 teeth (7/13). Root canal therapy success rates were 57.7% (15/26) for teeth that were overfilled, which was significantly lower (p<0.011) than teeth that were completely filled (88.9% or 16/18) or filled short (86.5% of 32/37). The authors did not disclose if these teeth were primary incisors or molars.

Other factors which were tested but found to have no statistical significance to the outcome of ZOE and formocresol root canal therapy were: timing for tooth loss, ZOE retention, enamel defects and age of the patient at treatment time (Coll & Sadrian 1996).

One caveat in both the Coll et al. 1985 and the Coll and Sadrian 1996 papers is the authors’ neglect to disclose the specific results for clinical and radiographic success rates. Rather they stated an undefined “overall success rate”, which leaves its readers guessing if overall success refers to clinical success, radiographic success or a mean of the former and latter. In addition, they neglected to describe how endodontically-treated primary molars were restored. Based on the figures in their published reports, it appears that they used stainless steel crowns to
restore treated teeth, however the reader cannot be certain if these were always the
restoration of choice since it was not clearly stated (Coll et al. 1985, Coll & Sadrian 1996).

Bawazir and Salama (2006) also reported using the root canal therapy technique proposed by
O’Riordan and Coll (1979), involving the placement of formocresol-moistened paper points in
canals for five minutes, followed by ZOE obturation. The authors’ prospective study was a 6-
month report on the treatment of 47 primary molars in patients between the ages of 4.5 and
9 years of age. A tooth was excluded from the study when it was unrestorable, had a
pathologic lesion extending to the succedaneous tooth germ or had evidence of extensive
internal or external pathological root resorption. A single operator performed all root canal
therapy procedures in one appointment and the teeth were immediately restored with a
stainless steel crown. The clinical and radiographic criteria for successful treatment included:
no abnormal mobility, no sensitivity to percussion, no swelling, resolution of preoperative
pathologic interradicular and/or periapical radiolucencies, absence of new postoperative
pathologic radiolucencies and absence of pathologic internal or external root resorption.

At the 6-month follow-up exam, the overall clinical and radiographic success rate was 93.6%
and 80.9%, respectively. The reasons for clinical failure included a fistula and pathologic
mobility. The reasons for radiographic failure included pathologic root resorption and
development of a new pathologic radiolucency. The authors also assessed the effect of root
canal filling quality on success rate and proposed that teeth that were optimally filled or
overfilled showed a higher radiographic success rate than underfilled teeth, which was
contrary to other reports (Holan & Fuks 1993, Coll et al. 1996, Fuks et al. 2002, Moskovitz et
al. 2005). They found a statistically significant difference in these groups (p<.05), however this
conclusion was based on a sample size of 25 optimally filled teeth, 16 underfilled teeth and 6 overfilled teeth.

Barr et al. (1991) reported an 82.3% radiographic success rate in a retrospective study of 62 primary molars treated by formocresol and ZOE root canal therapy over a follow-up time of 40.2 months on average (range = 12 to 74 months). The obturation paste consisted of a thick mixture of one drop of diluted formocresol (two parts glycerin, one part formocresol), mixed with eugenol and zinc oxide powder. All root canal therapy treatments were completed in one appointment, except in two cases (2/62 or 3.2%), which required re-treatment.

Barr et al. (1991) clearly defined their inclusion criteria, contraindications to root canal therapy and definition of successful outcome. Inclusion criteria included:

1. Prolonged pain
2. Presence of pathologic sinus or parulis
3. Limited mobility
4. Hemorrhagic or necrotic pulpal tissue
5. Minimal pathologic root resorption
6. Radiographic evidence of minimal bony degeneration

Contraindications to root canal therapy included:

1. Unrestorable tooth
2. Excessive root resorption and/or loss of bony support
The treatment outcome was judged to be successful under three conditions:

1. When the tooth had been maintained without radiographic evidence of pathologic changes
2. When there was evidence of a previously diagnosed radiolucency, but the bony lesion had decreased in size
3. When the loss of integrity of the lamina dura present in the pre-operative radiograph had not resolved but no other pathoses had developed

Although Barr et al. (1991) did not report any of the preoperative or postoperative clinical signs and symptoms, they did report that 9 teeth were extracted due to root canal therapy failure (six teeth were also extracted for orthodontic reasons). In addition, the authors proposed that advanced exfoliation of endodontically-treated teeth was observed in 56% of teeth while none of the endodontically-treated teeth demonstrated delayed exfoliation. However the authors neglected to describe the condition of the contralateral teeth (i.e. unrestored, restored pulpotomized, extracted) and they also neglected to characterize the range of reported advanced exfoliation times.

Mortazavi & Mesbah (2004) described a root canal therapy technique wherein a formocresol-moistened cotton pledget was temporarily sealed in pulp chambers for one to two weeks before a final obturation with ZOE was completed at a second appointment. All primary molars were restored with amalgam restorations and all primary incisors were restored with composite resin restorations.
This was a prospective study which compared two root canal therapy techniques: formocresol and ZOE obturation versus formocresol and Vitapex® obturation. Although the overall sample size was 58 subjects, only 29 primary molars and 2 traumatized primary incisors were treated by root canal therapy using formocresol and ZOE, while the remaining 26 primary teeth were treated by root canal therapy using formocresol and Vitapex®. Six subjects did not present for follow-up, and were thus excluded, reducing the final sample size to 52 subjects (Mortazavi & Mesbahi 2004). It was not clear from the published report which treatment groups lost the six teeth. Since the authors did not comment on specific final sample sizes, it cannot be assumed that these changes were accounted for in the overall results.

The criteria for selection of teeth included in this study were: the presence of abscess or sinus tract, evidence of pathologic processes radiographically (ranging from slight thinning of the trabecular pattern to large areas of radiolucency in the furcation and/or periapical region, little or no pulp tissue remaining when the pulp chamber was entered. Contraindications for root canal therapy in this study included: unrestorable crown or perforated pulpal floor (Mortazavi & Mesbahi 2004).

Clinical and radiographic follow-up for this study occurred at three months and again at 10 to 16 months. The clinical criteria for success included absence of pain, fistula, intra-oral swelling, extra-oral swelling or abnormal mobility. The radiographic criteria for success were assessed at the 10 to 16month follow-up. These criteria included reduction in the size of a radiolucent area if present pre-operatively and no newly formed radiolucency. In addition, the authors considered absence of deflection to the eruption of a succedaneous tooth to be a successful outcome (Mortazavi & Mesbahi 2004).
The authors reported a 78.5% overall success rate for the ZOE and formocresol root canal therapy technique. The manner in which this figure was calculated was left out of the paper. Table 3 suggests that the clinical success rate was 78.9% and table 4 suggests that the radiographic success rate was 75.0%. The paucity of evidence provided may leave some readers questioning the authors’ conclusions (Mortazavi & Mesbahi 2004).

It should be noted that an in vitro study by Mejare and Mejare (1978) reported that the presence of eugenol in a formocresol and zinc oxide pulp dressing gave a smaller initial release of formaldehyde, compared with the release of formaldehyde from ZnO alone, but a more prolonged diffusion. A higher initial release of formaldehyde was obtained when the formocresol was incorporated in ZnO alone compared with ZnO-eugenol cement (Mejare & Mejare 1978).

IV. Iodoform pastes

a. Kri 1 Paste

Kri 1 paste (Teva Pharmachemie – Europe) is radiopaque endodontic root filling containing 2.025% para-chlorophenol, 4.860% camphor, 1.215% menthol and 80.80% iodoform (remaining ingredients undisclosed), which was first described by Walkhoff in 1928 (Rifkin 1980). Camphor and menthol are reportedly mixed with the antimicrobial agent, parachlorophenol, in order to minimize coagulation with adjacent tissues. Iodoform is added as a vehicle to carry the antimicrobial agent as it is a non-irritant and radiopaque (Castagnola & Orlay 1952).
Rifkin (1980) reported treating abscessed primary teeth in one to three appointments by root canal therapy using Kri 1 paste as the root filling medicament. After one year, the author reported an 89% radiographic success rate with a sample size of 26 teeth (Rifkin 1980). In 1982, Rifkin reported that by the 2.5 to 4.5 year follow-up, a radiographic success rate of 86% (6/7) was observed. The sample size at this point however was only seven primary teeth (Rifkin 1982).

In a study by Holan and Fuks (1993), the overall success rate of a one-appointment Kri root canal therapy treatment for 44 irreversibly infected or necrotic primary molars over a follow-up period of 6 to 84 months (no mean time given) was 84% (37/44). The inclusion criteria as well as the definitions for clinical and radiographic success were clearly stated. However the results were only described as an overall success rate. No mention was made as to the reasons for failure. There was also no mention that any treated teeth were extracted.

An advantage of Kri paste is its resorbability in the event that the material is extruded beyond the apex of a root canal (Barker & Lockett 1971). Post-treatment radiographs have shown that Kri paste that is inadvertently extruded from root canals is quickly resorbed (Holan & Fuks 1993), often in as little as two weeks (Rifkin 1982).

Despite several claims that iodoform, once pressed to the dried walls of root canals, adheres very well to form a non-soluble paste (Castagnola & Orlay 1952, Rifkin 1982), the contrary statement has also been reported. Resorption of Kri paste from within root canals has been
observed, leaving the root canal with no medicament long before the exfoliation of the tooth (Barker & Lockett 1971, Holan & Fuks 1993, Sadrian & Coll 1993, Fuks et al. 2000).

Microscopic analysis of voided canals has shown ingress of periodontal tissues, which occasionally lay down cementum-like tissues along the canal walls (Barker & Lockett 1971). In the endodontics lexicon, there is a well known “hollow tube” effect where it is thought that an unfilled root canal can be permeated with tissue fluid that becomes stagnant and eventually a nidus for infection; whether this actually occurs still has to be determined (Goldman & Pearson 1965, Fuks et al. 2002).

b. Kri 3 Liquid

Kri 3 liquid is a solution of 25% para-chlorophenol, 60% camphor and 15% menthol (Teva Pharmachemie – Europe). This liquid differs significantly from the commonly used Kri 1 paste in that its para-chlorophenol, camphor and menthol concentrations are twelve times greater and hence possess greater antimicrobial properties (Garcia-Godoy 1987).

Castagnola and Orlay (1957) described a two session root canal therapy technique wherein pulp was first extirpated and dressed with Kri 3 liquid, thereafter being filled with Kri 1 paste.

Garcia-Godoy (1987) reported on a similar multi-visit root canal therapy procedure wherein Kri 3 liquid, was sealed into the chamber of treated primary teeth for three to seven days, or until no intracoronal exudate was found. The final root canal obturation material was Kri 1 paste, which was transported to canals using a lentulo spiral. For narrow canals, one drop of
Kri 3 liquid was added to Kri 1 paste to facilitate its flow. Inclusion criteria and definitions for clinical and radiographic success were clearly stated but lacked detail. It was noted that teeth with extensive bone resorption over the permanent tooth were excluded from the study, however no mention was made about the presence or absence of an intact follicle for the permanent successors.

Clinical and radiographic follow-up was completed at 6 to 24 months. A success rate of 95.6% (43/45) was reported. The two failures occurred because of an unresolved pre-operative radiolucency and a fistulous tract that persisted for 15 days post-operatively.

No specific information was given as to how many primary incisors versus primary molars were successfully treated. The author reported that Kri paste resorbed within one to two weeks (Garcia-Godoy 1987), though it was not clear how this was recorded, since follow-up radiographs were reported to have begun at six months.

c. **Maisto’s Paste**

Maisto’s paste differs from Kri paste in that it also contains zinc oxide, thymol and lanolin. This formulation change was made in order to reduce the resorption rate of the paste from within the canals of endodontically treated primary teeth (Mass & Zilberman 1989). Despite this, one dog study using Maisto’s paste for root canal therapy in uninfected primary teeth showed histological evidence of ingrowth of periodontal connective tissue suggesting resorption of the filling material within the canal (Murata *et al.* 2005).
Thymol, which is derived from the aromatic mint shrub *Thymus vulgaris* as well as other fresh herbs, is a recognized antiseptic, germicide, fungicide and counter-irritant (Meeker & Linke 1988). Lanolin is a yellow waxy substance that is secreted from the sebaceous gland of wool-bearing animals, presumably added to Maisto’s paste as a lubricant (Hoppe 1999).

Maisto’s paste is safe to the periapical tissues of endodontically treated primary teeth. When inadvertently extruded from the canals, it was resorbed within two weeks to three months, without damaging the succedaneous tooth (Mass & Zilberman 1989, Reddy and Fernandes 1996).

In a case report, Mass and Zilberman (1989) used Maisto’s paste for root canal therapy in a necrotic primary mandibular second molar. Pre-operatively the tooth exhibited both vertical and horizontal mobility as well as bony furcation radiolucency. At a 3.5-year follow-up, the authors reported that the tooth was retained without symptoms and showed radiographic signs of healing.

Reddy and Fernandes (1996) reported a 100% clinical and radiographic success rate using Maisto’s paste as an obturation material in fifteen necrotic or abscessed primary incisors and molars after a follow-up period of nine months. The authors used a non-traditional form of Maisto’s paste which included iodoform, zinc oxide, camphor, thymol and lanolin, omitting the para-chlorophenol. Rather, the root canal therapy protocol described by Reddy and Fernandes involved a formocresol dressing between the first and second appointment, which was repeated as many times as necessary until the treated teeth were asymptomatic (Reddy & Fernandes 1996).
V. Calcium Hydroxide

Since its introduction in 1930 by Hermann, calcium hydroxide has been proposed as an all-purpose medicament in dentistry (Nadkarni & Damie 2000). Calcium hydroxide is widely used as a liner for deep restorations, a temporary intracanal dressing and for apexification procedures in permanent teeth (Martin & Crabb 1977, Foreman & Barnes 1990, Rosendahl & Weinart-Grodd 1995). Calcium hydroxide is also recommended as a final obturation material for root canal therapy of primary teeth (Rosendahl & Weinart-Grodd 1995, Sari & Okte 1998, Ozalp et al. 2005). However, generally the use of calcium hydroxide for pulp therapy in primary teeth has been discontinued due to the fact that it is resorbable (Martin & Crabb 1977), has weak antimicrobial properties (Sato et al. 1992, Fuks 2002, Huang et al. 2007) and may lead to aggressive internal root resorption (Via 1955, Kubota et al. 1992).

The benefits of using calcium hydroxide in primary tooth root canal therapy include its high alkaline pH, its antibacterial properties, and its ability to activate alkaline phosphatase, promoting bone formation (Dominguez Reyes & Solano Reina 1989, Sato et al. 1992). Calcium hydroxide paste is easily prepared by mixing calcium hydroxide powder with water or other hydrosoluble non-viscous vehicle until the desired consistency is achieved. However this makes the paste soluble, allowing it to resorb from the periapical area and from within the root canal (Martin & Crabb 1977, Ozalp et al. 2005, Sari and Okte 2008). Despite this, there are sparse reports of highly successful outcomes for root canal therapy using a calcium hydroxide paste for primary teeth.
Rosendahl and Weinert-Grodd (1995) published a case report involving two primary molars treated with a calcium hydroxide paste. Both teeth were followed for three and a half years and were retained until exfoliation or near exfoliation.

Sari and Okte (2008) reported a 92.3% success rate after a three-year follow-up on 52 primary teeth (25 mandibular molars and 27 anterior teeth) that were endodontically treated and obturated with a two paste calcium hydroxide paste, marketed as Sealapex. The authors’ inclusion criteria were more restrictive than any paper mentioned in this review thus far. They excluded all teeth that had furcal or periapical radiolucenties and all teeth with internal or pathologic external root resorption and/or inadequate bone support. Furthermore, they consistently used cotton roll isolation in lieu of rubber dam isolation.

Among the teeth that were classified as successful, 31 teeth (59.6%) were extracted at some point in the three-year follow-up period due to physiologic root resorption while 4 teeth (7.7%) were extracted due to the presence of periapical lesions and/or pathologic resorption. The authors reported a non-statistically significant difference when degree of canal obturation was compared to outcome. In ten of the 17 overfilled teeth, extruded calcium hydroxide was resorbed within 6 to 12 months. However in the remaining seven overfilled teeth the calcium hydroxide did not resorb completely over the 3-year follow-up period (Sari & Okte 2008).

Ozalp et al. (2005) reported on the outcome of root canal therapy of primary molars using two calcium hydroxide pastes, Sealapex and Calcicur, which are marketed as being less water-soluble than the standard calcium hydroxide pastes. Root canals filled with Sealapex performed better (18/20 successful treatments) than those filled with Calcicur (16/20
successful treatments) over an 18-month period. Teeth that were found to have abnormal mobility, evidence of an abscess or fistula, evidence of internal or pathologic external root resorption and/or inadequate bone support were excluded from the study. Treated teeth were deemed successful if they were free of clinical symptoms, had no signs of pathologic radiolucencies and had a continuous lamina dura on radiographic exam. All of the failed treatments had undergone complete intra-canal resorption of their respective obturation materials, despite re-treatments being performed (Ozalp et al. 2005). Calcium hydroxide materials are henceforth considered to be inherently soluble (Martin & Crabb 1977, Foreman & Barnes 1990).

VI. Calcium Hydroxide Combination Pastes

a. Iodoform and Calcium Hydroxide Paste (Vitapex®)

Vitapex® is a syringe-loaded viscous pre-mixed paste composed of iodoform, calcium hydroxide and silicone (Neo Dental Chemical Products Co. Tokyo, Japan). One advantage of Vitapex® is its resorbability. When extruded from the apex of a primary tooth, Vitapex® can be resorbed as early as one week to three months, without causing a foreign body reaction (Kawakami et al. 1991, Nurko & Garcia-Godoy 1999). However, much like the concern with Kri paste and calcium hydroxide, some authors have observed early resorption of Vitapex® within root canals, which could encourage re-infection as microbes can easily flourish in an unfilled root (Holland et al. 1979, Nurko & Garcia-Godoy 2000, Ozalp et al. 2005).

Calcium hydroxide and iodoform paste, as well as Vitapex®, were reported to have the highest levels of biocompatibility when tested against a line of human osteosarcoma cells, U2OS,
compared to other commonly used root canal filling materials (Huang et al. 2007). Although biocompatible, calcium hydroxide and iodoform pastes have minimal to no antimicrobial properties (Tchaou et al. 1995, Tchaou et al. 1996, Huang et al. 2007).

Despite these facts, Nurko and Garcia-Godoy (1999) reported a 100% success rate following root canal therapy of 32 primary incisors and molars obturated with Vitapex® and a follow-up time of 3 to 22 months (no mean given). The inclusion criteria and definitions for clinical and radiographic success were clearly stated. The authors did not reveal the ratio of incisors to molars included in the study. The authors also neglected to comment on the radiographic evidence of worsening periapical radiolucency, grossly underfilled root canals and overt pathologic external root resorption, which was included in their published report. Based on these radiographs alone, it is difficult to accept the authors’ reported 100% success rate.

Nakornchai et al. (2005) reported a 96% (24/25) clinical success rate and a 56% radiographic success rate (14/25) using Vitapex® for root canal therapy in primary molars at the 12-month follow-up. The authors used wide inclusion criteria, accepting primary molars with root resorption up to one half of a root’s length. Eleven of the 25 teeth were treated in two appointments due to “a great deal of gingival swelling and discharge”. The definitions for successful clinical and radiographic outcomes were clearly stated. One of these criteria included stasis of a pre-existing radiographic pathology (furcation or periapical radiolucency, internal root resorption or pathologic external root resorption). The clinical failure was due to formation of an abscess, which was identified at the 12-month recall exam. The radiographic failures were reported for the following reasons: formation or progression of furcation
radiolucency, periapical radiolucency and/or external root resorption (Nakornchai et al. 2005).

b. **Endoflas F.S.**

Endoflas F.S. (Sanlor & Cia. S. en C.S. Columbia, South America) is an FDA-approved endodontic sealer composed of an iodoform powder (tri-iodmethane and iodine dibutylorthocresol) (40.6%), zinc oxide (56.5%), calcium hydroxide (1.07%), and barium sulphate (1.63%), which is mixed with a liquid of eugenol and paramonochlorophenol. A reported advantage of Endoflas F.S. is its ability to be resorbed when extruded beyond the apex without washing out from within the canals (Fuks et al. 2002).

Fuks et al. (2002) studied the outcome of root canal therapy using Endoflas F.S. in 55 primary teeth (27 maxillary incisors and 28 primary molars) over a follow up period of 6 to 52 months (no mean given) and found a 69% success rate. The authors attributed their low success to that fact that 62% of the teeth included in the study had periapical lesions at baseline, which was a finding that they suggested, had not been described in other studies. They reasoned that the presence of periapical lesions might have contributed to overfilling, decreasing their rate of successful outcomes. To substantiate this theory, the authors considered only the primary molars that had been obturated either flush to the apex or underfilled (83% of treated teeth fell into these two categories), and reported non-specific success rates similar to other studies using Kri and Maisto pastes (Fuks et al. 2002). The table to which the authors referred to in their conclusion, as well as two other tables, were missing in the publication.
Moskovitz et al. (2005) reported a clinical and radiographic success rate of 82% in a study of 139 primary molars treated by root canal therapy with Endoflas F.S. Most (80.6%) root canal therapy treatments were performed in one appointment but some were completed in two (13.6%) or three (5.8%) appointments. The authors did not provide a mean age for their sample group, however they did report an age range of 5 to 18 years old. It was not clear how many retained primary molars from adolescents were included in the study. The final restorations included stainless steel crowns (70.5%) and amalgam or composite resin restorations (9.4%) that were reportedly placed one month after treatment (20.1% of patients did not return for final restorations). The mean follow-up time for treated teeth was 21 months (range = 6 to 77 months, median = 19 months). Clinical inclusion criteria reported by the authors included: continued bleeding for greater than five minutes with dark to purple blood colour following pulp amputation, or pulp necrosis. Radiographically, teeth with furcation or periapical radiolucencies without involvement of the follicle of the permanent tooth were included in the study (Moskovitz et al. 2005).

Twenty-five of 139 (18%) treated teeth were considered failures. Three teeth were defined as failures within six months after treatment, presumably for clinical reasons given the fact that radiographs were not taken in the first six months after treatment. Nineteen teeth were defined as failures due to progression of pre-existing radiolucent defects and three teeth were defined as radiographically questionable and thus deemed failures (Moskovitz et al. 2005).

Interestingly, the authors compared the pre-operative radiographic findings to their final post-operative radiographs. Success was determined in 78% (94/121) of the teeth that had a pathologic radiolucent area pre-operatively compared to a 100% (18/18) success rate for teeth
that had no radiolucent areas pre-operatively. The authors did not report what (Moskovitz et al. 2005).

In 2010, Moskovitz et al. reported on the same root canal therapy technique as in 2005. The only differences in the design of the 2010 study were the following: all root canal therapy treatments were completed in one appointment, a larger sample was included (n= 242 primary molars) and a longer follow-up time was reported (mean follow-up time = 33.5 months, range = 6 to 113 months, median = 28.5 months). The authors described a 96.7% (234/242) clinical and radiographic success rate. Four of the treated teeth developed new radiolucent areas post-operatively while another four of the treated teeth that had pre-existing radiolucent areas enlarged over time. All eight of the failures were in primary mandibular molars (Moskovitz 2010).

A possible explanation for increased success rates in the 2010 study by Moskovitz et al. compared to their 2005 study may have been related to the presence of pre-existing radiographic pathologies. In the 2005 study, 86.9% of teeth included in the study had pre-operative radiolucent areas while only 17.5% of teeth included in the 2010 study had pre-operative radiolucent areas. According to Fuks et al. (2002), the presence of pre-existing radiolucent areas may decrease the outcome of success for root canal therapy.

c. Vitapex® and Formocresol

Mortazavi and Mesbahi (2004) reported a 100% success rate for root canal therapy using Vitapex® on 26 primary teeth (24 molars and 2 incisors, with up to six teeth lost to follow-up,
as discussed on page 29) over a follow-up time of 10 to 16 months. What the authors mentioned only once in the entire paper was that a formocresol-moistened cotton pledget was placed in the pulp chamber and temporarily sealed until a final obturation with Vitapex® was completed one to two weeks later. It was misleading that the authors neglected to discuss the impact that the use of a strong antimicrobial agent, like formocresol, could have on the outcome of their root canal therapy treatments beyond the use of Vitapex® alone.

d. Calcium Hydroxide, Kri-1 paste and Formocresol

Dominguez Reyes and Solano Reina (1989) is the only known group to have reported on a combination paste for primary tooth root canal therapy consisting of equal parts of pure calcium hydroxide and Kri-1 paste with one drop of formocresol. They reported a 100% success rate on a sample size of 53 children (presumably 53 primary molars, though not specifically described by the authors). All treatments were completed in one appointment, restored with stainless steel crowns and evaluated at, 6, 12 and 24 months post-operatively.

The results section of this study was only two paragraphs in length and left out many important details. For example, a 100% success rate was reported but the authors did not define what they considered to be a successful outcome. They also reported that all paruli and fistulae healed by 20 days post-operatively and that all areas of pre-operative periradicular radiolucencies showed healing by 17 to 24 months post-treatment. However, no specific numbers about treated teeth or the pre-operative conditions of the treated teeth were reported which left the reader to either blindly accept or to reject the authors’ conclusions (Dominguez Reyes & Solano Reina 1989).
e. **Calcium Hydroxide and Zinc Oxide Eugenol**

After a follow-up time of nine months, Nadkarni and Damie (2000) reported a 94% success rate after root canal therapy of 35 primary mandibular molars using a calcium hydroxide (0.2 gram powder, 0.5 gram paste) and zinc oxide eugenol (0.36 gram powder, 0.28 gram liquid) mixture. Inclusion criteria were clearly defined. Radiographically, teeth with furcation and periapical radiolucencies were included in the study but only if normal bony support of minimum 2/3 of at least one root was also present. All teeth with any sign of internal or external root resorption were excluded from the study. Treated teeth were defined as successful if radiographically, pre-operative pathologic radiolucencies either improved or did not worsen. Complete resorption of overfilled calcium hydroxide was observed at the three-month radiographic examination (Nadkarni & Damie 2000).

VII. **Antibiotic Pastes**

Lesion Sterilization and Tissue Repair Therapy (LSTR) is a new biologic approach in the treatment of carious lesions with or without pulpal and periapical involvement using a mixture of three antibiotics: metronidazole, ciprofloxacin and minocycline, referred to as 3Mix (Hoshino et al. 1990, Nakornchai et al. 2010). LSTR therapy involves a pulpotomy-like procedure where a sterile sharp spoon excavator is used to remove necrotic pulp tissue, hemostasis is controlled with 10% sodium hypochlorite and irrigation is completed with 2.5% sodium hypochlorite (Nakornchai et al. 2010). No mechanical instrumentation of the canals is negotiated as this can cause unnecessary enlargement of root canals and irritation of periapical tissues (Hoshino et al. 1996, Nakornchai et al. 2010).
The antibacterial mixture, 3Mix, reportedly sterilizes carious lesions, necrotic pulps and infected root dentine of primary teeth (Sato et al. 1993, Sato et al. 1996, Hoshino et al. 1996). Metronidazole was the first choice for dental lesion sterilization since it has a wide bactericidal spectrum, particularly against obligate anaerobes, which comprise the majority of microorganisms isolated from dentinal lesions (Ingham et al. 1975, Hoshino et al. 1988, Sato et al. 1993) and isolates from infected pulps (Sundqvist 1976). In permanent teeth, more than 99% of the bacteria of carious lesions were not recovered in the presence of 10 µm/ml of metronidazole (Hoshino et al. 1988, Hoshino et al. 1990). However, metronidazole, even at a concentration of 100 µg/ml, could not kill all bacteria, indicating that some additional drugs were necessary to sterilize the lesion (Hoshino et al. 1990, Sato et al., 1992). To compliment the antibacterial spectrum of metronidazole, ciprofloxacin, a second generation fluoroquinolone, and minocycline, a tetracycline, were chosen (Sato et al. 1993, Takushige et al. 2004).

In an in vitro experiment, Sato et al. (1992) demonstrated that a mixture of metronidazole, ciprofloxacin, minocycline and rifampicin could penetrate into carious lesions and sterilize them within one day.

Sato et al. (1993) proposed that minocycline and other tetracycline derivatives be substituted as the third antimicrobial agent for dental sterilization techniques in young patients with calcifying dentinal tissues to prevent staining of the permanent successor tooth. In their in vitro study (1993) they demonstrated that at a concentration of 100 µg/ml each, minocycline can be substituted by amoxicillin (aminopenicillin family), cefaclor (cephem family),
fosfomycin (fosfomycin family) or rokitamycin (macrolide family) to eliminate all bacteria from freshly extracted pulpally involved carious primary teeth (Sato et al. 1993).

a. Mixture of Metronidazole, Minocycline and Ciprofloxacin (3Mix)

In a 3Mix LSTR therapy study, Takushige et al. (2004) reported a 100% clinical success rate for 87 primary molars over a mean follow up time of 22 months (range = 2 to 80 months). Eighty percent of primary molars were treated in one appointment while 20% of teeth were treated in two or more appointments.

The inclusion criteria for this study differed somewhat from other root canal therapy studies (Coll et al. 1985, Coll et al. 1988, Dominguez Reyes & Solano Reina 1989, Barr et al. 1991, Holan & Fuks 1993) in that primary molars with excessive root resorption were included in the study. Fifteen percent (13/87) of teeth had ½ to over ¾ root resorption and 29% (25/87) teeth had ¼ to ½ root resorption. Only 6.9% (6/87) of teeth included in the study showed no signs of physiologic resorption (Takushige et al. 2004).

The mean age of the sample group was 8.4 years (range = 4 to 18 years) while other root canal therapy studies reported mean sample group ages of 4.0 years (Coll et al. 1996) and 6.7 years (Moskovitz et al. 2010), or age ranges from 2 to 9 years of age (Coll et al. 1985, Garcia-Godoy 1987, Nakornchai et al. 2000, Ozalp et al. 2005). A higher mean age in a sample group may have created a bias in the overall success rate of this study since more of the treated teeth would be closer to exfoliation than in similar studies (Coll et al. 1985, Garcia-Godoy 1987, Coll et al. 1996, Nakornchai et al. 2000, Ozalp et al. 2005, Moskovitz et al. 2010).
Furthermore the authors included an 18-year-old patient in their sample group (Takushige et al. 2004). Though not explicitly stated, the patient presumably had a retained primary molar due to a congenitally missing permanent successor.

Radiographic success was defined as any resolution or diminishment of a pre-existing radiolucent lesion. The authors reported that 54.1% (47/87) of teeth initially exhibited complete alveolar bone resorption, 8.0% (7/87) of teeth exhibited partial alveolar bone resorption and 37.9% (33/87) exhibited no alveolar bone resorption (Takushige et al. 2004).

Prabhakar et al. (2008) evaluated the success rate of 3Mix antibiotic paste using two different one-appointment pulp therapy techniques for necrotic primary teeth. The first technique involved removal of only the necrotic coronal pulp (Group A) while the second technique involved removal of both the necrotic coronal as well as the accessible radicular pulp tissue (Group B). In both techniques, the antibiotic paste was only placed in the pulp chamber. All teeth were restored with glass ionomer cement that was further reinforced with composite resin and were evaluated at 6 and 12 months. Forty-one children between the ages of 4 and 10 years (no mean given) who had 60 infected primary molars were selected for the study based on four exclusion criteria:

- Teeth with perforated pulpal floors
- Radiographic evidence of excessive internal root resorption
- Radiographic evidence of excessive bone loss in the furcation which involves the underlying developing tooth germ
- Non-restorable teeth
Treated teeth were defined as clinically successful if they were free of symptoms and radiographically successful if there was no increase in a pre-existing radiolucency (Prabhakar et al. 2008).

At the 12-month follow up exam, teeth in Group A displayed a 93.3% (28/30) clinical success rate and an 80% (23/30) radiographic success rate. Radiographically, bony regeneration was only observed in 36.7% (11/30) of treated teeth. However 40% (12/30) of treated teeth from this group displayed no change in their bony morphology, which according to the authors’ definition, was a success.

At the 12-month follow up exam, teeth in Group B demonstrated a 100% clinical success rate and an 83.3% (25/30) radiographic success rate. The authors thus concluded that for endodontic treatment of primary molars both the necrotic coronal as well as the accessible radicular pulp tissue should be removed for best results (Prabhakar et al. 2008).

Nakornchai et al. (2010) published a report on LSTR therapy of twenty-five primary molars with clinical and/or radiographic signs of irreversible pulpitis or necrosis. The authors reported a 96% (24/25) clinical success rate and a 76% (19/25) radiographic success rate after a 12 month follow up.

Although the Nakornchai et al. (2010) study had a small sample size and a short follow-up period, they thoroughly outlined their inclusion criteria, their definitions of clinical and
radiographic success as well as their preoperative and postoperative clinical and radiographic findings.

5) Formocresol Concerns

A. Systemic Impact of Formaldehyde

Daily formaldehyde exposure is a fact of life (Milnes 2006). It is found in the air we breathe, the water we drink and the food we eat (Health Canada 2011).

In addition to being exposed to exogenous sources of formaldehyde, the human body actually produces some formaldehyde endogenously during cellular metabolism (3 to 12 ng per gram of tissue) (Hileman 1984). As a result, the human body is physiologically equipped to absorb formaldehyde in the respiratory and gastrointestinal tracts.

The biologic half-life of exogenous formaldehyde is 60 to 90 seconds and is quickly cleared in human plasma (McMartin et al. 1979, Bhatt et al. 1988, Kahl et al. 2007). Formaldehyde, chemically known as CH₂O, is quickly oxidized to formate, a single carbon atom which can be metabolized three different ways. If inhaled, it is oxidized further into carbon dioxide and water and breathed out. If ingested, it can both be converted to a soluble sodium salt and excreted via the urinary tract or it can be incorporated into the “1-carbon pool” to synthesize future macromolecules, such as RNA, DNA and proteins (Milnes 2006, Health Canada 2011).

Many authors have raised concerns about the safety of formocresol use in pediatric dentistry due to its formaldehyde content (Rolling et al. 1976, Pereira & Petito 1982, Ranly 1984, Judd
et al. 1987, Casas et al. 2005). The justification presented is largely based on a few dental pulp therapy studies, by the same group of authors, involving rats, dogs and monkeys where formaldehyde labeled with radioactive carbon (¹⁴C) was reported to be distributed among the muscle, liver, heart, spleen and lungs (Pashley et al. 1980, Myers et al. 1981, Myers et al. 1983, Ranly & Horn 1987). These authors expressed concern regarding its systemic absorption and wide distribution to distant sites in the body. However, their studies were not conclusive in that they did not investigate if the ¹⁴C labeled moieties were actually covalently bound to formaldehyde (CH₂O) or if the ¹⁴C labels were bound to the various macromolecules produced by the metabolism of formaldehyde in the 1-carbon pool (Milnes 2006).

Casanova-Schmitz et al. (1984) performed a similar study to distinguish between the incorporation of the metabolites of ¹⁴C- labeled formaldehyde and actual covalent binding of ¹⁴C-labeled formaldehyde. In their study, claims of systemic distribution of formaldehyde were clearly refuted.

Furthermore, formaldehyde has been labeled as a human carcinogen by the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO 1989). However, formaldehyde falls into the same risk group as x-rays, solar radiation, alcohol and dental composite resin, which are not considered hazardous when used in moderation. The IARC classification of formaldehyde was based on a single National Cancer Institute (NCI) study in which a very small number of workers in one particular formaldehyde plant acquired nasopharyngeal cancer, a rare form of cancer. Because of the probable bias in this study, the NCI is currently updating this report (Wright et al. 2006). In 1987, the United States Environmental Protection Agency (EPA) classified formaldehyde as a probable human
carcinogen under conditions of “unusually high or prolonged exposure” (EPA 1989). Despite these risk classifications, to date there is no evidence that formaldehyde is mutagenic or carcinogenic at the doses used in dentistry (Zarzar et al. 2003, Ribeiro et al. 2004, Ribeiro et al. 2005).

Another concern regarding the use of formocresol in pulp therapy of the primary dentition is the potential for antibody formation, leading to immune sensitization (Casas et al. 2005). However, when 128 children with pulpotomized primary teeth were tested for sensitivity against formaldehyde, eugenol and cresol using a patch test, none of them responded positively (Rolling et al. 1976). Hence this study would not support a concern for immune sensitization with the use of formocresol in pulp therapy.

B. Ubiquity of Formaldehyde-Based Products

Humans inhale and ingest formaldehyde daily. According to the World Health Organization (WHO), daily consumption of formaldehyde approximates 1.5-14mg/day with a mean of 7.8mg/day (WHO 1989). Conversely, others have calculated estimated means for formaldehyde intake to be higher and in the range of 10.55mg/day to 11mg/day (Owen et al. 1990, Milnes 2006).

Common sources of formaldehyde exposure include: atmospheric synthesis (photochemical oxidation of hydrocarbons in the troposphere; estimated production $4 \times 10^{11}$ kg/year), internal combustion of engine exhaust (varies greatly according to country), use of catalytic converters and grade of fuel used (not quantifiable according to the WHO), industrial production
(approximately $3.5 \times 10^9$ kg/year), building products (insulation, carpets, latex paints, adhesives, particle board, plywood), household products (gas cookers, open fireplaces, dishwashing liquid, antiseptics and disinfectants, carpet cleaners, furniture), personal use products (cosmetics, permanent press fabrics), tobacco products (smoking 20 cigarettes per day corresponds to 1mg/day through inhalation), food products (range from 1.5 to 14mg/day), drinking water (generally 0.1mg/liter, resulting in a daily mean of 0.2mg/day) (Perrera & Petito 1982, Avram & Pulver 1989, WHO 1989).

Given the ubiquity of formaldehyde and its recognized daily intake, it seems unlikely that the microgram quantities of formaldehyde used in formocresol pulp therapy of the primary dentition is of any significant impact (Milnes 2006).

The only human clinical trial involving formocresol in dentistry was reported by Kahl et al. (2008). In this study, formocresol was applied to the amputated pulp stumps of 85 primary molars during pulpotomy procedures while children were sedated under general anesthetic. Preoperative, intraoperative and postoperative peripheral venous samples were collected from each of 30 pre-school aged children. Analysis of the blood samples revealed that formaldehyde was undetectable above baseline plasma concentration and that cresol was undetectable in all samples. Benzyl alcohol, a byproduct of cresol metabolism, was present in all samples except the baseline preoperative samples. However, the levels of benzyl alcohol detected were in the range of 0 to 1 mg/ml, which is far below the Food and Drug Administration’s recommended daily allowance. The authors concluded that formocresol, when used in the doses typically employed for one to five vital pulpotomy procedures, was unlikely to pose any risk to children (Kahl et al. 2008).
6) **Effects of Primary Tooth Root Canal Therapy**

A. **Retention of ZOE Following Root Canal Therapy of Primary Teeth**

In 1979, it was speculated that the resorption rate of ZOE within root canals and the root itself differed, resulting in small areas of ZOE paste possibly being retained (Allen 1979).

Spedding (1985) published a case report involving a primary maxillary incisor and a primary maxillary second molar that were treated by ZOE and formocresol root canal therapy. Both teeth had to be extracted to prevent ectopic eruption of their respective permanent successors. Radiographic exam following extractions of the endodontically treated primary teeth featured incomplete ZOE resorption after a follow-up time of greater than five years. Neither permanent successor had any enamel defects but the authors advocated periodic radiographs to assess any changes and possibly excision of filler particles, if necessary (Spedding 1985).

Coll et al. (1985) reported that in eight of 17 (47%) patients treated by primary molar root canal therapy, small 1mm by 1mm pieces of ZOE were discovered radiographically in the gingival sulcus at the time of premolar eruption. This retention did not cause any apparent clinical problem and was curetted out of the sulcus in two of eight cases at the time of tooth exfoliation. In 1988, the same group reported that 11 of 15 endodontically treated primary teeth had ZOE retained in the tissue after exfoliation.

Flaitz et al. (1989) reported findings for 87 primary incisor teeth treated by ZOE root canal therapy, in which 84% were rated a success after a mean time of 37 months. Subsequent to a
reader’s question from a 1991 paper, the same group of authors wrote that in their 15 years of practice and hundreds of primary tooth root canal therapy procedures, they had never observed ZOE on a radiograph after the loss of an endodontically treated molar (Barr et al. 1991). They did however acknowledge that ZOE was occasionally observed after the exfoliation of primary incisors. The authors stated that they did not find this retained ZOE to be problematic and that it always resorbed over time (Barr et al. 1991). Other groups also reported not observing residual ZOE paste in gingival tissues after the exfoliation of endodontically treated primary molars (Yacobi et al. 1991, Holan & Fuks 1993).

Sadrian and Coll (1993) reviewed the charts of 65 children receiving 81 ZOE root canal therapy treatments. After a mean follow up time of 40.2 months, the ZOE retention rate was 49.4% based on the first radiograph after treatment and 27.3% based on the final radiograph available. Primary molars had a 52.1% (25/48) ZOE retention rate and primary incisors had a 44.8% (13/29) retention rate, which was not statistically significant. Endodontically treated primary teeth filled 1mm or more short of the apex showed 35.3% ZOE retention while 65.4% of primary teeth that were filled long retained ZOE. The authors commented that it was possible to remove the ZOE by curettage immediately following exfoliation or extraction of the treated primary tooth. If ZOE was retained initially, 80% totally or partially resorbed with time, while 20% showed no evidence of resorption. No pathology was noted around any of the retained ZOE particles and there were no signs of gingival swelling or pain that had been noted from the treating dentist’s chart notes (Sadrian & Coll 1993).

The resorbability of ZOE reported by Sadrian and Coll (1993) did not agree with Erausquin and Muruzabal whose 1966 in vitro study concluded that ZOE was insoluble in rat body fluids over
a 90-day post-operative period. They noted that a fibrous capsule formed around extruded ZOE, which slowed resorption. The authors also suggested that ZOE may produce necrosis of bone and cementum (Erausquin & Muruzabel 1967). Barker and Lockett (1971) reported that in dogs, extruded ZOE was not resorbed and caused a mild foreign body reaction.

Moreover, Campbell et al. (1978) as well as Stuart et al. (1979) found that set ZOE was not antigenic in either guinea pigs or rabbits, respectively. This finding was reportedly not surprising to Stuart et al. (1979) since zinc oxide and eugenol are inorganic and have relatively low molecular weights, which tends to make them poor antigenic candidates. Consequently, Stuart et al. (1979) concluded that factors other than humoral response to ZOE were the cause of root canal therapy failure.

Ozalp et al. (2005) reported that six of 20 primary molars treated by ZOE root canal therapy had overfilled root canals. Two of these teeth showed complete resorption of the overfilled ZOE while four teeth showed a reduction in size over the 18 months of follow-up (Ozalp et al. 2005).

Holan and Fuks (1993) reported on the outcome of ZOE root canal therapy of 34 primary molars wherein none of the treated teeth were found to have retained ZOE. Yacobi et al. (1991) also reported on ZOE root canal therapy of 49 primary molars, none of which had retained ZOE post-treatment.

Based on the aforementioned clinical studies, it would seem that most extruded ZOE is resorbed but that a small proportion either resorbs very slowly or is not resorbed. Care must
therefore be taken to avoid overfilling the canals of primary teeth, thereby extruding obturation material past the apex (Garcia-Godoy 1987). In the event that this should occur, it is unclear whether or not the outcome of root canal therapy would be affected. Some studies show that teeth, which were overfilled with ZOE, have lower success rates (Yacobi et al. 1991, Holan & Fuks 1993) while others show no difference in outcome (Flaitz et al. 1989, Barr et al. 1991, Sadrian & Coll 1993, Ozalp et al. 2005). Regardless, it is believed that retained ZOE does not constitute a long-term problem (Coll et al. 1985).

B. Exfoliation of Primary Teeth treated by Root Canal Therapy

Very few authors have reported on the timing of exfoliation following primary tooth root canal therapy; those that have, reported on techniques that involved formocresol and ZOE as pulp medicaments and obturation materials (Coll et al. 1985, Barr et al. 1991).

Coll et al. (1985) evaluated the exfoliation times of primary molars treated by root canal therapy using formocresol and ZOE and compared them to non-pulp treated contralateral teeth as well as pulpotomy treated contralateral teeth. They found that endodontically treated molars tended to resorb faster when compared to contralateral molars, which had no pulp therapy. However, this difference was not statistically significant. If the contralateral tooth had been treated by pulpotomy then there tended to be no difference in the relative root resorption between the two groups. At a second long-term follow-up evaluation, between five years to six years and ten months, the primary molars treated by root canal therapy were not over-retained (Coll et al. 1985).
Barr et al. (1991) reported on the reasons for tooth loss following ZOE and formocresol root canal therapy of 62 primary molars. Exfoliation occurred with approximately 60% of tooth losses, while the remaining teeth were extracted. When the exfoliation times of treated teeth were compared with their antimeres, advanced exfoliation was present in 56% of the cases. How the authors defined advanced exfoliation was not made clear, however they did state that normal exfoliation was observed with 44% of treated primary molars. No cases of delayed exfoliation were observed (Barr et al. 1991).

Many authors have suggested that the reason for accelerated external root resorption in endodontically treated primary teeth may be due to the irritating nature of formocresol. They proposed that formocresol from the treated teeth leaches into the surrounding periapical tissue, leading to a chronic inflammatory reaction (Oberszstyn 1963, Fuks & Bimstein 1981). Alternatively, the increased rate of external root resorption may be due to the presence of chronic inflammation in inadequately pulpectomized primary teeth (Fuks & Bimstein 1981).

The risk of uneven or abnormal root resorption may deter some clinicians from routinely performing root canal therapy in primary molars. However, a study of root resorption in 625 healthy primary molars by Prove et al. (1992), demonstrated that uneven root resorption is a common occurrence; 36% in normal untreated teeth. Thus, occasional altered root resorption rates with or without root canal therapy is considered normal. Proper diagnosis and controlled management of pre-existing pathosis should remain the basis of all primary root canal treatment techniques (Fuks et al. 2002).
C. Ectopic Eruption of Succedaneous Teeth Following Root Canal Therapy of Primary Teeth

Some obturation materials, namely those containing ZOE, have reportedly been retained after overfilling an endodontically treated primary tooth, sometimes even after its exfoliation (Erausquin & Muruzabel 1967, Spedding 1985, Gould 1972, Garcia-Godoy 1987, Holan & Fuks 1993, Sadrian & Coll 1993, Mortazavi & Mesbahi 2004). Retained ZOE particles have been observed by several authors (Coll et al. 1985, Garcia-Godoy 1987, Barr et al. 1991, Yacobi et al. 1991, Sadrian & Coll 1993), however, no pathology has been directly associated with the latter (Barr et al. 1991, Yacobi et al. 1991, Sadrian & Coll 1993). Notwithstanding, some authors have proposed that retained obturation material may deflect erupting permanent successors (Coll et al. 1985, Garcia-Godoy 1987).

Coll and Sadrian (1996) reported a higher than expected rate of ectopic eruption following root canal therapy in primary teeth using ZOE as a dressing material. They reported a 20% incidence of succedaneous tooth anterior crossbite or palatal eruption following primary incisor root canal therapy, and a 21.6% ectopic eruption rate of premolars following primary molar root canal therapy. This value is at the high end of most estimates for prevalence of posterior crossbites in the mixed dentition, which range from 8% to 23% (Kutin and Hawes 1969, Magnusson 1977, Binder 2004).

Furthermore, Coll and Sadrian (1996) reported that although treated teeth were mobile, 29.6% (24/81) of endodontically treated teeth had to be extracted because they were mobile and over-retained when the permanent successors were erupting.
D. **Enamel Defects on Permanent Successors Following Root Canal Therapy of Primary Teeth**

Reports of enamel opacities and enamel defects in the permanent dentition of children living in optimally water-fluoridated communities (0.3 to 0.5 part per million fluoride) in various countries range from 23% to 82% (Angelillo et al. 1990, Nunn et al. 1994, Ekanayake & van der Hoek 2003). Despite the high prevalence of enamel defects, several authors have proposed a correlation between root canal therapy in primary teeth and enamel defects on permanent successor teeth (Rifkin 1982, Coll et al. 1985, Garcia-Godoy 1987, Coll & Sadrian 1996).

Rifkin (1982) found that in a 2.5 to 4.5 year follow-up on 30 teeth treated by root canal therapy using Kri paste, three permanent successors had 1mm enamel white spots and two permanent successors erupted with minimal caries. Garcia-Godoy (1987) also reported colour changes in the form of small white spots of approximately 1mm in size in three of 45 cases involving a Kri root canal therapy technique.

A study by Moskovitz et al. (2010) reported on the results of 242 primary molars treated by Endoflas root canal therapy. Of the 17 successor teeth evaluated clinically, one premolar presented with a hypocalcified enamel defect.

Coll et al. (1985) reported that of the 17 premolars that erupted following root canal therapy with formocresol and ZOE of the antecedent primary molars, two teeth erupted with enamel defects, one of which required a restoration.
Jerrell and Ronk (1982) published a case report describing a five-year-old male with extensive caries throughout his posterior primary dentition. Both mandibular primary second molars were treated with ZOE and formocresol root canal therapy. Immediate postoperative films revealed that the right primary mandibular second molar was adequately obturated but the left primary mandibular second molar was overfilled. After a five year follow-up period, the authors concluded that the extruded obturation material had penetrated the follicle of the permanent successor, leading to delayed development and malformation of the right mandibular second premolar. They attributed this dental defect to the “toxic nature of the filling material” which contacted the developing tooth (Jerrell & Ronk 1982). It was not stated in the authors’ report if an appropriate periapical had been taken preoperatively to assess the initial integrity of the successor’s developing follicle.

In an outcome study regarding formocresol and ZOE root canal therapy in primary molars, Coll and Sadrian (1996) reported that 18.7% (14/75) of succedaneous teeth displayed enamel defects. They determined that the incidence of enamel defects was related to the amount of preoperative root resorption of the endodontically treated primary molars (p = 0.005). The authors did not define preoperative root resorption. As a result, it was unclear by their report if they were referring to physiologic root resorption and/or pathologic root resorption. However according to their results, there was a 44% chance of finding an enamel defect on the succedaneous tooth if the endodontically treated primary molar had greater than 1mm of pre-operative root resorption, a 23.1% chance if there was 0 to 1mm pre-operative root resorption, but only a 3.6% chance if there had been no pre-operative root resorption (Coll & Sadrian 1996). The authors did not define if the root resorption was physiologic or pathologic, which would be important in the interpretation the authors’ results and conclusions.
They further characterized the enamel defects and reported that 11 of the defects in permanent successors were small, white enamel opacities or small buccal defects that required no treatment. The presence of enamel defects was not related to the length of ZOE fill (P = 0.36) or to root canal therapy outcome (P = 0.19). When these were compared to 33 untreated contralateral permanent tooth controls, no significant difference in enamel defects was found, suggesting that the observed enamel opacities were coincident findings rather than secondary to pre-operative chronic inflammation or root canal therapy treatment itself (Coll & Sadrian 1996).

The remaining three enamel defects in the permanent successor teeth required restorations for brown hypoplastic defects. Of the 81 root canal therapy treatments reviewed, these three cases were the only ones in which the primary teeth were found to have extensive pre-operative root resorption and extruded ZOE, which approximated the developing permanent successors (Coll & Sadrian 1996).

Aside from Coll and Sadrian (1996), none of the above-mentioned authors considered pre-operative periapical inflammation to be a possible etiology for enamel defects in the permanent successor teeth. Rather, they all proposed that enamel defects were due to the medicaments used in the various root canal therapy techniques.

Turner first described a localized type of enamel hypoplasia in 1912. He noted that defects in the enamel of two premolars and traced the defects to apical infection of the nearest primary molars. Enamel hypoplasia resulting from local infection has since been termed “Turner’s
tooth” (McDonald 2004). This was confirmed histologically by Bauer (1932 & 1946) and Morningstar (1937). Bauer (1946) concluded from a study of five autopsy specimens that the periapical inflammatory processes of primary teeth can extend toward the buds of the pertinent permanent teeth, and breach the follicle of the developing successor, destroying its reduced enamel epithelium and exposing enamel to inflammatory edema and granulation tissue. Histologically, the enamel appeared eroded due to the activity of the lacunar osteoclasts. The lacunar surface of the enamel lesions was lined with a layer of intensely and somewhat irregularly calcified cell-free substance, which resembled acellular cementum. Baume (1946) concluded that this metaplastic cementum upon the corroded enamel was responsible for the yellowish, spotty areas seen in the so-called “Turner teeth”.

In addition Baume (1946) described that in one patient who had chronically abscessed primary right central and lateral incisors at the age of four years, the successors emerged with shorter clinical crowns than the contralateral teeth. The mesial marginal portion of the labial surface of the central incisor was occupied by a rough, nodular yellowish substance of hard consistency, which extended beneath the inflamed flabby marginal gingival (Bauer 1946).

Matsumiya (1968) sought to determine the relationship between periapical inflammation, root canal therapy and the effect of both on the growth and eruption of the permanent tooth germ. After extirpation of the pulp, the root canals of primary teeth of healthy dogs were exposed to the oral cavity for varying periods of time. A proportion of them were subsequently sterilized and obturated with various materials, including calcium hydroxide, iodoform and chlorophenol as well as a Hanazawa’s triozinc paste, a formaldehyde-based paste. The animals were then sacrificed and the periapical tissues were examined
histologically. In all 462 cases there was evidence that periapical inflammation had developed but destruction of the enamel organ or interference with enamel formation was observed in only 23% of cases. The pattern of resorption of the primary molar roots was abnormal being of an erosive type and occurring in the absence of osteoclasts. Treatment of the infected canals resulted in resolution of the periapical inflammation, but the damage to the tooth germ was not repaired (Matsumiya 1968).

Winter and Kramer (1972) reported on the effects of no treatment in 38 necrotic monkey primary molar teeth for approximately 100 days. Three of the permanent successors had degenerative changes in the enamel epithelium and one of the permanent successors showed evidence of enamel hypoplasia of the forming enamel matrix. Furthermore, another two monkeys showed pathologic resorption of the adjacent uninfected primary molar root in the region of the inflammatory spread (Winter & Kramer 1972).

Likewise, in a study of periapical inflammation in monkeys, Valderhaug (1974) concluded that pulpal or periapical inflammation prior to pulp therapy may cause damage to the permanent successors.

Given the strong evidence from these extensive reports, it is reasonable to assume that if a primary tooth experiences chronic inflammation or necrosis, it is more likely that an enamel defect will develop on the permanent successor.

Another factor to consider in the discernment of possible etiologies for an area of localized enamel hypoplasia, is the timing during which the crowns of permanent successors are formed
and calcified. Calcification of the enamel of permanent teeth takes place as long as the enamel is covered by the enamel epithelium, which is organically united with the surface of the enamel. If inflamed connective tissue comes in contact with the surface of the enamel, the latter could easily be destroyed (Morningstar 1937).

For permanent incisors, enamel development is complete by four to five years of age. For first premolars, enamel development is complete by five to six years of age while for second premolars and permanent canines, enamel development is complete by six to seven years of age (Rifkin 1982, McDonald et al. 2004). Based on these findings, it would seem likely that enamel defects on permanent teeth would develop prior to the completion of enamel on the permanent successors. To the author’s knowledge there is however no published study to support this hypothesis.
C. EXPECTED OUTCOMES

1. A root canal therapy treatment in primary molars using one drop of full strength Buckley’s formocresol and one drop of eugenol and pure zinc oxide powder, has a better or equal outcome compared to other commonly used root canal therapy techniques.

2. The root canal therapy technique under investigation will have little to no effect on succedaneous teeth and on exfoliation times when compared to contralateral unrestored teeth.
D. AIMS AND OBJECTIVES

1. To assess the clinical and radiographic success rates of a formocresol and ZOE root canal therapy technique in non-vital primary molars.

2. To radiographically assess the degree of obturation in canals and determine its effect on root canal therapy outcome.

3. To evaluate the relationship between the formocresol and ZOE root canal therapy technique on primary teeth and enamel defects in their succedaneous teeth.

4. To examine the effect of root canal therapy treatment on the timing of exfoliation versus contralateral teeth.
E. MATERIALS AND METHODS

This retrospective study was approved by the University of Toronto Health Sciences Research Ethics Board and supported by the Associate Dean of Graduate Studies, Faculty of Dentistry, as having scientific merit. Inclusion criteria for the study and possible benefits to the subjects were described in the protocol submission to the Research Ethics Board. In addition, informed consent processes and confidentiality procedures were also analysed (Appendix I).

1) Sample

The subjects selected for this study were treated by non-vital root canal therapy by a single operator (P.A) at a private paediatric dental office in the greater Toronto area between the years 1996 and 2010. Informed consent for treatment was obtained at the time of treatment (Appendix I). An additional letter was mailed to inform patients and their parents that their radiographs would be used on an anonymous basis for research purposes and towards the obtainment of a graduate qualification. This letter also instructed patients and parents who to contact should they wish to withdraw from the study (Appendix II).

The inclusion criteria included healthy children requiring at least one non-vital root canal therapy on a primary molar with a minimum follow up period of 6 months. Any case with less than 6 months follow up period was excluded from the study. All root canal therapies 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 root canal therapy included:
i. Possible history of pain, either stimulated or spontaneous

ii. Restorable tooth

iii. Strategically important tooth

iv. Hyperemic pulp and/or non-vital pulp

v. Possible minimal mobility

vi. Possible evidence of a draining fistula or parulis

The radiographic indications for root canal therapy included:

i. Minor or no physiologic root resorption (<1mm, non-perforating)

ii. Minor or no internal root resorption (<1mm, non-perforating)

iii. Minor or no periapical root resorption (<1mm, non-perforating)

iv. Furcation bone resorption that did not invade the developing follicle

v. No resorption or pathology of the succedaneous tooth

The sample size required to achieve 80% power and a 0.05 alpha level was 91 teeth (Appendix III).

2) Operative Procedure

The clinical evaluation and operative procedure described herein, was completed by a single operator (P.A).
I. Radiographic Assessment

Radiographic assessments were made by examining bitewing and/or periapical radiographs. A standardized bisecting angle technique was performed using bitewing tabs and a Rinn XCP holder for periapical films. The film speed used over the duration of the study was either E speed (Kodak, Ektaspeed) or F speed (Kodak, Insight) film depending on availability. Films were processed using an Air Technique AT 2000 automatic developer operated with Kodak solutions.

II. Anaesthesia

Inferior alveolar nerve block or infiltration of local anesthetic using 2% lidocaine 1:100,000 epinephrine was administered for buccal and lingual/palatal infiltration. Inferior alveolar nerve block was used only if inadequate anesthesia was achieved using infiltration techniques.

III. Cavity Access and Caries Removal

The involved tooth was isolated with a rubber dam and all coronal caries were removed. To ensure a clean operating field the last carious dentin to be removed was that overlying the pulp.
IV. **Pulpal Access and Assessment**

Normally fresh sterilized and disinfected instruments and burs were used for pulp removal. The roof of the pulp chamber was outlined and removed using a No. 558 straight crosscut fissure bur. The exposed coronal pulp was subsequently amputated with a #6 slow speed round bur and debris was removed with copious amounts of water irrigation.

V. **Canal Debridement and Obturation - One appointment Procedure**

The opening to the canals was enlarged to remove the dentinal triangle using a #3 to #5 Gates Glidden slow speed bur (Henry Schein®). A trial length for files was obtained by measuring the tooth on the pre-operative radiograph and subtracting 1-2mm.

Pulpal filaments were removed from the root canals with NiTi K-files, which were usually size #25 or #30, but ranged from #20 to #45. Root apices were located based on the operator’s clinical judgment. Care was taken to avoid enlarging the pulpal canals. Canals were irrigated with 3% hydrogen peroxide using a 27-gauge needle then dried with paper points.

The canals were filled with a mixture of: one drop of full strength Buckley’s formocresol, one drop of eugenol and pure zinc oxide (Henry Schein®) mixed to a creamy mixture. This was applied using lentulo spiral burs (Henry Schein®) and finally pressed into place using water dampened cotton pledgets. Care was taken to avoid filing beyond the apex.
If a furcal radiolucency was present radiographically then the hydrogen peroxide irrigant was used to flush the inflamed tissues via the sulcular epithelium. If an abscess with a draining fistula was present then the parulis was irrigated with hydrogen peroxide and digital manipulation was used to express any pus.

VI. Restorative Procedure

All teeth were restored with a zinc oxide eugenol (ZOE) base and stainless steel crowns (NI-Cro), which were cemented using glass ionomer cement (KETAC-CEM) (Henry Schein®). The contact points, margins and occlusion of the stainless steel crown were assessed prior to cementation. Following cementation, the stainless steel crown was checked for proper adaptation, excess cement was removed and appropriate occlusion was confirmed.

VII. Postoperative Radiographs

Whenever possible a post treatment periapical radiograph was taken using the technique described above. In the event that an immediate post-operative radiograph was not taken on the day of final treatment, the patients were asked to return for follow up a few days later. At this appointment, a postoperative film was taken. In rare cases when patients did not return to the clinic as instructed, a postoperative periapical radiograph was taken at the next recall appointment.
VIII. Two Appointment Procedure

A two-appointment procedure was performed in the event of a non-draining soft tissue swelling and/or cellulitis. The first appointment consisted of radiographic assessment, anaesthesia, cavity access, caries removal, pulpal access, and canal debridement as described above in the “one appointment procedure”. In this case the only difference in the two appointment technique involved a temporary seal with a formocresol moistened cotton pellet and cavit. Oral antibiotics (amoxicillin, 50mg/kg TID, or in the event of a penicillin allergy, clindamycin, 20mg/kg TID) were also prescribed to all patients who presented with a non-draining abscess and/or cellulitis that were febrile.

The second appointment was scheduled at least one week from the initial appointment. At this appointment, the following steps were taken: local anaesthesia, rubber dam isolation, removal of cavit and formocresol moistened pellet, renegotiation and debridement of canals with NiTi K-files, irrigation and drying of canals, as described in the one appointment procedure. Obturation of the canals, restoration of teeth with stainless steel crowns and post operative radiographs were also completed as described above.
3) Data Collection

Patient files were randomly coded numerically and stored digitally on an encrypted memory key. Only the code numbers were used for statistical analysis. All radiographs were read on an illuminated viewbox. The following data was collected from each subject’s records:

i. Date of birth

ii. Gender

iii. Tooth number treated

iv. One appointment vs. two appointments

v. Initial clinical signs and symptoms: pain, abscess (either with or without the presence of pus), parulis and/or cellulitis

vi. Pre-operative radiographic findings: widened periodontal ligament space or loss of lamina dura, furcation radiolucency, periapical radiolucency, radiolucency near follicle of succedaneous tooth, pathologic internal root resorption, pathologic external root resorption

vii. Date of treatment

viii. Number of canals treated

ix. Degree of obturation in each canal (underfill, adequate fill, or overfill)

x. Outcome of each tooth clinically and radiographically over time

xi. Retreatment and reason for retreatment, if applicable

xii. Extraction date and reason for extraction, if applicable

xiii. Exfoliation date compared to the contralateral side, if available.
xiv. Condition of the succedaneous tooth (present, normal position, altered position, hypomineralised)

In the evaluation of exfoliation times, the condition of the contralateral tooth acted as a control for the treated tooth, and was scored as one of the following: Untouched (U), Restored with an amalgam restoration or stainless steel crown, Pulpotomy (P), Root canal (E), or Absent (A). In the event that the state of the contralateral tooth changed from the time of treatment, the latest recorded state was noted. In the event that the contralateral tooth was also treated by root canal therapy, these teeth were omitted from the study.

4) Statistical Methods

The principal investigator (KS) was standardized with two other experienced faculty members in the Department of Paediatric Dentistry at the University of Toronto (PA and HN), in order to determine the inter-rater reliability by independently reading radiographs from 30 randomly selected patients with carious primary molars with pulpal involvement. Inter-rater reliability was calculated using Cohen’s Kappa test with SPSS statistical analysis (IBM SPSS Inc., Armonk, New York, USA). The observations of the principal investigator were subsequently evaluated for intra-rater reliability also using Cohen’s Kappa test with SPSS statistical analysis (IBM SPSS Inc., Armonk, New York, USA).

All radiographs were read digitally on a 14” computer screen. Based on Landis and Koch (1977), measures of inter-rater and intra-rater reliability were classified as poor (<0), slight
(0.0 – 0.20), fair (0.21 – 0.40), moderate (0.41 – 0.60), substantial (0.61 - 0.80) and almost perfect (0.81 - 1.00).

Survival analysis for treated teeth was calculated by log-rank test. Kaplan-Meier survival plots were used to graphically demonstrate clinical and radiographic survival over time. A $\chi^2$ test was used to evaluate radiographic failures between arch and molar types. A multivariate survival analysis was used to evaluate either, 1) the time until a tooth was lost due to clinical and/or radiographic failures, or 2) the last follow-up period of the tooth.

In the comparison of contralateral non-treated and restored teeth to teeth treated by root canal therapy, pairs were tabulated in 2 x 2 tables according to presence or absence of enamel defects. The latter distributions were statistically tested using the paired Student’s T-test at the 5% significance level.

5) **Outcome Assessment**

Clinical interpretation was determined by the following criteria: presence of symptoms from the treated tooth, state of the surrounding soft tissues (unremarkable, presence of gingival abscess (with or without the presence of pus), presence of parulis), presence of pathologic mobility, presence of facial cellulitis, and need for extraction and the reason for extraction.

The criteria for each radiograph assessed included the following descriptions: unremarkable, underfilled canal (>2mm short of apex), overfilled canal (any radiopaque material extruded
beyond the apex), and adequately filled canal (within 2mm of apex). As per Bawazir and Salama (2005), the quality of root canal filling was defined as:

1) Underfilled: all the canals were filled by more than 2mm short of the apex;
2) Adequately filled: one or more of the canals was filled within 2mm of the apex;
3) Overfilled: one or more canal with obturation material expressed beyond the apex.

The following radiographic observations were also recorded, if present: widened periodontal ligament space, pathologic external root resorption, internal root resorption, furcation radiolucency, periapical radiolucency, resorbed extra-radicular root filling, unresorbed extra-radicular root filling, early exfoliation compared to the contralateral tooth, delayed exfoliation compared to the contralateral tooth.

Outcomes deemed to indicate clinical successes included:

i) Absence of reported of pain (spontaneous or stimulated)
ii) Absence of soft tissue abscess
iii) Absence of parulis
iv) Absence of facial cellulitis
v) Absence of pathologic tooth mobility
vi) 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 root resorption (either new or worsening of existing)

iii) Absence of pathologic internal root resorption (either new or worsening of existing)

iv) Improvement or stasis of a pathologic radiolucency when present preoperatively

v) Succedaneous tooth and follicle were not affected by treated primary molar

vi) Root filling did not alter the path of eruption of the succedaneous tooth

A successful outcome was determined when a) clinical findings were as noted above, b) radiographic findings were as noted above, and c) treated teeth exfoliated in response to natural eruption of succedaneous tooth. In the event of congenital absence of a permanent successor, teeth were excluded from the study regarding outcomes on succedaneous teeth.

Clinical and radiographic outcomes were separated by first vs. second primary molars and by one appointment vs. two appointment procedures, in order to determine if success was higher in either scenario. Preoperative and postoperative radiographic findings were compared in order to assess radiographic changes of treated teeth more accurately.

In order to determine the effect of acute or chronic pulpitis and root canal therapy on treated teeth, any abnormality in the enamel of succedaneous teeth was noted by evaluating chart entries and radiographs.
The survival time or lifespan of teeth treated by ZOE and formocresol root canal therapy 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.

Radiographic and clinical success rates were compared to those in the published literature using other root canal therapy techniques.
F. RESULTS

One hundred and sixty-one subjects (males = 98, females = 64) with a mean age of 72 months (6 years) ± 19 months with a range of 33 months to 148 months were included in the study (two subjects actively withdrew from the study prior to data analysis). These subjects comprised 211 treated teeth. Table 1 shows the distribution of teeth treated by root canal therapy according to molar type and arch.

Two hundred teeth were treated by root canal therapy in one appointment while eleven teeth were treated in two appointments. When assessed by Pearson chi-square test, no significant difference was found between number of appointments for treatment and clinical or radiographic outcome (p= .922 and p=.536, respectively). Antibiotics were prescribed in 50% of root canal therapy treatments.

Table 1. Distribution of Primary Molars Treated by Root Canal Therapy.

<table>
<thead>
<tr>
<th></th>
<th>Primary First Molar</th>
<th>Primary Second Molar</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Maxillary</td>
<td>69</td>
<td>16</td>
<td>85</td>
</tr>
<tr>
<td>Mandibular</td>
<td>73</td>
<td>53</td>
<td>126</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>142</td>
<td>69</td>
<td>211</td>
</tr>
</tbody>
</table>
1) Clinical Findings

All teeth were assessed at each recall appointment as clinically sound according to the previously discussed outcome assessment criteria. Subjects’ preoperative clinical signs and symptoms were recorded and included: abscess (26.5%), parulis (2.4%), pain (7.6%). Almost half of the subjects (46%) presented with no clinical signs and symptoms while 17.5% of the subjects presented with more than one clinical sign or/and symptom (Figure 1). Facial cellulitis was observed in six patients however it was always present with either pain or with an associated soft tissue abscess.

**Figure 1.** Distribution of Preoperative Clinical Signs and Symptoms.

The mean follow up period was 36 months ± 21 months with a range of 6 months to 111 months. Two hundred and eleven teeth were available for clinical evaluation after 6 to 11
months. One hundred and eighty-five primary molars were available for clinical evaluation after one year. One hundred and forty primary molars were available for clinical evaluation after two years. One hundred primary molars were available for clinical evaluation after three years. Sixty primary molars were available for clinical evaluation after four years. Thirty-two primary molars were available for clinical evaluation after five years. Fifteen primary molars were available for clinical evaluation after six years and five primary molars were available for clinical evaluation after seven years. Incidence of clinical success for each 12-month increment is reported in Table 2. Clinical success rates with cumulative failures over time are reported in Figure 2.

**Table 2.** Incidence of Clinical Success over Time.

<table>
<thead>
<tr>
<th></th>
<th>6 – 11 Months</th>
<th>12 – 23 Months</th>
<th>24 – 35 Months</th>
<th>36 – 47 Months</th>
<th>48 - 59 Months</th>
<th>60 – 71 Months</th>
<th>72 - 83 Months</th>
<th>&gt; 84 Months</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong># of Teeth</strong></td>
<td>22/26</td>
<td>39/45</td>
<td>35/40</td>
<td>35/40</td>
<td>27/28</td>
<td>17/17</td>
<td>10/10</td>
<td>5/5</td>
<td>190/211</td>
</tr>
<tr>
<td><strong>Clinical Success Rate (%)</strong></td>
<td>84.6</td>
<td>86.7</td>
<td>87.5</td>
<td>87.5</td>
<td>96.4</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>90.0</td>
</tr>
</tbody>
</table>
**Figure 2.** Clinical Success Rates with Cumulative Failures over Time.

Overall, 190 of the 211 primary molars treated by root canal therapy exhibited no clinical signs or symptoms over their respective follow up periods, accounting for a clinical success rate of 90.0%. There were no significant differences in the sample representation by gender or by molar type according to the Breslow (generalized Wilcoxon) chi-square test ($p = .786$ and $p = .497$, respectively). Logistic regression analysis showed no correlation between age at treatment time and clinical outcome ($p = .3$). Preoperative clinical signs and symptoms were not related to clinical outcome of treated teeth according to Spearman’s rank correlation coefficient ($p = .553$).

Clinical failures were most likely to occur in the first 36 months following root canal therapy (Figure 2). Twenty-one primary molars were reported to have exhibited more than one clinical sign or symptom following root canal therapy. The first reported clinical symptom developed
at one month postoperatively and the last reported clinical symptom developed at 49 months postoperatively. The type of clinical signs and symptoms with associated time periods are represented in Table 3. The clinical success data from all of the treated molars was used to perform a Kaplan-Meier survival analysis (Table 4).

Table 3. Distribution of Types of Clinical Signs and Symptoms Over Time*.

<table>
<thead>
<tr>
<th></th>
<th>6 to 11 Months</th>
<th>12 to 23 Months</th>
<th>24 to 35 Months</th>
<th>36 to 47 Months</th>
<th>48 to 59 Months</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abscess</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>-</td>
<td>9</td>
</tr>
<tr>
<td>Parulis</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Mobility</td>
<td>2</td>
<td>-</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Pain</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>6</td>
<td>7</td>
<td>4</td>
<td>2</td>
<td>25</td>
</tr>
</tbody>
</table>

* More than one clinical sign(s) and/or symptom(s) may have been reported in individual teeth.
Table 4. Estimated Kaplan-Meier Survival for Clinical Failures.

<table>
<thead>
<tr>
<th>Time (Months)</th>
<th>Probability of Survival</th>
<th>Standard Error</th>
<th>Time (Months)</th>
<th>Probability of Survival</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>.995</td>
<td>.005</td>
<td>54</td>
<td>.950</td>
<td>.016</td>
</tr>
<tr>
<td>12</td>
<td>.995</td>
<td>.005</td>
<td>60</td>
<td>.950</td>
<td>.016</td>
</tr>
<tr>
<td>18</td>
<td>.995</td>
<td>.005</td>
<td>66</td>
<td>.944</td>
<td>.017</td>
</tr>
<tr>
<td>24</td>
<td>.979</td>
<td>.010</td>
<td>72</td>
<td>.937</td>
<td>.018</td>
</tr>
<tr>
<td>30</td>
<td>.974</td>
<td>.012</td>
<td>78</td>
<td>.923</td>
<td>.021</td>
</tr>
<tr>
<td>36</td>
<td>.968</td>
<td>.013</td>
<td>84</td>
<td>.923</td>
<td>.021</td>
</tr>
<tr>
<td>42</td>
<td>.968</td>
<td>.013</td>
<td>90</td>
<td>.923</td>
<td>.021</td>
</tr>
<tr>
<td>48</td>
<td>.956</td>
<td>.015</td>
<td>96</td>
<td>.907</td>
<td>.023</td>
</tr>
</tbody>
</table>

The cumulative probability that any one tooth would be clinically successful at one year was 0.995. According to the Kaplan-Meier survival test the mean clinical survival time was 97 months with a standard error of 2.686. The associated survival analysis is plotted in Figure 3.
According to the Breslow (generalized Wilcoxon) chi-square test there were no significant differences in clinical success rates between first and second primary molars ($p=0.495$) or between maxillary and mandibular primary molars ($p=0.489$). A chi-square analysis for clinical outcome of molars, in an ungrouped analysis, was not possible as there were no clinical failures for primary maxillary second molars. The chi-square test showed no significant difference between clinical success rate and gender ($p=0.786$) and a logistic regression analysis showed no significant difference between clinical outcome and age ($p=0.3$).
2) Radiographic Findings

All treated teeth were assessed radiographically both preoperatively and postoperatively when films were available using the previously discussed outcome assessment criteria. Highly significant inter-rater reliability was observed with a score of 0.81 (p<0.001). Likewise, intra-rater reliability scored 0.84 (p<0.001). Two hundred and six teeth had available preoperative radiographs and 176 treated teeth had appropriate postoperative radiographs.

As previously mentioned, the mean follow up period was 36 months ± 21 months with a range of 6 months to 111 months. One hundred and seventy six teeth were available for radiographic evaluation after 6 to 11 months. One hundred and fifty nine teeth were available for radiographic evaluation after one year. One hundred and twenty eight primary molars were available for radiographic evaluation after two years. Ninety-five primary molars were available for radiographic evaluation after three years. Fifty-six primary molars were available for radiographic evaluation after four years. Twenty-nine primary molars were available for radiographic evaluation after five years. Fifteen primary molars were available for radiographic evaluation after six years and five primary molars were available for radiographic evaluation after seven years. In the event that the outcome of a treated tooth changed, its most recent outcome was reported. All teeth that were considered clinical failures were also found to be radiographic failures (Figure 4). Incidence of radiographic success for each 12-month increment is reported in Table 5. Radiographic success rates with cumulative failures over time are reported in Figure 5.
**Figure 4. Clinical and Radiographic Outcomes.**

**Table 5. Incidence of Radiographic Success over Time.**

<table>
<thead>
<tr>
<th></th>
<th>6 – 11 Months</th>
<th>12 – 23 Months</th>
<th>24 – 35 Months</th>
<th>36 – 47 Months</th>
<th>48 - 59 Months</th>
<th>60 – 71 Months</th>
<th>72 - 83 Months</th>
<th>&gt; 84 Months</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong># of Teeth</strong></td>
<td>13/17</td>
<td>25/31</td>
<td>27/33</td>
<td>27/39</td>
<td>21/27</td>
<td>10/14</td>
<td>9/10</td>
<td>4/5</td>
<td>136/176</td>
</tr>
<tr>
<td><strong>Radiographic Success Rate (%)</strong></td>
<td>76.5</td>
<td>80.6</td>
<td>81.8</td>
<td>69.2</td>
<td>77.8</td>
<td>71.4</td>
<td>90.0</td>
<td>80.0</td>
<td>77.3</td>
</tr>
</tbody>
</table>
Figure 5. Radiographic Success Rates with Cumulative Failures over Time.

Overall, 136 of 176 primary molars treated by root canal therapy were considered radiographically successful according to the previously discussed outcome assessment criteria, accounting for a radiographic success rate of 77.3%.

Over the course of the follow up periods of treated teeth, seventy of 176 (39.8%) radiographically evaluated teeth were judged to be within normal limits following root canal therapy. Twenty-eight of 176 (15.9%) radiographically evaluated teeth with pre-operative pathologies showed signs of healing following root canal therapy. Thirty-eight of 176 (21.6%) radiographically evaluated teeth with preoperative pathologies showed no signs of improvement or worsening following root canal therapy. Forty of 176 (22.7%) radiographically evaluated teeth with preoperative pathologies showed progressive worsening of pathologic signs (Figure 6).
Figure 6. Radiographic Outcomes by Subcategory.

The preoperative radiographic findings were compared to the postoperative radiographic findings in Table 6. A 40% reduction in furcation radiolucency and a 65% reduction in periapical radiolucency were observed following root canal therapy. When these radiolucencies approached the follicle of the succedaneous tooth healing was less likely. Over the course of the follow up periods of treated teeth, external root resorption increased by more than twice while internal root resorption decreased by approximately 20%. The eruption path of two succedaneous teeth appeared to have been altered by unresorbed ZOE.
Table 6. Preoperative and Postoperative Radiographic Healing*.

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (%)</th>
<th>Postoperative (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furcation Radiolucency</td>
<td>74.8</td>
<td>44.9</td>
</tr>
<tr>
<td>Periapical Radiolucency</td>
<td>38.8</td>
<td>13.6</td>
</tr>
<tr>
<td>Radiolucency near Follicle of Succedaneous Tooth</td>
<td>16.5</td>
<td>14.8</td>
</tr>
<tr>
<td>Widened PDL or Loss of Lamina Dura</td>
<td>11.2</td>
<td>6.8</td>
</tr>
<tr>
<td>External Root Resorption</td>
<td>4.4</td>
<td>9.7</td>
</tr>
<tr>
<td>Internal Root Resorption</td>
<td>5.8</td>
<td>4.5</td>
</tr>
<tr>
<td>Within Normal Limits</td>
<td>14</td>
<td>40</td>
</tr>
<tr>
<td>Altered Eruption Succedaneous Tooth</td>
<td>n/a</td>
<td>1.1</td>
</tr>
</tbody>
</table>

* More than one type of radiographic finding may have been observed in individual teeth.

Of the 211 treated teeth in this study, 108 teeth were followed to the end of their survival time, which was until a tooth was either extracted or exfoliated. The survival time of these teeth was distinguished from those that were lost to follow up and recorded in Figure 7. Five teeth or less required an extraction in each of the first three years of follow up. None of treated teeth required an extraction after the fourth year of follow up. The third year of follow up was the year with the highest rate of exfoliating treated teeth.
Figure 7. Survival of Treated Teeth Followed until Exfoliation or Extraction.

According to the Breslow (generalized Wilcoxon) chi-square test there were no significant differences in radiographic success rates of the four primary molar types treated (p=.088). This was also true when molars were grouped as maxillary versus mandibular primary molars (p=.249). When molars were grouped as first versus second primary molars, a significant difference was recorded (p=.037). The chi-square test showed no significant difference between radiographic success rate and gender (p=.645) and a logistic regression analysis showed no significant difference between radiographic outcome and age (p=.764).

The radiographic outcome data from all of the treated molars was used to perform a Kaplan-Meier survival analysis (Table 7). The cumulative probability that any one tooth would be radiographically successful at one year was 0.826. The probability declined at a fairly steady
rate with each subsequent year. According to the Kaplan-Meier survival test the mean radiographic survival time was 82 months with a standard error of 6.413. The survival analysis is plotted in Figure 8.

**Table 7.** Estimated Kaplan-Meier Survival for Radiographic Failures.

<table>
<thead>
<tr>
<th>Time (Months)</th>
<th>Probability of Survival</th>
<th>Standard Error</th>
<th>Time (Months)</th>
<th>Probability of Survival</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>.893</td>
<td>.045</td>
<td>54</td>
<td>.950</td>
<td>.016</td>
</tr>
<tr>
<td>12</td>
<td>.826</td>
<td>.056</td>
<td>60</td>
<td>.950</td>
<td>.016</td>
</tr>
<tr>
<td>18</td>
<td>.802</td>
<td>.059</td>
<td>66</td>
<td>.944</td>
<td>.017</td>
</tr>
<tr>
<td>24</td>
<td>.692</td>
<td>.072</td>
<td>72</td>
<td>.937</td>
<td>.018</td>
</tr>
<tr>
<td>30</td>
<td>.655</td>
<td>.077</td>
<td>78</td>
<td>.923</td>
<td>.021</td>
</tr>
<tr>
<td>36</td>
<td>.655</td>
<td>.077</td>
<td>84</td>
<td>.923</td>
<td>.021</td>
</tr>
<tr>
<td>42</td>
<td>.968</td>
<td>.013</td>
<td>90</td>
<td>.923</td>
<td>.021</td>
</tr>
<tr>
<td>48</td>
<td>.956</td>
<td>.015</td>
<td>96</td>
<td>.907</td>
<td>.023</td>
</tr>
</tbody>
</table>

Antibiotic use had a negative correlation with radiographic success according to Spearman’s rank correlation coefficient (p < .05), which suggests that patients who presented with clinical symptoms requiring antibiotic use were less likely to have a successful outcome by radiographic standards. This correlation was not significant for clinical outcome.
3) Radiographic Assessment of Obturation Material

All treated teeth with radiographic follow up were assessed for degree of obturation in each canal using the previously described assessment criteria. Twenty-eight of the treated teeth were categorized as underfilled. One hundred and twenty treated teeth were categorized as being adequately filled. Of these, two of the adequately filled teeth had intracanal ZOE that resisted physiologic resorption. Forty-eight treated teeth were categorized as being overfilled. Of these, ZOE resorbed in 30 treated teeth; while in 18 teeth, the ZOE did not resorb by the
time of exfoliation or by the last radiographic examination of the study period. Fifteen treated teeth had no postoperative radiograph that captured the entire root canal obturation. These results are depicted in Figure 9.

There was no statistically significant correlation between degree of obturation and clinical success rate according to the Spearman’s rank correlation coefficient or Kendall’s Tau-b (p = .321 and .300, respectively). There was however a significant correlation between degree of obturation and radiographic success according to Spearman’s rank correlation coefficient and Kendall’s Tau-b (both p< .05) (Table 8).

**Figure 9.** Radiographic Assessment of Root Canal Therapy Obturation.
Table 8. Clinical and Radiographic Success Rates Relative to Root Canal Therapy Obturation.

<table>
<thead>
<tr>
<th></th>
<th>Overfill</th>
<th>Adequate Fill</th>
<th>Underfill</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Success Rate (%)</strong></td>
<td>85.4</td>
<td>91.2</td>
<td>91.8</td>
</tr>
<tr>
<td><strong>Radiographic Success Rate (%)</strong></td>
<td>61.7*</td>
<td>73.5*</td>
<td>79.4*</td>
</tr>
</tbody>
</table>

* p < .05

4) Condition of Succedaneous Teeth.

Enamel defects were observed on seven of the first premolars that succeeded treated primary molars. No enamel defects were observed on second premolars. The defects ranged from hypocalcified or hypoplastic enamel lesions to frank carious lesions (Table 9).

Table 9. Clinical Charting Descriptions of Affected Succedaneous Teeth.

<table>
<thead>
<tr>
<th>Tooth #</th>
<th>Notes from Clinical Charts</th>
<th>Report of Caries or Restoration</th>
</tr>
</thead>
<tbody>
<tr>
<td>19A</td>
<td>“Hypoplastic”</td>
<td>Restoration placed 6 months after eruption</td>
</tr>
<tr>
<td>90B</td>
<td>“Enamel chipping off... hypoplastic”</td>
<td>None</td>
</tr>
<tr>
<td>119</td>
<td>“Hypocalcified”</td>
<td>None</td>
</tr>
<tr>
<td>122</td>
<td>“Pre-eruptive caries”</td>
<td>Restoration placed at time of eruption/first clinical exam</td>
</tr>
<tr>
<td>136A</td>
<td>“Pre-eruptive caries”</td>
<td>Restoration placed at time of eruption/first clinical exam</td>
</tr>
<tr>
<td>140B</td>
<td>“Hypoplasia”</td>
<td>None</td>
</tr>
<tr>
<td>156</td>
<td>“Hypoplasia”</td>
<td>Restoration placed 12 months after eruption</td>
</tr>
</tbody>
</table>

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. Therefore the calculated enamel defect rate was 7/103 or 6.8%.
When age at time of treatment was considered for these 103 subjects, those who developed enamel defects in their succedaneous teeth had a mean age of 54.1 months, while those that did not develop enamel defects had a mean age of 77.2 months. According to the independent student’s T-test, this difference was significant (p ≤ .001, equal variances assumed) and suggests that enamel defects were more likely to occur in younger subjects requiring root canal therapy (Table 10).

Table 10. Enamel Defects in Succedaneous Teeth versus Age at Time of Root Canal Therapy.

<table>
<thead>
<tr>
<th></th>
<th>Number of Teeth Affected</th>
<th>Mean Age at Treatment (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permanent Teeth with Enamel Defects</td>
<td>7</td>
<td>54.1</td>
</tr>
<tr>
<td>Permanent Teeth without Enamel Defects</td>
<td>96</td>
<td>77.2*</td>
</tr>
</tbody>
</table>

• = p ≤ .001

A chi-square analysis revealed that there was no systematic relationship between radiographic success rate and the presence of enamel defects on succedaneous teeth (Cramer’s V = .096, p = .206). Degree of ZOE obturation (including ZOE extrusion) was also unrelated to enamel defects on succedaneous teeth (Cramer’s V = .118, p = .120).

5) Exfoliation of Treated Teeth.

In order to study the effect that root canal therapy had on the timing of exfoliation, treated teeth were compared to unrestored, contralateral teeth. According to the paired Student’s T-test, this revealed no significant difference between the survival times of treated teeth compared to unrestored teeth (p = .228). The sample size however, was only 16 teeth. In order to increase the sample size, treated teeth were then compared to contralateral teeth
that were either unrestored or restored (without pulp therapy). According to the paired Student’s T-test, this analysis showed a significantly longer survival time for contralateral teeth relative to root canal therapy treated teeth (p< .001). The results of these two analyses are shown in Table 11.

Table 11. Survival Time of Root Canal Therapy Treated Teeth vs. Contralateral Teeth.

<table>
<thead>
<tr>
<th></th>
<th>N = 16</th>
<th>Mean Survival (months)</th>
<th>N = 79</th>
<th>Mean Survival (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated Teeth</td>
<td></td>
<td>29.8</td>
<td></td>
<td>38.6</td>
</tr>
<tr>
<td>Unrestored</td>
<td></td>
<td>36.9</td>
<td></td>
<td>46.2*</td>
</tr>
<tr>
<td>Contralateral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teeth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* p < .001

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 had a significantly shorter survival time (p = .049, paired T-test, equal variances assumed). Treated teeth that were considered clinically successful had a mean survival time of 40.5 months that was similar to the 44.4-month survival time of the contralateral tooth group (p= .777, equal variances assumed). This comparison differed markedly for treated teeth that were considered clinical failures since their mean survival time was 23.4 months compared to the contralateral tooth group with a mean survival time of 60.2 months (Table 12). The same analysis was performed for radiographic outcome but no significant differences in survival time were found (Table 13).
**Table 12.** Survival Time vs. Clinical Outcome in Treated vs. Contralateral Teeth.

<table>
<thead>
<tr>
<th></th>
<th>Sample Size</th>
<th>Survival Time (months)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated Tooth – Success</td>
<td>70</td>
<td>40.5</td>
<td>p = 0.777</td>
</tr>
<tr>
<td>Contralateral Unrestored or Restored – Success</td>
<td>70</td>
<td>44.4</td>
<td></td>
</tr>
<tr>
<td>Treated Tooth – Failure</td>
<td>9</td>
<td>23.4</td>
<td>p = 0.049</td>
</tr>
<tr>
<td>Contralateral Unrestored or Restored - Failure</td>
<td>9</td>
<td>60.2</td>
<td></td>
</tr>
</tbody>
</table>

**Table 13.** Survival Time vs. Radiographic Outcome in Treated vs. Contralateral Teeth.

<table>
<thead>
<tr>
<th></th>
<th>Sample Size</th>
<th>Survival Time (months)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated Tooth – Success</td>
<td>49</td>
<td>44.2</td>
<td>p = 0.460</td>
</tr>
<tr>
<td>Contralateral Unrestored or Restored – Success</td>
<td>49</td>
<td>48.6</td>
<td></td>
</tr>
<tr>
<td>Treated Tooth – Failure</td>
<td>17</td>
<td>36.2</td>
<td>p = 0.570</td>
</tr>
<tr>
<td>Contralateral Unrestored or Restored - Failure</td>
<td>17</td>
<td>56.4</td>
<td></td>
</tr>
</tbody>
</table>
G. DISCUSSION

Preservation of an intact primary dentition until the eruption of the permanent successors is very important in maintaining the arch form. In the event of a pulpal insult to a primary tooth, resolution of the pathologic process through pulp therapy can help to preserve arch space and restore function. In addition to preserving arch form, utilization of pulp therapy to maintain the integrity of the primary dentition may also prevent aberrant tongue habits, prevent speech problems, maintain normal masticatory function and preserve esthetics (Goerig & Camp 1983, Barr et al. 1991).

Despite the inarguable benefits of preserving an intact primary dentition, root canal therapy in primary teeth was reportedly one of the approaches to pulp therapy with the least amount of consensus amongst educators in a 1997 survey by Primosch et al. (1997). Comparing the results of this 1997 survey to a similar 2005 survey, primary tooth root canal therapy was taught and used less by 2005 directors of predoctoral pediatric dental school programs and diplomates of the American Academy of Pediatric Dentistry (AAPD). This difference was not however significantly different from the 1997 results (94% versus 85%) (Primosch et al. 1997, Dunston & Coll 2008).

Significantly more respondents in the 2005 survey reported using other non-ZOE filler pastes (i.e. calcium hydroxide and iodoform) than did the 1997 directors and diplomates (6% versus 33%). However ZOE, with or without the use of formocresol, remained the material of choice for obturation of root canals in primary teeth in 2005 by directors of pediatric dentistry

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

The root canal therapy 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 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 predetermined. Patients did not always have routine follow up. Ideally patients would have had routine clinical and radiographic follow up of their treated teeth and their contralateral until exfoliation, as well as a consistent clinical assessment of their succedaneous teeth. As for other comparable studies, a minimum follow up period of six months was required to be included in the study. However any treated tooth that required an extraction prior to six months follow up would not have been identified (Coll et al. 1985, Coll & Sadrian 1996, Fuks et
Although it would not have been appropriate to perform statistical analysis on teeth that had less than 6 months follow up, it would have been interesting to note how many treated teeth failed within the first 6 months.

Furthermore, chart and radiographic analysis relied solely upon the principal investigator (KS). In order to standardize the principal investigator’s radiographic analysis, a standardization exercise was completed. Highly significant inter-rater reliability was observed with a score of 0.81 ($p < .001$). Likewise, intra-rater reliability scored 0.84 ($p < .001$). 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, Yacobi et al. 1991, Coll & Sadian 1996, Bawazir & Salama 2006).

The present retrospective study design has the advantage of allowing a larger sample size and thus detecting smaller differences in outcome. It was previously determined that a sample size of 91 teeth was required to achieve 80% power and a 5% statistically significant level. The final sample size of this study was 211 primary molars from 161 healthy subjects (Appendix II).

1) Clinical Outcomes

In the present investigation treated teeth were considered clinically successful according to the following criteria:

i) Absence of reported pain (spontaneous or stimulated)

ii) Absence of soft tissue abscess
iii) Absence of parulis
iv) Absence of facial cellulitis
v) Absence of pathologic tooth mobility
vi) Absence of extraction of treated tooth

Preoperative signs and symptoms were reported in 54% of patients according to clinical records. Postoperatively, only 10% of patients exhibited signs and symptoms. Therefore the overall clinical success rate was 90.0% based on the 21 clinical failures of 211 treated teeth followed over a mean period of 36 months (range 6 to 111 months). Clinical failures occurred within the first four years following root canal therapy (Figure 2 and Table 2). In the event of a clinical failure, the signs and symptoms most commonly reported included abscess, pathologic tooth mobility and pain (Table 3). This clinical success outcome is among the higher outcomes for root canal therapy studies, which range from 65% to 95.5% (Gould 1972, Yacobi et al. 1991, Holan & Fuks 1993, Payne et al. 1993, Coll & Sadrian 1996, Nadkarni & Damie 2000, Fuks et al. 2002, Mortazavi & Mesbahi 2004, Bawazir & Salama 2006).

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

Clinical outcomes for specifically formocresol and ZOE root canal therapy studies range from 74.5% to 95.5% (Table 14) (Coll & Sadrian 1996, Mortazavi & Mesbahi 2004, Bawazir & Salama 2006). The formocresol and ZOE root canal therapy study by Barr et al. (1991) did not report
specific clinical outcomes. Coll and Sadrian (1996), who presented their results for ZOE and formocresol root canal therapy without differentiating between clinical and radiographic failures, reported an overall success rate of 74.5% (38/51) over a mean follow-up period of 90 months.

Bawazir and Salama (2006) reported a 93.6% overall clinical success rate of formocresol and ZOE root canal therapy after a 6 month follow up period of 47 treated primary molars. More specifically a clinical success rate of 95.5% (21/22) was observed in teeth that were obturated with a slow-speed handpiece-mounted lentulo spiral while the clinical success rate with a hand-held lentulo spiral was 92.0% (23/25). These results should be interpreted cautiously due to the very short 6 month follow up period observed in the study.

The clinical inclusion criteria were usually broader and the definitions of clinical success were equivalent in the present investigation to published studies for root canal therapy (Gould 1972, Yacobi et al. 1991, Holan & Fuks 1993, Payne et al. 1993, Coll & Sadrian 1996, Nadkarni & Damie 2000, Fuks et al. 2002, Mortazavi & Mesbah 2004, Bawazir & Salama 2006). As a result, the clinical outcome of 90% for formocresol and ZOE root canal therapy is a highly acceptable outcome.

2) Radiographic Outcomes

In the present investigation treated teeth were considered radiographically successful according to the following criteria:
i) Absence of new furcation or periapical radiolucency

ii) Absence of pathologic external root resorption (either new or worsening of existing)

iii) Absence of pathologic internal root resorption (either new or worsening of existing)

iv) Improvement or stasis of a pathologic radiolucency when present preoperatively

v) Succedaneous tooth and follicle were not affected by the treated primary molar

vi) Root filling did not alter the path of eruption of the succedaneous tooth

An overall radiographic success rate of 77.3% was calculated based on the 40 radiographic failures of 176 treated teeth over a mean follow up period of 36 months (range 6 to 111 months). Radiographic failures occurred most often in the third and fifth years after treatment (Figure 5 and Table 5). Just under 40% of treated teeth had normal radiographic findings postoperatively. Another 15.9% of teeth showed healing or improvement in their radiographic pathologies relative to their preoperative radiographic conditions while 21.6% of treated teeth had static radiographic pathologic findings. Finally 22.7% of treated teeth showed worsening of preoperative radiographic findings or development of new radiographic pathologies over their respective follow up periods (Figure 6). There was no significant difference in follow up time in any of the above-listed groups therefore bias in follow up times was not a factor.
The radiographic success rate of this investigation is near the average for comparable formocresol and ZOE root canal therapy studies, which range from 72% to 90.9% (Barr et al. 1991, Coll & Sadrian 1996, Mortazavi & Mesbahi 2004, Bawazir & Salama 2006). Table 14 summarizes the main differences between the relevant formocresol and ZOE root canal therapy studies. Of particular note is the fact all of the listed studies restored endodontically-treated primary molars with stainless steel crowns, with the exception of Mortazavi and Mesbahi (2004), who restored all endodontically-treated primary molars with amalgam restorations. Coll and Sadrian (1996) did not clearly state how their treated teeth were restored. The figures in their studies implied that treated molars were restored with stainless steel crowns, however this information was disclosed in their 1996 publication or their previous publications of the same technique (Coll et al. 1985, Sadrian & Coll 1993).

In terms of sample size, the current investigation has the largest reported for formocresol and ZOE root canal therapy – three to seven times the sample size of previous reports.

Follow up time is a critical assessment factor in the determination of a successful root canal therapy treatment. Figures 2 and 5 clearly demonstrate the gradual decline in success rate observed in the current study.

Coll and Sadrian (1996) reported the longest follow up time for formocresol and ZOE root canal therapy with an overall 7.5 year (90 months) follow up period. The mean reported patient age at treatment time for this study was 52 months (4 years), with a range of 19 to 111 months. Technically a 7.5 year follow up period would be possible since most primary molars exfoliate between age 10 and 12. However the incongruity lies in the fact that the study also
included 30 primary incisors. With 36% (30/84) of the overall sample exfoliating between age 6 and 8, it would seem implausible that treated teeth could be followed up for an average of 7.5 years.

Table 14. Summary of Formocresol (FC) and ZOE Root Canal Therapy Studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Follow Up Time (months)</th>
<th>Technique</th>
<th>Clinical Success Rate</th>
<th>Radiographic Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barr et al. 1991</td>
<td>62 primary molars</td>
<td>Range = 12 to 74, Mean = 40</td>
<td>FC mixed with ZOE</td>
<td>Not reported</td>
<td>82.3%</td>
</tr>
<tr>
<td>Coll &amp; Sadrian 1996</td>
<td>54 primary molars</td>
<td>Range = 20 to 177, Mean = 90</td>
<td>FC paper points then ZOE</td>
<td>Overall 74.5%</td>
<td>Overall 74.5%</td>
</tr>
<tr>
<td>Mortazavi &amp; Mesbahi 2004</td>
<td>29 primary molars</td>
<td>Range = 10 to 16, No mean given</td>
<td>FC pledget sealed in chamber for 1-2 weeks then ZOE</td>
<td>78.9%</td>
<td>75.0%</td>
</tr>
<tr>
<td>Bawazir &amp; Salama 2006</td>
<td>47 primary molars</td>
<td>6</td>
<td>FC paper points then ZOE</td>
<td>Overall 93.6%</td>
<td>Overall 80.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- handpiece + lentulo = 95.5%</td>
<td>- handpiece + lentulo = 90.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- handheld lentulo = 92%</td>
<td>- handheld lentulo = 72%</td>
</tr>
<tr>
<td>Stallaert et al. 2011</td>
<td>211 primary molars (clinical), 176 primary molars (radiographic)</td>
<td>Range = 6 to 111, Mean = 36</td>
<td>FC mixed with ZOE</td>
<td>90.0%</td>
<td>77.3%</td>
</tr>
</tbody>
</table>
Bawazir and Salama (2006) reported an overall 80.9% radiographic success rate of formocresol and ZOE root canal therapy after a 6 month follow up period. More specifically a radiographic success rate of 90.9% was observed in teeth that were obturated with a slow-speed handpiece-mounted lentulo spiral while the radiographic success rate with a hand-held lentulo spiral was only 72.0%. Had the present investigation only considered radiographic failures that occurred in its initial 6 to 11 month follow up period the reported radiographic success rate would have been 97.7% (172/176) (Figure 5). This was far from the study's final reported radiographic success rate with over 7 years of follow up, demonstrating how inaccurate a short follow up period can be.

In the present investigation, preoperative and postoperative radiographic findings were compared for two reasons. The first reason for this analysis was to emphasize the wide inclusion criteria of this study. The high rate of preoperative radiographic findings in the present investigation was indicative of the degree of pathoses present in both the pulpal tissues of treated teeth and their surrounding supporting structures. Variable inclusion criteria in primary tooth root canal therapy 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 root canal therapy treatment. It is well established that radiographic healing in permanent teeth with apical periodontitis is a slow process (Ørstavik 1996, Dugas et al. 2002, Molven et al. 2002, Fristad et al. 2004, Metzger et al. 2009). In fact, less than half of permanent teeth with apical periodontitis are healed one year after root canal therapy; approximately 90% are
healed after four years and approximately 95% are healed after 6 years. The remaining approximate 5% require an even longer period to heal completely (Ørstavik 1996, Dugas et al. 2002, Molven et al. 2002, Fristad et al. 2004, Metzger et al. 2009).

There are no studies that extensively assess the rate of healing following root canal therapy in primary teeth. However one may postulate that endodontic healing should occur over time in primary teeth as it does in permanent teeth. It is for this reason that in the present investigation, stasis of preoperative radiographic pathologies were considered to be successful treatments. Other studies, also with wide inclusion criteria, defined improvement or stasis of preoperative radiographic findings as a successful outcome (Barr et al. 1991, Fuks et al. 2002, Prabhakar et al. 2008, Moskovitz et al. 2010, Nakornchai et al. 2010).

In the present investigation, 74.8% of the teeth had preoperative furcation radiolucencies and 38.8% had preoperative periapical radiolucencies. Postoperatively furcation radiolucencies were observed in 44.9% of treated teeth and periapical radiolucencies were observed in only 13.6% of treated teeth. This was a 29.9% reduction in furcation radioluencies and a 25.2% reduction in periapical radioluencies (Table 6).

Preoperative furcation and/or periapical radioluencies were observed to extend near the follicle of the succedaneous tooth in 16.5% of treated teeth however only 1.7% of these lesions improved or resolved. When these radiolucencies approached the follicle of the succedaneous tooth healing was much less likely. External root resorption increased by 5.3% following root canal therapy, however this maybe due to the fact that it was difficult to differentiate from physiologic root resorption.
The greatest number of radiographic failures tended to occur within the first year and then again between three and six years following treatment. Patients who were prescribed antibiotics were more likely to have negative radiographic outcomes (p< .05). As a result, in the event that a child presented with a fever and a non-draining abscess and/or cellulitis, careful radiographic diagnosis should be used in determining if the associated tooth is suitable for root canal therapy treatment. Long term clinical and radiographic follow up of these teeth is advisable if root canal therapy treatment is performed.

3) Effects of Obturation on Root Canal Therapy Outcome.

Degree of canal obturation was statistically unrelated to clinical outcome in this investigation. However there was a trend towards higher clinical success rates for treated teeth that were underfilled or adequately filled (91.5%) relative to teeth, which had been overfilled (85.4%).

Degree of canal obturation was statistically correlated to radiographic outcome (Table 8). These results are consistent with both Coll and Sadrian (1996) and Fuks et al. (2002), who reported a success rate of 57 to 58% for teeth with overfilled canals and an 83 to 87% success rate for teeth with adequately filled or underfilled canals. It is possible that the degree of pathosis may have contributed to overfilling of canals and the decreased success rates.

In the present investigation, 9% of treated teeth exhibited obturation material that was expressed beyond the apex of at least one canal and did not resorb by the time of exfoliation or by the last radiographic examination of the study period. The only observed consequence
of this was the deflection of the eruption path of two succedaneous teeth. Ectopic eruption of succedaneous premolars following root canal therapy of primary molars was observed in 21.6% of cases in a Coll and Sadrian (1996) study (n= 51). The authors themselves reported that this rate was unusually high and postulated that retained ZOE was the reason for the high incidence of ectopic eruptions. Barr et al. (1991) reported that they had never observed retained ZOE after the exfoliation of a primary molar treated by formocresol and ZOE root canal therapy, not only in their study but also in 15 years of practice.

Retention of obturation material particles was not statistically related to clinical or radiographic success of root canal therapy (p = .361 and .130, respectively, which coincided with the Coll and Sadrian (1996) findings (p = .11). It is possible that the degree of pathosis of a treated tooth may have contributed to the overfill of obturation material and the decreased success rate.

4) Effect on Enamel of Succedaneous Teeth.

One hundred and three succedaneous teeth of endodontically-treated primary molars were assessed clinically. Of these, seven premolars had enamel defects ranging from mild to severe enamel hypocalcification or enamel hypoplasia. As a result some of these newly erupted teeth were more susceptible to caries. Age at time of root canal therapy treatment proved to be a significant factor in determining which patients might develop enamel defects in their succedaneous teeth (p ≤ .001). A survey of the literature indicates there are no previous studies that evaluate the effect of age at the time of irreversible pulpitis and root canal
therapy treatment in primary molars and the incidence of enamel defects in succedaneous teeth.

The overall mean age at time of treatment for primary molar root canal therapy in this investigation was 72 months. However age at time of treatment for the 103 aforementioned subjects was 72.9 months (6 years of age) for those that did not develop enamel defects in their succedaneous teeth and 54.1 months (4 years of age) for those that did develop enamel defects in their succedaneous teeth (p ≤ .001). All enamel defects were observed in first premolars while no enamel defects were observed in second premolars.

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. Likewise a younger child would be more likely to have an error in enamel calcification in a first premolar than a second premolar since enamel calcification is completed earlier in first premolars.

Other contributing factors could be that first primary molars erupt, on average one year earlier than second primary molars (AAPD 2011) and that 69% of primary molars included in this investigation 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 (Zurcher 1925):
• The pulp occupies a larger proportional space in first primary molars.
• The coronal enamel and dentin thickness is much thinner in first primary molars.
• The mesiobuccal pulp horn is more prominent in first primary molars relative to second primary molars (Figure 10).

Figure 10. Radiographic Examples of Anatomical Differences in Pulpal Anatomy of Primary First and Second Molars.

For these reasons, it is probable that a primary first molar would be at higher risk for pulpal involvement than a second primary molar.

Although this study does not rule out the possibility that formocresol and ZOE root canal therapy was responsible for the enamel defects in succedaneous teeth, it is the belief of the authors that the process of chronic infection with eventual necrosis of a primary molar is more likely to have caused the enamel defects that the root canal therapy itself.

Coll and Sadrian (1996) also reported enamel defects on the succedaneous teeth of primary incisors and molars treated by formocresol and ZOE root canal therapy. They also proposed
that enamel defects were the result of infection prior to root canal therapy rather than the endodontic procedure itself. They also proposed that excessive (>1mm) preoperative root resorption could be indicative of pre-existing infection and that primary teeth with greater than 1mm of root resorption were consequently at increased risk of enamel defects on the succedaneous teeth. The authors did not describe how they assessed minute degrees of root resorption nor did they describe how they differentiated between pathologic root resorption and physiologic root resorption.

Degree of ZOE obturation was unrelated to the occurrence of enamel defects in this investigation, which coincided with the results from Coll and Sadrian (1996).

Given the evidence presented thus far, one may propose that a patient’s age should be considered in planning the treatment of a hyperemic or necrotic primary molar. Since the enamel of first premolars develops until the age of five years and the enamel of second premolars develops until the age of six years, these along with clinical signs and symptoms and radiographic findings could be important in predicting the outcome of root canal therapy treatment.

5) Effect of Root Canal Therapy on Exfoliation Times.

The exfoliation times of teeth treated by root canal therapy were compared to the exfoliation times of contralateral teeth that were unrestored or restored without pulp therapy. On average, treated teeth exfoliated 7.6 months earlier than their contralateral teeth, which was statistically significant (p < .001) but not clinically significant. However, when this same group
of paired 79 teeth was compared for clinical outcome, it was found that treated teeth considered clinical failures were significantly more likely to exfoliate earlier (p < .05), on average 36.8 months earlier (n= 9). If treated teeth were rated as clinical successes then no significant difference was found in the timing of their exfoliation (p = .777).

Coll et al. (1985) also found that teeth treated by formocresol and ZOE root canal therapy were significantly more likely to exfoliate earlier than their contralateral teeth (p= .01). Likewise treated teeth that were rated failures were also more likely to exfoliate sooner than their respective contralateral teeth, but similar if rated successes. One difference in the comparison by Coll et al. (1985) was the inclusion of all contralateral teeth, including teeth that were extracted, pulpotomized or untreated by pulp therapy. As a result their analysis of contralateral teeth may have been biased by the presence of inflammatory mediators produced by both carious processes and the consequent dental therapy.

Barr et al. (1991) reported that 56% of teeth treated by ZOE and formocresol root canal therapy exhibited advanced exfoliation relative to their contralateral teeth. The authors did not describe the condition of the contralateral teeth, which again, is a potential bias and reduced the validity of their statement. In addition they did not characterize the range of reported advanced exfoliation times or mention if it was statistically relevant.
SUMMARY

In summary, the results from the present investigation suggest that the described formocresol and ZOE root canal therapy technique described herein is a viable alternative to extraction and space maintenance for primary molars.

Preoperative risk factors for radiographic outcome include: radiolucencies that approach the follicle of the succedaneous teeth, particularly if the enamel of the succedaneous tooth is not completely developed, and patients who would require antibiotic therapy due to the presence of a fever and a non-draining abscess and/or facial cellulitis. Postoperatively, periodic radiographic evaluation following root canal therapy is critical to ascertain that inflammatory processes are healing and not posing risk to the follicles of the succedaneous teeth.

CONCLUSIONS

1. Root canal therapy in primary molars using one drop of full strength Buckley’s formocresol, one drop of eugenol and pure zinc oxide powder as the root filler demonstrated a high clinical success rate (90.0%) and a moderate radiographic success rate (77.3%).

2. Length of ZOE obturation and presence of ZOE expressed beyond the apex of a canal had no effect on clinical success rate. However a significant correlation between degree of obturation and radiographic outcome was observed with higher radiographic success rates observed for teeth that were underfilled or adequately filled ($p < .05$).
3. Enamel defects in first premolars were rarely observed (6.8%) following root canal therapy in antecedent primary first molars but when present, they were more likely to occur in a younger child.

4. Root canal therapy treatment may shorten the lifespan of primary tooth relative to a contralateral tooth, particularly if the tooth has a negative clinical outcome.
APPENDIX I: INFORMED CONSENT

CONSENT TO DENTAL TREATMENT

I, (relationship), have been informed by Dr. Paul Andrews of the need to undergo dental treatment as presented to me for my (son or daughter) on the treatment plan dated

I have been fully informed about the details of the recommended treatment and alternative approaches including their risks, benefits and fees. I fully understand them, and agree to accept the treatment as recommended by Dr. Andrews.

I understand that individual reactions to treatment cannot be predicted, and that if any unanticipated reactions occur during or following any treatment, I agree to report them to the office as soon as possible.

I have been told that the success of the recommended treatment depends upon my cooperation in keeping scheduled appointments, following home care instruction, including oral hygiene and dietary instructions, and reporting to the office any change in my child’s health status as soon as possible.

I acknowledge that no guarantees or assurances have been given by anyone as to the results that may be obtained.

I have discussed all of the above with Dr. Andrews, and all my questions have been answered.

I hereby authorize Dr. Andrews to complete the treatment as presented to me on the treatment plan dated

______________________________  ______________________________
Patient/Parent/Guardian Signature  Date

______________________________  ______________________________
Witness Signature  Doctor’s Signature
to advise you of treatment options

to enable us to contact you and maintain communication with you

to offer and provide treatment, care and services in relationship to the oral and maxillofacial complex and dental care generally

to communicate with other treating health-care providers, including specialists and general dentists who are the referring dentists and/or peripheral dentists

to allow us to efficiently follow-up for treatment care, billing and collect unpaid accounts for teaching and demonstrating purposes on an anonymous basis

to complete and submit dental claims for third party adjudication and payment

to deliver your charts and records to the dentist’s insurance carrier to enable the insurance company to assess liability and quantify damages, if any

to comply with legal and regulatory requirements, including the delivery of patients’ charts and records to the Royal College of Dental Surgeons of Ontario in a timely fashion, when required, according to the provisions of the Regulated Health Professions Act

to comply with agreements/undertakings entered into voluntarily by the member with the Royal College of Dental Surgeons of Ontario, including the delivery and/or review of patients’ charts and records to the College in a timely fashion for regulatory and monitoring purposes

to prepare materials for the Health Professions Appeal and Review Board (HPARB)

to permit potential purchasers, practice brokers or advisors to evaluate the dental practice

to invoice for goods and services

to process bank card and credit card payments

to assist this office to comply with all regulatory requirements

to comply generally with the law

By signing the consent section of this Patient Consent Form, you have agreed that you have given your informed consent to the collection, use and/or disclosure of your personal information for the purposes that are listed. If a new purpose arises for the use and/or disclosure of your personal information, we will seek your approval in advance.

Your information may be accessed by regulatory authorities under the terms of the Regulated Health Professions Act (RHPA) for the purposes of the Royal College of Dental Surgeons of Ontario fulfilling its mandate under the RHPA, and for the defence of a legal issue.

Our office will not under any conditions supply your insurer with your confidential medical history. In the event this kind of a request is made, we will forward the information directly to you for review, and for your specific consent.

When unusual requests are received, we will contact you for permission to release such information. We may also advise you if such a release is inappropriate.

You may withdraw your consent for use or disclosure of your personal information, and we will explain the ramifications of that decision, and the process.
Patient Consent

For Collection Use and Disclosure of Personal Information

I have reviewed the above information that explains how your office will use my personal information, and the steps your office is taking to protect my information.

I know that your office has a Privacy Code, and I can ask to see the Code at any time.

I agree that Dr. [patient's name] can collect, use and disclose personal information about [patient's name] as set out above in the information about the office’s privacy policies.

_________________________  __________________________
signature                 print name

_________________________  __________________________
date                      signature of witness
CONSENT FOR ROOT CANAL TREATMENT

I, (relationship), hereby authorize Dr. Paul Andrews to perform root canal treatment for my (son or daughter) on the following tooth (teeth):

The nature and purpose of root canal treatment, and possible alternative methods of treatment have been explained to me and I fully understand them and their risks, benefits and fees.

I understand that during the treatment there may be periods of discomfort.

I further understand that many factors contribute to the success of root canal treatment and cannot be determined in advance. Therefore, in some cases treatment may have to be discontinued before it is completed, or may fail following treatment. Some of these factors are: resistance to infection, the location and shape of the canals, etc.

I have been informed that should the treatment have to be discontinued before completion, or if it fails following treatment, other procedures may be necessary to save the tooth, or it may have to be extracted.

I further understand that during and following the treatment, I am to contact Dr. Andrews office if I have any additional questions, or if any unexpected reactions occur.

I acknowledge that no guarantees or assurances have been given by anyone as to the results that may be obtained.

I have discussed all of the above with Dr. Andrews, and have had all my questions answered.

Patient/Parent/Guardian Signature                                      Date

Witness Signature                                                      Doctor’s Signature
APPENDIX II: LETTER TO PARENTS

Faculty of Dentistry
University of Toronto
Graduate Program in Pediatric Dentistry

May 1, 2010

Dear Parents of ________________,

An investigation studying the outcomes of primary molar root canal therapy is being conducted through the University of Toronto, Department of Pediatric Dentistry for a graduate qualification. This study shall include certain dental x-rays of patients from the private dental office of Dr. Paul Andrews. These x-rays will only be used on an anonymous basis.

Should you wish to learn more about this study or should you wish to withdraw from this study, please contact the office of Dr. Paul Andrews at (905)270-4700.

Sincerely,

Dr. Michael J. Sigal
Professor and Head, Discipline of Pediatric Dentistry
Director, Graduate Program in Pediatric Dentistry

Dr. Paul B. Andrews
Assistant Professor
Department of Pediatric Dentistry

Dr. Karen Stallaert
Masters Student
Pediatric Dentistry
APPENDIX III: SAMPLE SIZE CALCULATION

1. The following is a sample size calculation for a study with one proportion known (chi-square test).

2. The research question is “Does the described ZOE and formocresol root canal therapy technique perform better than the existing one?”


4. It was estimated that the proposed technique from this study would generate an 85% success rate.

5. What sample size would be required in order to detect the above-stated differences with 80% power and a 5% level of statistical significance?

\[ N = \frac{(Z_1\sqrt{\pi_{\text{known}}(1-\pi_{\text{known}})} + Z_2\sqrt{\pi_{\text{2}}(1-\pi_{\text{2}})})^2}{\delta^2} \]

where:

- \( Z_1 \) is a Z critical value, based upon \( \alpha = .05 \), one-tailed.
- \( \pi_{\text{known}} \) refers to the proportion of success using the traditional method (74.5%)
- \( Z_2 \) is a Z critical value, based upon \( 1 - \beta \) (or, power), which is set at .80, one-tailed.
- \( \pi_{\text{2}} \) refers to the expected proportion of successes, using the new method (80%)
- \( \delta \) refers to the difference between the two proportions (.745 - .80)
\[ N = \frac{Z_{.95}\sqrt{.745(1-.745)} + Z_{.80}\sqrt{.85(1-.85)}}{(.745-.85)^2} \]
\[ = \frac{(1.64\sqrt{.189975} + .815\sqrt{.1275})^2}{0.011025} \]
\[ = \frac{[1.64(0.436)+.815(0.357)]^2}{0.011025} \]
\[ = (.715+.291)^2 / 0.011025 \]
\[ = 1.006 / 0.011025 \]
\[ = 91.25 \]

The pre-determined sample size calculation to obtain an 80% power at a 5% level of statistical significance in 91 teeth.

## APPENDIX IV: INTER- AND INTRA-RATER RELIABILITY

<table>
<thead>
<tr>
<th>Kappa Test</th>
<th>KS 1</th>
<th>KS 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>KS 1</td>
<td>---</td>
<td>0.84</td>
</tr>
<tr>
<td>KS 2</td>
<td>0.84</td>
<td>---</td>
</tr>
<tr>
<td>PA/HN</td>
<td>0.84</td>
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