A RETROSPECTIVE REVIEW OF BIODENTINE PULPOTOMY OUTCOMES IN PRIMARY MOLARS

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Abstract

Purpose: This study aimed to determine the effectiveness of Biodentine, a calcium-silicate material, as a pulpal medicament for primary molars requiring a pulpotomy procedure.

Methods: A retrospective chart review was conducted on children who received a Biodentine pulpotomy procedure on one or more primary molar(s) while receiving dental rehabilitation under general anesthesia from January 1, 2013 to May 1, 2018. Five clinical and radiographic outcomes were used to determine the success of the pulpotomy. The teeth were evaluated at intermittent recalls for up to 30 months post-treatment. Survival curves of the Biodentine pulpotomized teeth were estimated by nonparametric maximum likelihood methods for interval censored data.

Results: A total of 608 teeth from 208 children were evaluated over a 30-month post-treatment period. There was a total of twenty teeth with a failed pulpotomy procedure over the study period. Six teeth were identified as having both a clinical and radiographic failure. The remaining 14 failures were either a clinical or a radiographic failure – three were clinical failures, while eleven radiographic failures exclusively. A survival analysis curve indicated that the overall cumulative probability of survival at 30 months was 97.3% (95% CI = 83.7-99.2%) clinically, and 85.6% (95% CI = 76.3-93.7%) radiographically.

Conclusions: Pulpotomy procedures on primary molars utilizing Biodentine as the pulpal medicament had favourable clinical and radiographic results up to 30 months.

Lay Summary

When a child has a cavity that is deep enough to involve the nerve of a primary tooth, a pulpotomy, or “baby root canal” can be performed to avoid tooth extraction. A medicament is placed over the remaining tooth nerve and pulp tissue as part of the procedure. Various medicaments have been utilized to perform pulpotomies, but no consensus exists as to which one is superior. Biodentine is a calcium-silicate pulpotomy medicament that is relatively new to the market with characteristics that favour pulp tissue regeneration as well as ease of use in a pediatric dental setting. A retrospective chart review of 208 children who had received at least one Biodentine pulpotomy procedure was conducted. An overall success rate of 97.3% was observed in 608 primary molars with Biodentine pulpotomies from 208 patients, with favorable clinical and radiographic outcomes at 30 months post-treatment.

Preface

This thesis is an original work of the author, Bryan Wong, with guidance from research supervisor, Dr. Kavita Mathu-Muju, and committee members, Dr. Mark Casafrancisco, Dr. Elsa Hui-Derksen, and Dr. Jeff Coil. Regular meetings were held with the research supervisor and committee members in attendance.

Statistical analyses were completed by Eric Fu from the Department of Statistics, University of British Columbia.

Ethics approval for this study was granted by The University of British Columbia Ethics Board (Certificate number H18-01290). The online ethics training module Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics (TCPS 2: CORE) was issued and completed on August 8, 2016.

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List of Abbreviations

AAE – American Association of Endodontists

AAPD – American Academy of Pediatric Dentistry

ATSDR – Agency for Toxic Substances and Disease Registry

CH – Calcium Hydroxide

CSH – Hydrated Calcium Silicate

FC - Formocresol

FS – Ferric Sulphate

EPT – Electric Pulp Test

ES - Electrosurgery

GIC – Glass Ionomer Cement

IARC – International Agency for Research on Cancer

IPT – Indirect Pulp Therapy

MTA – Mineral Trioxide Aggregate

OTC – Over-the-counter

PDL – Periodontal Ligament

USEPA – United States Environmental Protection Agency

WHO – World Health Organization

ZOE – Zinc Oxide Eugenol

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Finally, a very special and heartfelt thanks to my wife, Ann Lu, for your unwavering love throughout my pediatric dental residency. You have been my rock and without a doubt, this road would have been impossible without you.

Dedication

This thesis is dedicated to my family, who have always been supportive of my journey to fulfill my life's pursuits. I would also like to dedicate this thesis to my source of inspiration, the children and families whom I have had the privilege of serving throughout my residency.

Chapter 1: Introduction

1.1 Role of Primary Dentition

While trauma, ectopic eruption, congenital disorders, and arch length discrepancies are known causes of premature tooth loss in the primary dentition, dental caries still remains the most common etiology (1). Failure to maintain the primary dentition influences a child's general health, quality of life, and growth and development (2). Furthermore, early childhood caries and subsequent premature tooth loss can have aesthetic consequences which can impact a child's self-esteem and social development (3). The American Academy of Pediatric Dentistry (AAPD) recognize that the maintenance of the primary dentition also plays a critical role in preserving arch length integrity which facilitates the eruption of the permanent dentition (4). Premature primary molar loss, due to caries, may predispose the permanent dentition to malocclusions as well as alter the eruption timing and sequence of the succedaneous teeth (4). As a result, it is imperative that a systematic approach is taken when evaluating the viability of primary molars when caries approximate the pulp.

1.2 Diagnosis of Pulp Vitality

1.2.1 Permanent Teeth

As the treatment options for a vital and non-vital tooth vary significantly, the diagnoses of pulp vitality of the tooth in question should be comprehensive. According to the American Association of Endodontics (AAE), endodontic evaluation of a pulp-involved carious tooth requires appropriate query of the chief complaint and thorough clinical and radiographic examination (5). History of the chief complaint should include the length of time the symptoms

have persisted, the location of the pain, the spontaneity of the pain, what solicits or relieves the pain, and what medications are currently taken for pain relief. A clinical examination involves examining facial symmetry and soft tissues, the presence or absence of a sinus tract, the periodontal status, restoration, and caries related to affected tooth. Clinical testing can provide information about the periapical and pulpal status of the tooth. The former is done by percussion, palpation, and bite test, and the latter involves cold testing, heat testing, and electric pulp testing (EPT). Radiographic evaluation comprises of periapical radiographs to evaluate the periodontal ligament (PDL) space, and to evaluate for the presence or absence of periradicular or furcation radiolucencies. A correct endodontic diagnosis must be made to avoid improper management. The following table summarizes the AAE diagnostic terminology for endodontic diagnosis (6):

Table 1. AAE Terminology for Endodontic Diagnosis

Pulpal Diagnosis	
Normal	Vital pulp which is symptom-free and has a normal pulp response to stimuli. Cold testing elicits response for no more than 1-2 seconds removal of stimulus
Reversible Pulpitis	Inflammation of the vital pulp expected to resolve to normal with appropriate management. Cold or sweet elicits transient discomfort. Often caused by caries or deep restorations.
Symptomatic Irreversible Pulpitis	Inflammation of a vital pulp which is unable to heal. Root canal treatment is indicated. Symptoms includes pain to temperature stimulus, prolonged pain following stimulus removal, spontaneous pain, and referred pain. Postural changes can accentuate painful symptoms. Over-the-counter (OTC) analgesics may be ineffective.
Asymptomatic Irreversible Pulpitis	Inflammation of a vital pulp which is unable to heal. Root canal treatment is indicated. No clinical symptoms, responds normally to pulp testing. Either due to trauma or due to deep caries that will expected to cause pulp exposure.
Pulp Necrosis	Non-vital pulp. Root canal treatment is indicated. Asymptomatic, no response to clinical pulp testing.

Periapical Diagnosis	
Normal Apical Tissues	**Clinical** – No percussion sensitivity, no palpation sensitivity, no mobility. **Radiographic** – Intact lamina dura, intact/uniform PDL space.
Symptomatic Apical Periodontitis	**Clinical -** Pain on biting, percussion, and palpation due to inflammation at apical periodontium. **Radiographic** – Depending on the progression of the pulpal disease, may or may not have radiographic changes.
Asymptomatic Apical Periodontitis	**Clinical** – No clinical symptoms. **Radiographic** – Apical radiolucency due to apical periodontal destruction.
Chronic Apical Abscess	**Clinical** – Little or no clinical discomfort, associated with a sinus tract with intermittent pus discharge. **Radiographic** – Apical radiolucency due to apical osseous destruction.
Acute Apical Abscess	**Clinical** – Spontaneous pain, extreme sensitivity to percussion and palpation, pus formation, tissue swelling. Necrosis is rapid. Patient may be febrile and experience malaise and lymphadenopathy **Radiographic** – Due to its rapid nature, may not see apical destruction.

1.2.2 Primary Teeth

Determining the pulpal diagnosis in the child patient can sometimes be complicated by unreliable reports of symptoms and responses to clinical testing (7–9). This is particularly true in children exhibiting pain-avoiding behaviours which can bias their response (7). Furthermore, undesirable behaviour and poor patient cooperation may result from percussion testing, thermal testing, and electric pulp testing in a child that perceives these stimuli as unpleasant (7). A 2011 study by Hori et al. reviewed literature from 1965 to 2010 and found insufficient literature supporting the efficacy of pulp testing (EPT, hot, and cold testing) in the primary dentition (10,11). As these diagnostic tests may be difficult to attain and are potentially of minimal diagnostic value, the emphasis of endodontic evaluation for the deciduous dentition depends primarily on clinical and radiographic assessment.

The routine assessment of clinical and radiographic findings in the primary dentition is otherwise similar to that of the permanent dentition. If there is a history of pain, the differentiation between pain that is provoked and pain that is spontaneous can aid in indicating the inflammatory nature of the pulp (12). Moreover, a tooth with a history of constant or throbbing pain has been found to demonstrate extensive degenerative changes of the pulp extending into the radicular pulp histologically (13). There are, however, some notable distinctions that need to be accounted for when examining the primary dentition. While tooth mobility can be a clinical sign of an ongoing abscess, similar clinical findings can present in an exfoliating primary tooth (12). Also, on radiographic examination of a primary molar, a pathologic radiolucency secondary to a pulpal necrosis may not present periapically – a typical finding in the permanent dentition. Rather, primary molars have a high prevalence of furcal accessory canals resulting in pathological furcation radiolucency secondary to a necrotic pulp (14).

1.3 Pulp Management of the Primary Dentition

With any carious tooth requiring restorative intervention, the depth of the caries and the extent to which the pulpal health has been compromised will influence which treatment modality will be most appropriate. Non-vital pulp therapy is appropriate for a pulpal diagnosis of irreversible pulpitis, either symptomatic or asymptomatic, and pulpal necrosis. Conversely, vital pulp therapy is suitable for a deep carious lesion with a potential for pulpal exposure on either an asymptomatic tooth or one which demonstrates symptoms of reversible pulpitis.

1.3.1 Non-Vital Pulp Therapy

With a confirmed diagnosis of irreversible pulpitis or necrosis in the primary tooth pulp, extraction is always an option, though not always preferable. When both the coronal and radicular pulp tissue of a primary tooth is irreversibly inflamed or necrotic, a pulpectomy is a viable treatment option if the offending tooth does not have a periapical infection affecting the permanent successor, does not exhibit internal and external root resorption, has no soft tissue pathology, and is appropriately restorable (15,16). Otherwise, extraction of the involved tooth is the only option (17). The pulpectomy procedure involves removal of infected and necrotic coronal and radicular pulpal tissue, debridement, shaping, and disinfection of the root canal system, and placement of a canal medicament (16). The root canal system of a primary tooth is complex due to continued secondary dentin deposition and root resorption (18). Therefore, root canal preparation in the primary tooth is often not ideal as the success of the pulpectomy procedure relies heavily upon the medicament utilized (19). Pulpectomy medicament characteristics should include the following (15,20,21):

1. Nontoxic
2. Antiseptic
3. Radiopaque
4. Easily fill the root canal, and adhere to the canal walls
5. Easily removable when necessary
6. Should be readily resorbed if extruded past the root apex
7. Should not cause root resorption of the primary tooth
8. Should be resorbed as the root of the primary tooth resorbs
9. Should not interfere with the development of the succedaneous tooth

Various pulpectomy medicaments have been used including Zinc Oxide-Eugenol (ZOE), Calcium hydroxide paste (CH), and Iodoform; however, none of these materials individually exhibit ideal pulpectomy characteristics (19,20). ZOE, used since the early 1930s, has demonstrated successful clinical outcomes but can irritate periapical tissues if extruded through the root apex (20,22). Furthermore, ZOE overfills are difficult to retrieve, not readily resorbable, and are potentially toxic (19,23). Potential concerns of ZOE extrusion in the periapical areas have been reported in studies and include the necrosis of periapical tissues, developmental arrest of succedaneous teeth, and delayed physiologic root resorption (24–26). Hardened and unresorbed extruded ZOE can also disrupt the eruption pathway of the succedaneous permanent tooth (27).

Iodoform-based paste (KRI 1 paste) is a bactericidal, resorbable, and easily retrievable medicament (23). When overfills have unintentionally occurred, resorption of the material occurred when observed over a 1-2 week period (20). KRI pastes have exhibited success in pulpectomy treatment of primary teeth both clinically and radiographically (20,28). In comparing KRI to ZOE success rates for pulpectomy procedures in primary molars, Holan and Fuks found that over a 12-48 month period, KRI had a higher overall success rate of 84% as opposed to 65% (23). Overfilling of the pulp canal and extrusion of ZOE was associated with a 59% failure rate – significantly more than the 21% failure rate noted with KRI (23). Unlike ZOE pastes, placement of KRI paste tend to be less technique sensitive as the material consistency is less viscous (23).

CH pastes are used widely as an intra-canal therapy agent in the permanent dentition, but reports of its use as a medicament in primary dentition pulpectomy have demonstrated internal

root resorption (29,30). However, CH/Iodoform mixtures have demonstrated successful clinical outcomes and therefore its use in pulpectomies is still advocated (16). CH/Iodoform pastes, namely the Japanese product, Vitapex, has garnered interest due to its excellent material characteristics. It consists of a mixture of 40.4% iodoform, 30.3% calcium hydroxide, and silicone 22.4% marketed in a syringe-dispensing system (31). It is non-toxic, radiopaque, and easily resorbable. The mechanism of resorption is completed either through simple diffusion or through macrophage clearance (32). Vitapex has shown excellent success rates, however comparison studies between Vitapex and other pulpectomy medicaments have shown conflicting result. When Vitapex was compared to ZOE in a study by Mortazavi et al. 2004, a statistically significant difference in success rates of 100% versus 78.5% respectively was found (33). Conversely, a more recent study done in 2016 showed no statistical difference of pulpectomy outcomes following a 30 month observation of Vitapex, RC Fill (ZOE with iodoform), and Pulpdent (ZOE) – all three medicaments were equally effective (34).

1.3.2 Vital Pulp Therapy

In a carious primary tooth, a pulpal diagnosis of either normal pulp or reversible pulpitis makes it a candidate for vital pulp therapy. While there are numerous treatment options for treating a vital carious tooth, the most suitable option depends largely on the extent of the carious lesion and whether or not pulp exposure has occurred. Vital pulp therapy options in the primary dentition include indirect pulp therapy, direct pulp capping, and pulpotomy.

1.3.2.1 Indirect Pulp Therapy (IPT)

During the caries removal process, affected dentin in close proximity to the pulp chamber is sometimes left deliberately at the clinicians' discretion in the interest of preventing a pulp exposure (35). Subsequently, a biocompatible material, such as dentin bonding agent, resin modified glass ionomer (RMGI), CH, ZOE, or glass ionomer cement (GIC), is placed over the carious dentin, and a sound final restoration is placed to ensure minimal bacterial leakage (36–38). The primary aim of IPT is create an optimal metabolic state in the dentin-pulp complex to capitalize on the reparative potential of odontoblasts to form a tertiary dentin (39). A joint symposium between the AAE and AAPD was held in 2007 to review the current prospective on vital pulp therapy and a post-symposium surveyed showed a trend towards a more positive attitude about IPT for primary teeth (40). Contrary to past doubts about the IPT method, more recent publications have shown growing evidence of long-term IPT success in the primary dentition (41,42). Moreover, IPT has been shown to cost less, allow for better exfoliation timing of the offending tooth, and better success in treating a carious vital tooth than a formocresol or ferric sulfate pulpotomy (35,37,38). In a study by Farooq (2000) comparing success rates of FC pulpotomy versus IPT in primary teeth with deep caries, IPT outperformed FC pulpotomies by 93% to 74% respectively (38). Al-Zayer et al.'s retrospective study (2003) of 187 primary teeth exhibited a 95% success with IPT (42). In addition, while FC pulpotomized teeth exhibited early exfoliation, all primary teeth treated with IPT exfoliated normally (38). Ultimately, given the evidence of IPT success in the primary dentition, this conservative approach for caries management is preferable, when indicated.

1.3.2.2 Direct Pulp Cap (DPC)

Direct pulp capping is a procedure involving the placement of a medicament to a mechanically exposed, but otherwise vital pulp, in attempt to preserve its vitality by inducing reparative dentin formation (36,43). The procedure is contraindicated in carious pulp exposures (35). In the deciduous tooth, however, even under favourable circumstances, DPCs have been found to be unsuccessful and often lead to internal resorption or abscess formation; hence, DPCs have not generally been recommended in the primary dentition (36). Where a primary tooth is expected to exfoliate within a short period of time, DPC may be a suitable option (36).

The medicament used primarily in DPC has been CH, which has potential to induce reparative dentinal bridge formation (44). Unfortunately, CH-induced dentinal bridge formation often exhibit defects resulting in poor pulpal sealing (44). More recently, mineral trioxide aggregate (MTA) has become a potential candidate as a DPC medicament due to its regenerative characteristics. There are only few publications in the literature, however, regarding direct pulp capping in the primary dentition. The first case report published concerning MTA as a direct pulp capping material in a primary molar reported no clinical or radiographic pathologies after 18 months (45). Tuna and Ölmez (2008) compared clinical outcomes of CH DPCs and MTA DPCs on 25 pairs of primary molars (43). Over 24 months, none of these primary molars failed clinically nor radiographically (43). Luczaj-Cepowicz et al. (2017) reported 5 failures out of 30 primary molars treated by MTA DPCs over 24 months (46). While these studies advocate that direct pulp capping with MTA is a treatment option for mechanical or carious pulp exposures, a pulpotomy procedure has been the primary treatment option in the primary dentition.

1.3.2.3 Pulpotomy

According to the latest AAPD guidelines, “a pulpotomy is performed in a primary tooth with extensive caries but without evidence of radicular pathology when caries removal results in a carious or mechanical pulp exposure” (37). One of the main reasons for pulpotomy failure, as alluded to in the literature, is the failure to accurately diagnose pulpal status (47). A pulpotomy is contraindicated when the signs or symptoms of the offending tooth includes the following (36,37):

1) Soft tissue swelling
2) Soft tissue fistula
3) Pathologic mobility
4) Pathologic external root resorption
5) Internal root resorption
6) Periapical or interradicular radiolucency
7) Pulp calcifications
8) Excessive bleeding of the amputated radicular pulp
9) Spontaneous or nocturnal pain
10) Tenderness to percussion or palpation

The pulpotomy procedure requires that the inflamed coronal pulp of the carious tooth is removed while the remaining radicular pulp stump is treated with a medicament, allowing for final tooth restoration, and retention of the primary tooth. While there are numerous techniques and medicament for radicular pulp management, it is generally agreed that there are three categorizations: devitalization, preservation, and regeneration (35,48). Devitalization, renders the

pulpal tissue inert with the goal of preventing future infection and internal resorption. Devitalization agents such as formocresol, and devitalization techniques such as electrosurgery and laser, are examples of this method of pulp management (35,48). Preservation of the radicular pulp involves the preservation of the function of the pulp tissue apical to the clot. While some of the pulp preservation agents include ZOE and glutaraldehyde, the more commonly known preservation agent for pulpotomies is ferric sulphate (FS) (35,48).

Current thinking supports regeneration as the preferred strategy of pulp management (40). The goal of pulp regeneration is to stimulate pulpal healing of the radicular tissue as well as dentin bridge formation (35,40). With the various medicaments proposed for pulpal management, the question arises as to which of these medicaments is considered superior. A 2014 Cochrane intervention review recognized identifying a superior pulpotomy medicament would require that future studies have sufficient sample sizes, follow-up periods, and a fixed set of outcome variables that could be used for comparison in systematic reviews and meta-analyses (21).

1.4 Pulpotomy Medicaments and Techniques

The search for the "ideal" pulpotomy medicament has not gone without controversy (36). Similar to medicaments for pulpectomy procedures, the ideal properties of a pulpotomy medicament should include the following (36,49,50):

1) Non-toxic
2) Non-mutagenic
3) Non-carcinogenic

4) Biocompatible
5) Dimensionally stable
6) Bactericidal
7) Harmless to the pulp and surrounding structures
8) Promote healing of the radicular pulp
9) Does not interfere with the physiological process of root resorption

1.4.1 Formocresol

Formocresol (FC) was introduced into the US at the turn of the 20th century by Buckley and has been widely regarded as the gold standard for pulpotomies in the primary dentition (51,52). It is composed of a combination of 19% formaldehyde, 35% tricresol, 15% glycerin, and 31% water (53). While most American pediatric dentists (78%) prefer to use FC in its full strength concentration form, it is also used in its 1:5 diluted concentration (20% Buckley's FC, 20% water, 60% glycerol) (53–55). The first documented method of formocresol use as a pulpotomy agent was by Charles A. Sweet in 1930. At the time, Sweet proposed that complete mummification of the remaining pulp had to be achieved; therefore, he sequenced five appointments for this treatment (56). Over the course of history, Doyle et al. reduced this to a two-visit procedure, while Spedding et al. and Redig further reduced this to a one-visit procedure (48,57–59). Unlike the original method of complete radicular pulp tissue mummification, the current method of FC use aims to devitalize only a portion of the pulp while leaving the remaining pulp tissue partially vital (60). While the FC pulpotomy typically results in clinical success and preservation of the tooth, the pulp is left in a vulnerable state that can lead to internal root resorption or abscess formation (48).

The mechanism of action by which FC primarily acts is through its formaldehyde component. Formaldehyde is an indiscriminant tissue fixative and creates chemical bonds between side chain amino acids of proteins, regardless of pulpal or bacterial origin; therefore, formaldehyde is also considered bactericidal (60). The fixed tissue product of formaldehyde-treatment is effectively inert and resistant to enzymatic breakdown (53).

Formocresol exposure to the vital radicular pulp during the pulpotomy procedure creates three distinct zones of histological appearance which appear within 7 to 14 days (60). The coronal radicular tissue in direct contact with FC appears as a zone of fixation which is acidophilic. Apical to this, where the exposure to FC is decreased, there is a zone of diminished cells and fibers. The zone of chronic inflammation is the most apical zone and is characterized by an increased number of inflammatory cells (60).

The clinical and radiographic outcomes of formocresol pulpotomies in the primary dentition has been studied extensively. Reported success rates have been inconsistent, partly due to the variation in methodology and dissimilarities in the criteria defining what is considered successful (61). A literature review by Chandrashekhar and Shashidhar (2014) indicates the clinical success rate of FC ranges between 70-90% (53). However, some of the available literature on FC success rates ranges from as high as 98% and as low as 55 % (49,61,62).

Failures of pulpotomies using FC as a medicament commonly report findings of internal root resorption. Holan et al. (2002) reported a 14% failure rate in a study evaluating FC pulpotomies in 341 primary molars. Internal root resorption (36%), external resorption (31%),

inter-radicular radiolucency (22%), and periapical radiolucency (11%) were reported pathological findings. Pulp canal obliteration was observed in 80% of all FC pulpotomized teeth (63). As a sequelae of pulpotomy failures, premature exfoliation may occur and result in the need for space maintenance. In a study completed at the University of Iowa, 15% of 85 primary teeth requiring pulpotomies were lost prematurely due to abscess formation (64). Another potential complication of FC pulpotomy procedures first proposed in the 1970's was the possible relationship between formocresol and enamel defects in permanent succedaneous teeth (65). While Pruhs et al. (1977) reported a correlation between the prevalence of enamel defects in succedaneous teeth and FC pulpotomies in the preceding primary dentition, Coll et al. (1985) reported no significant evidence that could confirm this relationship (65,66).

While formaldehyde exposure to humans occurs on a daily basis through air, water, or food, concerns regarding the safety of FC use in pediatric dentistry are warranted, though controversial (36,67). Formaldehyde is classified as a carcinogen to humans by Health Canada, the International Agency for Research on Cancer (IARC), the Agency for Toxic Substances and Disease Registry (ATSDR) in the US Department of Health and Human Services, and the US Environmental Protection Agency (USEPA) (68). An estimated daily consumption of formaldehyde by the World Health Organization (WHO) averages approximately 7.8mg, and ranges from 1.5mg to 14mg (67). In contrast, an estimated 0.02 to 0.1mg exposure to a FC pulpotomy was suggested by Milnes in 2006, assuming a 1:5 diluted FC solution was placed on a number 4 cotton pellet that was squeezed dry (68). No correlation between FC pulpotomies and cancer in patients has ever been demonstrated (39). Regardless of the carcinogenicity of FC, further concerns have been raised in other papers including FC's potential for systemic

disturbance, immune sensitization, mutagenicity, and cytotoxicity (53,69,70). In vitro animal studies have demonstrated that FC exposure can cause formation of DNA-protein cross-links and is therefore mutagenic. In vivo studies, conversely, have yet to be able to produce conclusive evidence of mutagenicity (53). Advocates of FC being a safe medicament have argued that formaldehyde is a product of normal cellular mechanisms in the human body, that it is not a potent human carcinogen under low level exposures, and that its use in pediatric dentistry poses insignificant risks (68). Amidst the controversy, it appears that FC use, worldwide, is on the decrease as alternative pulpotomy medicaments with wider margins of safety and with equivalent or better success rates, become available (36,39,69).

1.4.2 Ferric Sulphate

Ferric sulphate (FS), marketed as Astringedent™ (Ultradent Products, Inc., Salt Lake City, UT) is a commonly used hemostatic agent in dentistry (61). It is distributed as a 15.5% solution, has an acidic pH of approximately 1.0, and acts to preserve the vitality of the radicular pulpal tissue following coronal pulp amputation (48,61). While its exact mechanism of action is still somewhat unclear, it is thought when FS makes contact with blood, iron and blood proteins agglutinate to form a ferric ion-protein complex. Hemostasis is subsequently achieved when this complex occludes the orifices of blood vessels (71).

The method of the FS pulpotomy requires removing the inflamed coronal pulp tissue, then applying FS to the radicular pulp stump for 10 to 15 seconds. The radicular pulp tissue is then irrigated, hemostasis is confirmed, and then the coronal pulp chamber is sealed with ZOE (55,72). The first documented use of FS as a pulpotomy medicament was completed in monkeys

(73). Landau et al. (1988) demonstrated FS pulpotomies resulted in favorable histological findings including secondary dentin and dentin bridge formation (73). Research has demonstrated that FS has comparably equivalent or better clinical and radiographic success rates than FC in primary pulpotomies (72,74–77). A recent systematic review by Cochrane in 2014, suggested that FS was the preferred pulpotomy agent over FC, given the inherent safety concerns of FC (21). Consequently, FS has be recommended as a suitable replacement for FC (39,78–81).

Despite these recommendations, potential undesirable effects of FS have not escaped scrutiny. Histological studies demonstrate that FS, like FC, can also cause inflammatory reactions in the remaining radicular pulp (82–84). This type of pulpal response may contribute to internal root resorption and subsequent premature exfoliation (64).

Literature comparing outcomes for FC and FS pulpotomies have generally resulted in similar outcomes. Huth et al. (2005) performed a randomized controlled trial comparing four pulpotomy agents and techniques of which FS and 1:5 diluted FC success rates were reported to be 100% and 96% respectively – no significant difference (85). Markovic et al. (2005) reported similar outcomes in overall success rates comparing FC (84.8%) and FS (81.1%) in a study involving 104 primary molar pulpotomies (80). Erdem et al. (2011) ran a 24-month study involving 128 carious primary molars requiring pulpotomies and compared MTA, FS, FC (1:5 dilution), and ZOE. The reported FS and FC success rates were identical, 88% (86). Finally, a systematic review and meta-analysis involving 11 studies reported that pulpotomies in primary teeth with FC or FS show similar clinical and radiographic success (79). Despite relatively

successful outcomes in the literature, both FC and FS are widely falling out of favour as bioregenerative agents are become the medicament of choice (21).

1.4.3 Zinc Oxide Eugenol

Eugenol, derived from the oil of cloves, when combined in a mixture of zinc oxide was found to form a material with therapeutic properties that were analgesic, antibacterial, and sedative (87). Zinc oxide eugenol (ZOE), historically, has been used in numerous dental applications – as a cement for restorations, as a temporary restorative material, and as a liner for unexposed deep carious lesions (88). During the pulpotomy procedure in the primary tooth, ZOE is typically applied as a base material, approximately 3-4mm in thickness, to adequately seal the radicular pulp orifices after the medicament treatment (17). Utilizing ZOE as a pulpotomy medicament calls for elimination of the initial medicament placement - the placement of ZOE is direct following dry cotton pellet application to achieve hemostasis (47).

Ranly (1994) classifies ZOE as a preservative agent when used for treating vital radicular pulp as it provokes minimal devitalization and it is non-inductive of reparative dentin (47,48). Histological analysis of the effect that ZOE has on pulpal tissues have reported cytotoxic findings as well as an induction of an intense inflammatory response (89). This adverse reaction is due to the eugenol component. Incidentally, though uncommon, some patients have also exhibited allergic sensitivities towards eugenol either through a contact dermatitis reaction, or a true anaphylactic reaction (88,90). Studies have suggested that due to the inflammatory effect of ZOE on the pulpal tissue, there is an anticipated risk of internal resorption (86).

The research regarding the use of ZOE as a pulpotomy medicament and its overall success rates is limited. Chien et al. (2001) evaluated ZOE and ferric sulphate as pulpotomy agents in 145 primary teeth and found a success rate of 100% for both materials (91). Hui-Derksen et al. (2013) evaluated 190 primary molars retrospectively that were treated with reinforced ZOE and found a similarly high overall success rate of 94% with furcation radiolucencies noted as the most frequent pathological pulp response (47). In contrast, a 24-month split-mouth design study published in 2011 showed that ZOE, as a pulpotomy medicament, had a significantly lower success rate (68%) compared to MTA (96%) (86). Success rates of FS and FC were also reported as 88% and 88% respectively, but this difference was not significant when compared to ZOE (68%) (86). This study indicated that nearly 27% of primary molars treated with ZOE as a pulpotomy medicament demonstrated internal resorption (86). Reasons for failure of ZOE pulpotomies have not only included internal resorption and furcal radiolucencies, but also severe chronic pulpal inflammation and abscess formation (47,92–94). Due to the varying evidence on reported outcomes for ZOE pulpotomies, further evaluation through randomized controlled trials and histological studies should be considered.

1.4.4 Glutaraldehyde

Historically, glutaraldehyde has been utilized for its disinfective properties (95). Glutaraldehyde possesses fixation characteristics similar to FC but are considered to be more effective (96). Glutaraldehyde has been found to be less toxic than FC, penetrates tissue minimally, and causes less tissue damage thereby preserving the vitality of the radicular pulp (97).

The use of glutaraldehyde as a pulpal medicament was reportedly proposed in the early 1970s but studies of its use in primary molar pulpotomies emerged in the next decade (98,99). Similar to aforementioned pulpotomy medicaments, various overall success rates have been reported with glutaraldehyde. While Kopel et al. (1980) reported successful use of glutaraldehyde in primary molar pulpotomies, a study by Fuks et al. (1990) reported a much higher failure rate for glutaraldehyde pulpotomies when compared to FC (98,100). Internal resorption, furcation pathology, periapical pathology, and abscess formation was documented in 48.6% of 35 primary teeth in a pulpotomy study with 2% unbuffered glutaraldehyde (101). Another study that followed 258 treated primary molars over 36 months demonstrated success rates of 87.5% with 5% buffered glutaraldehyde and 74.1% with 5% unbuffered glutaraldehyde (102). Studies have utilized buffered, unbuffered, or both variations of glutaraldehyde solution. Some studies have even made no distinction between the two options. The distinction between buffered and unbuffered glutaraldehyde is important as it has been shown that buffered glutaraldehyde solutions are twice as effective in fixation as compared to unbuffered solutions (103). Unfortunately, buffered glutaraldehyde solutions have short shelf lives and must be frequently prepared, making it an impracticality in practice (104).

1.4.5 Electrosurgery

The electrosurgery (ES) pulpotomy is a method of non-pharmacological devitalization which was first demonstrated in primates in 1983 (105). Following the amputation of infected coronal pulp tissue, the remaining radicular pulpal tissue and remaining bacterial contaminants undergo electrosurgical carbonization and heat denaturation. The advantages of electrosurgery include the following: 1) Quick and efficient, 2) Self-limiting, 3) Good hemostasis, 4) Good field

visibility, 5) No systemic disturbance, 6) Sterilization of the site (105). However, some potential disadvantages have also been suggested. It has been questioned as to if excessive heat production during ES application to pulpal tissues could cause potential insult to perifurcal tissues (106). Literature from a 1987 primate study reported pathologic root resorption after ES was used as a pulpotomy technique on deciduous teeth (107). Conversely, Ruemping et al. (1983) reported favourable pulpal responses with no incidence of periapical or furcal pathology when utilizing low intensity currents for ES pulpotomies in monkeys (105).

Reports of clinical and radiographic outcomes of ES pulpotomies are varied in the literature. Mack & Dean (1993) reported a 99.4% success rate of ES pulpotomies and concluded that this success rate was statistically higher than success rates of FC pulpotomies (108). Fishman et al. (1996) examined ES pulpotomies on 47 primary molars and demonstrated dissimilar results when using either ZOE or CH as a base (109). When using ZOE as a base, a clinical success of 77.39% and a radiographic success of 54.6% was determined (109). When using CH as a base, a clinical success of 81% and a radiographic success of 57.3% was determined (109). Though the Fishman et al. (1996) article reported poor ES outcomes, more recent literature has been more promising. A paper by Dean et al. (2002) reported clinical and radiographic success rates of 96% and 84% respectively for ES pulpotomies (110). Their comparison of ES pulpotomies to FC pulpotomies determined that there was no statistically significant difference between techniques (110). Bahrololoomi et al. (2008) performed a slightly larger randomized clinical trial on 70 primary molars comparing outcomes of ES to FC pulpotomies (111). Their results were similar to Dean et al. (2002) - clinical and radiographic success rates for the ES group were 96% and 84% respectively; and for the formocresol group,

100% and 96.8% respectively (111). Most recently, an in-vivo study by Yadav et al. (2014) demonstrated a 100% success rate of in 15 primary molars treated with ES pulpotomies over a 9 month follow-up period and concluded that ES appears to be an acceptable alternative to current pulpotomy agents (106). While ES does appear to be a suitable alternative to pulpotomy medicaments, the price of owning an ES unit may be considered a deterrent (111).

1.4.6 Laser

Laser radiation use in dental procedures has been used as an adjunct or even a replacement for certain more traditional dental techniques (112). Today, many different types of lasers are available: Diode, CO_2, Argon, Neodymium-yttrium-aluminum-garnet (Nd:YAG), and Erbium-yttrium-aluminum-garnet (Er:YAG) lasers (113,114). Studies have shown that lasers have shown advantages not only for hemorrhage control and sterilization, but also in pulp vitality preservation, and in stimulating dentinal bridge formation (114,115). Moreover, the use of lasers, unlike other pharmacologic agents, does not bring inherent concerns of cytotoxicity and mutagenicity (113). Laser application to pulp tissue has been shown to accelerate wound healing. Much like in the ES pulpotomy, laser irradiation of the radicular pulp tissue creates a zone of coagulation necrosis while leaving the more apical radicular pulp tissue unharmed (116).

The outcomes of treatment of laser pulpotomy in primary teeth have been compared to the "gold-standard" method utilizing FC. Elliott et al. (1999) found no significant difference between FC and CO_2 laser pulpotomy groups in a 28-day and 90-day post-treatment longitudinal study in 30 caries and restoration free primary cuspids (117). Liu et al. (2006) compared the outcomes of Nd:YAG lasers to FC (1:5 dilution) for primary molar pulpotomies in primary

molars over 66 months and reported significantly higher clinical success rates of 97% in the laser group to 85.5% in the FC group (114). Radiographic success rates demonstrated similar results: 94.1% in the laser group, 78.3% in the FC group (114). Conversely, Odabas et al. (2007) found no significant difference between Nd:YAG laser and 1:5 dilution FC pulpotomies in 42 carious primary molars (118). A recent 2014 study completed by Yadav et al. (2014) demonstrated a remarkable 100% clinical success rate when using an 810nm Diode laser set at 7 Watts in 15 primary molar pulpotomies (106).

The difficulty in assessing laser-assisted pulpotomies has been duly noted as various laser types, laser settings, and clinical conditions have led to confusing evidence. A recent systematic review by De Coster et al. (2013) identifying high-quality articles comparing the use of lasers versus conventional pulpotomy procedures. They remark that there is currently weak evidence that laser use in pulpotomies can create better treatment outcomes that conventional pulpotomy techniques; therefore, clinical laser use to perform pulpotomies in primary teeth cannot yet be recommended (113). Future research requires that clinical trials be standardized and comparable before definitive recommendations can be made.

1.4.7 Calcium Hydroxide

Calcium hydroxide (CH) has found many applications in the field of dentistry since its introduction by Herman in the 1920s as a potential root canal filling material (119). The hydroxyl component of CH, which is responsible for the agent's alkaline pH of 12.5, is critical for the mechanism of action in pulp therapy (120). While the caustic nature of CH causes necrosis on the superficial pulp layer, radicular pulp tissue apical to this layer is typically

characterized by mild inflammation (121). Unlike other pulpotomy medicaments, CH creates an alkaline environment which prompts intrinsic reparative mechanisms - lactic acid produced in osteoclasts is neutralized thereby, preventing dentin dissolution; alkaline phosphatase is stimulated, which induces dentin bridge formation (121). It is this distinctive attribute of CH which categorizes this medicament as a regenerative agent (48). Unfortunately, this reparative cascade is not a consistently observed outcome. Magnusson (1979) stated that the pulpal response to CH is a balance between that of repair and resorption, of which the latter has been more frequently observed (122).

Waterhouse et al. (2000) compared the relative efficacy of FC versus CH in 84 primary molars in a parallel study with blinded examiners and found the success rates were 84% and 77% respectively – this was determined to be an insignificant difference (123). Other studies have found significantly worse outcomes with CH in comparison to alternative medicaments. Huth et al. (2005) stated that the total failure rate of CH pulpotomies in 50 primary molars was reported to be 47%, similar to findings by Schröder (1978) and Benz et al. (1998) who reported 41% and 43%, respectively (85,124,125). A more recent 24-month study by Moretti et al. (2008) reports a 36% success rate of pulpotomies in the CH group when compared to FC and MTA (126). Liu et al. (2011), also similarly comparing CH and MTA, reported CH to have a 64.7% success rate in a split-mouth study (29).

The majority of failures with this pulpotomy medicament manifest as internal root resorption (127). Possible reasons for why internal resorption occurs in CH pulpotomies have been postulated: 1) Overstimulation of the pulp causing odontoclastic metaplasia (128), 2)

Unresolved chronic pulp inflammation (124,129,130), and 3) Poor sealing properties of CH leading to microleakage over time (131).

Schröder (1973) proposed that if a blood clot is present at the coronal aspect of the amputated radicular pulp, it is possible that CH is hindered from initiating pulp regenerative processes (132). The presence of a blood clot may further precipitate an inflammatory response in the remaining pulp and subsequently cause internal resorption (132,133). Recent literature has indicated that the current thinking for why these poor success rates are typically observed are due to the inability of CH to form an effective biological seal (29). On the contrary, despite the fact that CH plays an integral role in the mechanism of action in calcium silicate materials, their sealing abilities are superior and therefore possibly explains the more favourable outcomes observed with these materials (29).

1.4.8 Mineral Trioxide Aggregate

Prior to its FDA approval in 1998, mineral trioxide aggregate (MTA) was first studied in the 1990s for its sealing ability in root canal therapy (134,135). MTA is dispensed in powder form and is comprised of tricalcium silicate, dicalcium silicate, tetracalcium aluminoferrite, calcium sulphate dehydrate and bismuth oxide (136). MTA is commercially available in two different types, gray MTA and white MTA, with the difference primarily due to lower iron oxide content in white MTA (137). White MTA also lacks tetracalcium aluminoferrite, and has adjusted proportions of silica and alumina than gray MTA (70). Furthermore, as white MTA has smaller, finer, and more homogenous particle sizes, its strength and ease of handling exceeds that of grey MTA (138).

The setting reaction of MTA occurs in the presence of water and as a result, its storage requires it to be kept in a dry, sealed container (139). When sterile water is added to MTA, a 3 to 4 hour hydration setting reaction occurs which initially forms a colloidal gel that then strengthens to a material with the compressive strength similar to IRM - 70 Mpa (139). CH is one of the main reaction products of this hydration reaction which is responsible for similar pH levels for both MTA and CH (131). The alkalinity of MTA initially starts at approximately pH 12, but tends to diminish during the setting reaction (140). This transiently high pH level of MTA can potentially cause tissue denaturation, but also creates an antimicrobial effect which is beneficial to the pulp (120).

Studies have reported that MTA is biocompatible, non-cytotoxic, non-mutagenic, and can stimulate healing and regenerative mechanisms (120). Pulpal tissue has been shown to respond with less hyperemia, necrosis, and inflammation with MTA application in comparison to CH (141). Minimal inflammation was similarly observed with unintentional MTA extrusion in root perforation studies, further validating the biocompatible capabilities of the material (135,142). Like CH, MTA has the capacity to induce dentinal bridge formation; however, studies have shown that dentin bridges formed by MTA are typically thicker (141). Dentinogenesis of MTA is due to not only its biocompatibility and alkalinity, but also its sealing abilities (139). It should be noted that the management of a tooth would be unlikely to change whether or not a dentin bridge was observed, especially if adverse clinical signs and symptoms were absent. Caicedo et al. (2006) reported that successful clinical outcomes can occur regardless of radiographic evidence of dentin bridge formation (143). Furthermore, this study indicated that radiographic evaluation

of dentinal bridge formation may not be reliable because in a number of MTA treated teeth, dentin bridge formation was noted histologically, but not radiographically (143)

The sealing ability of MTA has been thought to prevent microleakage of bacteria which may be contributory to the favourable success rates observed (144,145). Dye leakage studies comparing a medicament's sealing abilities have compared MTA to CH, amalgam, intermediate restorative material (IRM), super-ethoxybenzoic acid (EBA), and resin-modified glass ionomer cement (RMGIC) - MTA has shown to have equal or superior sealing ability (146,147).

The introduction of MTA has impacted the field of endodontics as it has applications in numerous procedures including apexification, apexogenesis, root perforations, pulp capping, and root-end fillings (139). The use of MTA has expanded into primary dentition applications as well, including pulp capping, pulpotomies, pulpectomies, furcation perforation repairs, and resorption repairs (43,137). Eidelman et al. (2001) compared MTA and FC in randomly assigned 54 primary molars and reported very high clinical and radiographic success with MTA (148). This report also suggested that that MTA could serve as a potential replacement for FC. Agamy et al. (2004) investigated prospectively over 12 months the pulpotomies of 60 primary teeth using grey MTA, white MTA, and FC – success rates were 100%, 80%, and 90% respectively. The authors attributed the different success rates of grey and white MTA to their difference in chemical composition, but suggested that further studies were required to confirm their results (70). Holan et al. (2005) performed a similar study comparing MTA and FC but over a longer follow-up period averaging 38 months. Their results indicated that MTA showed a higher, though not statistically significant, success rate than FC (136). A statistically significant

difference in success rate between MTA and FC was presented in a 24-month study by Farsi et al. (2005) in 74 pulpotomized molars: none of the MTA treated teeth showed failure, whereas the FC treated group were successful in 86.8% radiographically and 98.6% clinically (149). One hundred percent clinical success rates for MTA was reiterated in a 42-month prospective study of MTA of 69 pulpotomized primary molars with periodic follow-ups completed every 6 months (150). Finally, a recently published study evaluating 252 primary molars undergoing pulpotomies with either MTA or 1:5 diluted FC demonstrated similar clinical success between both groups, but significantly higher radiographic failure in the FC group than MTA (49).

MTA is the first material that has established consistently equal or greater success rates as a pulpotomy material in primary teeth than the "gold standard" FC (17). According to a survey conducted at a joint pulp therapy symposium by the AAE and the AAPD in 2007, both professional bodies agreed that FC will be replaced as the preferred primary tooth pulpotomy agent, and that MTA is the overwhelmingly favoured choice likely to take its place (40). However, there are disadvantages associated with the clinical use of MTA as a pulpotomy agent in primary teeth.

Discolouration of MTA treated teeth is one commonly reported drawback of this material. A systematic review regarding regenerative endodontic therapy indicated that approximately 40% of studies have reported discolouration after MTA treatment (151). Bismuth, aluminum, magnesium, and iron are all potential components that can cause tooth discolouration (152). While discolouration is a valid concern in the permanent dentition, for the treatment of primary molars, full coverage restoration negates this adverse outcome (153).

1.4.9 Biodentine

Septodont introduced Biodentine, a non-cytotoxic and non-mutagenic calcium-silicate material, for commercial use in 2009. While the composition of Biodentine is similar to that of MTA, the addition of accelerators and a new trituratable-capsule dispensing system improves its handling characteristics when compared to MTA (154). Biodentine is comprised of a capsule of powder and a liquid-dosing container composed of the following (155):

Table 2. Chemical Composition of Biodentine

Powder	
Tri-calcium Silicate (C_3S)	Main core material
Di-calcium Silicate (C_2S)	Second core material
Calcium Carbonate and Oxide	Filler
Iron Oxide	Shade
Zirconium Oxide	Radiopacifier
Liquid	
Calcium Chloride	Accelerator
Hydrosoluble Polymer	Water-reducing agent

Biodentine was designed as a "dentin replacement" with mechanical properties comparable to dentin (155). Grech et al. (2013) demonstrated that over a period of 28 days, the compressive strength of Biodentine continued to increase until it demonstrated a compressive strength of 72.6 $\pm$ 8 MPa – superior to both IRM and MTA (156). The modulus of elasticity of Biodentine in comparison to dentin is 22.0 GPa and 18.5 GPa respectively (154). Biodentine is less porous and therefore more dense when compared to MTA (157).

One of the advantages Biodentine has over MTA in a clinical setting is its setting time. Due to the addition of the calcium chloride accelerator in the liquid complement of Biodentine, the initial setting time of Biodentine is approximately 12 minutes, with a final setting time of 45 minutes (156,158). Comparatively, MTA takes 3 to 4 hours for final setting to be completed

(136,148). This is of particular importance for restorative procedures where Biodentine is utilized as a layer under another restorative material, as is typical when performing direct or indirect pulp therapy.

The sealing and adhesion ability of Biodentine to dentine has been evaluated through microleakage studies. Koubi et al. (2012) reported that Biodentine and resin-modified glass ionomer cements exhibited similar results having undergone glucose diffusion testing at the dentin interface (159). Dye leakage studies with 1% methylene blue have shown significantly better marginal sealing of Biodentine in comparison to MTA and glass ionomer cement (160). Microscopy studies have shown that marginal sealing is in part due to Biodentine's interaction with dentinal tubules via mineral tags (161). Moreover, calcium silicate positively modulates pulpal growth factors that moderate dentin bridge formation which further contributes to marginal sealing (162,163).

The setting reaction of Biodentine is initiated when tricalcium silicate interacts with water to form hydrated calcium silicate gel (CSH) and CH (161). These two reaction products have dissimilar mechanisms of action:

1) CSH gel, which is relatively impermeable to water, forms on the surface between unreacted tricalcium silicate grains. This tricalcium silicate and CSH gel conglomerate exhibits an intrinsic sealing ability (161).
2) At the material-tooth interface, calcium hydroxide with surrounding phosphate ions precipitates into a hydroxyapatite-like molecule which can be incorporated into dentin

(154,161). The high alkalinity of CH also stimulates the reparative process of osteoblasts via these mechanisms (121).

Through these two mechanisms of action, Biodentine develops both an intrinsic seal and a seal at the material-dentin interface (161). Ultimately, Biodentine's ability to form a seal against bacterial microleakage, to stimulate pulpal reparative processes within the tooth, and its reduced setting time, make it a promising dental material for clinical use in pulp therapy.

A preliminary study in the literature examining Biodentine use as a pulpal medicament demonstrated that both Biodentine and MTA performed significantly better than FC when evaluating histological outcomes in 180 primary pig teeth (164). More recent longer-term prospective studies comparing Biodentine to other pulp therapy materials have been published. Cuadros-Fernandez et al. 2016 compared 39 pairs of primary teeth pulpotomies completed with Biodentine with MTA at 12 months. The results showed comparable success rates both clinically and radiographically (165). Another 12 month prospective study published in 2017 comparing Biodentine and MTA at 1 month, 3 months, 6 months, and 12 months reported comparable findings - no significant clinical or radiographic differences between the two materials (166). Rajasekharan et al. (2017) reported the clinical and radiographic success of primary molar pulpotomies at an 18-month follow-up with Biodentine as 95.24% and 94.4% respectively, and MTA as 100% and 90.0% respectively. They also concluded that there was no significant difference between the two materials at 18 months (167). A randomized controlled study conducted for 24 months compared MTA and Biodentine primary molar pulpotomies on 34 patients ranging from ages 2 to 9 years (168). The two medicaments had similar clinical and radiographic results: Biodentine had a success rate of 96.8% clinically and 93.6%

radiographically, while MTA had a success rate of 96.8% clinically and 87.1% radiographically (168). The majority of failures were reported as radiographic furcation lesions in both the Biodentine and MTA groups. A systematic review and meta-analysis published recently in 2018 by Stringhini Junior et al. identified 233 publications comparing MTA and Biodentine of which only 9 studies fulfilled their inclusion criteria. Their results showed that at 6 months, 12 months, and 18 months, there was no superiority of one material over the other when Biodentine and MTA were compared. They did reiterate that MTA, though recently considered the gold standard material for pulpotomies, has characteristics including poor handling, staining potential, and a lengthy setting time which suggests that clinical use of Biodentine may be preferred (169).

1.5 Pulpotomy Outcome Variables

One of the difficulties in comparing pulpotomy medicament therapies is owed to the heterogenicity of reported outcomes in the literature. With investigators defining their own criteria for success or failure, research comparing outcomes between studies for various pulpotomy medicaments is challenging. A 2014 Cochrane intervention review outlined this concern directly in the pulp treatment for extensively decayed primary teeth and the authors offered a recommended core set of outcomes in a separate article (78).

In this article, Smaïl-Faugeron et al. (2013) systematically reviewed randomized controlled trials to extract all outcomes assessed in the literature – a total of 83 reported outcomes characterizing pulp treatment failure were compiled. These outcomes were grouped into categories based on their similarities. Finally, expert authors and dentists participated in a 3-round Delphi process to identify a set of preferred outcomes to define failure of a pulp treatment.

Through this process, three clinical and two radiographic outcomes variables were identified as the most relevant in defining pulp therapy failure:

1) Determinants of clinical failure - pain, pathologic mobility, and soft tissue pathology,

2) Determinants of radiographic failure - pathologic radiolucency, and pathologic root resorption.

Chapter 2: Rationale and Objectives

Several review articles have supported the use of Biodentine in primary molar pulpotomies; however, the majority of existing studies have restricted sample sizes with limited follow-up periods. Previous studies that fulfilled the inclusion criteria of a 2018 systematic review and meta-analysis on MTA and Biodentine have sample sizes ranging from 22 to 90 patients and 20 to 45 teeth (166–170). Many reports in the literature reviewing primary molar Biodentine pulpotomies have monitored post-treatment outcomes over a period from 6 months to 12 months, with fewer studies reviewing up to 18 or 24 months (165–168,170–173). The purpose of this research is to enrich the understanding of the clinical and radiographic outcomes of Biodentine pulpotomies in primary molars utilizing a large sample size. The hypothesis is the clinical and radiographic success rates of Biodentine pulpotomies in primary molars will be no higher than that reported in the literature.

Chapter 3: Methods

Permission was obtained from a private pediatric dental group practice in Vancouver, Canada to conduct a retrospective chart review of patient records. The study was approved by the Clinical Research Ethics Board (CREB) of The University of British Columbia, Vancouver, British Columbia (UBC CREB Number H18-01290).

3.1 Sample

All patients who had received dental rehabilitation under general anesthesia (GA) at the pediatric group practice between January 1st, 2013 and May 1st, 2018 were identified. Upon review of the identified patients' records, subjects included for the study met the following inclusion criteria:

1) Patient had at least 1 primary molar which had undergone pulpotomy with Biodentine.
2) The tooth was restored with a full coverage restoration.
3) The patient had returned for a minimum of one recall evaluation.

3.2 Procedure

All treatment was provided under general anesthesia with rubber dam isolation. Treatment was completed by certified pediatric dentists of the pediatric group practice. The following method for Biodentine dentine was performed: caries removal until pulp exposure, high-speed access cavity preparation with water spray, coronal pulp amputation with a slow-speed round bur, achievement of radicular hemostasis with slightly moistened cotton pellet application, placement of Biodentine in the pulp chamber, restoration with full coverage crown cemented with a glass ionomer cement (Ketac Cem).

3.3 Data Collection

All data collection for patient information, clinical outcomes, and radiographic outcomes were completed by the principal investigator. Each patient was designated a unique identification number to maintain anonymity. The following data was collected for each individual:

1) Gender
2) Treatment provider
3) Tooth number treated
4) Restoration type
5) Age at treatment
6) Age at recall

Clinical and radiographic assessments were made by reviewing patient chart entries pertaining to each treated tooth. The tooth was followed until exfoliation, extraction, or until the last date a recall entry was made on standardized recall forms by the pediatric dental office (Appendix A).

Radiographs examined included both digital and analogue films. Analogue films were visualized on a LED radiograph viewing box and subsequently digitized with a digital single-lens reflex camera (Canon EOS 80D). Upon digitization, analogue films were evaluated for radiographic outcomes. Digital films were unaltered for radiographic outcome evaluation.

3.3.1 Clinical Outcomes

Due to the lack of consistency in reported outcomes for primary molar pulpotomy techniques and medicaments in the literature, the clinical outcomes recommended by the 2013 Cochrane systematic review on this issue were adhered to (78). The clinical outcomes that constituted a clinical failure included:

1) Pain
2) Pathologic mobility
3) Soft tissue pathology (fistula or swelling).

The presence of one or more of these clinical findings were considered a clinical failure of the Biodentine pulpotomy. Absence of notation constituted a treatment clinical success.

The presence or the absence of the full coverage crown was noted. Where the crown was lost at recall examination, it was difficult to discern whether the failure of the pulpotomy medicament occurred prior to or after the loss of the crown. As a result, it was decided that a crown loss constituted a clinical failure.

For treated teeth that exfoliated and were notably absent at the time of recall, the decision was made to use the last documented date that the tooth was present. An exfoliated tooth that did not exhibit a failed clinical or radiographic outcome was considered a clinical success. A tooth lost due to extraction, understandably, was considered a clinical failure.

3.3.2 Radiographic Outcomes

For evaluating radiographs of pulpotomy treated molars, a criteria for determining a radiograph's diagnostic value was established. A radiograph was declared non-diagnostic if any one of the following conditions were violated:

1) Diagnosis was hindered by an artifact or motion artifact
2) Furcation area was not visible
3) Mesial and/or distal cementoenamel junction was not visible
4) Less than ½ the root length visible

Given that this was a retrospective study, radiographs taken at recall examinations were taken with the intent of assessing the presence or absence of interproximal caries. While both diagnostic and non-diagnostic radiographs were tallied, only diagnostic radiographs were evaluated for radiographic outcomes for the molars receiving Biodentine pulpotomies.

Similar to the clinical outcomes assessed, the radiographic outcomes applied were developed from the recommendations in the Smaïl-Faugeron et al. (2013) article. The following radiographic outcomes were evaluated:

1) Pathologic root resorption
2) Pathologic radiolucency

Pathologic radiolucency, by definition, can be a collective term that includes numerous findings such as periapical radiolucency, furcation radiolucency, periodontal ligament space widening, and loss of lamina dura. Pathologic root resorption collective comprises findings of

external root resorption and internal root resorption. Radiolucencies and root resorption can often be challenging to assess in the primary dentition due to the physiologic process of exfoliation. A finding of root resorption and/or radiolucency was considered pathologic unless there was clear evidence that the eruption of a succedenous peramanent tooth was the precipitating factor for this radiographic finding.

A subset of radiographs from the sample population was utilized to determine rater reliability – all radiographs with a failed outcome were included along with a randomized sample of radiographs with success outcomes at a 1:2 ratio. Independent evaluation of the radiographs were completed by both the principle investigator and a practicing pediatric dentist to determine inter-rater reliability of radiographic diagnosis.

3.4 Data Analysis

All Information was recorded and compiled on a Microsoft Excel spreadsheet (Microsoft Corp., Redmond, Wash) by the principal investigator. Data for continuous variables, including the age at treatment, number of teeth treated per patient, and number of recall examinations per patient, were calculated as means and standard deviations. Percentages were used to summarize categorical data, including overall clinical and radiographic outcomes, over the study period.

Survival analysis were conducted to estimate the probability of clinical success and radiographic success over the observation time post-treatment for each tooth. Survival curves were estimated by nonparametric maximum likelihood methods for interval censored data.

Statistical analysis was completed with R-project (R Foundation for Statistical Computing, Vienna, Austria).

Chapter 4: Results

The final study sample consisted of 208 patients (104 males, 104 females). At the time of pulpotomy treatment, the mean age of the patients was 4.9 years (± 1.4 SD, range = 2.0 - 8.9). The final number of primary molars treated was 608 by 6 different treatment providers. The distribution of tooth type and arch are tabulated in Table 3. The mean number of teeth treated per patient was 2.9 teeth (± 1.8 SD, range = 1 - 8) as seen in Figure 1. The mean number of recall examinations per patient being 2.4 visits (± 1.1 SD, range = 1 - 5). Recall times ranged between 37 days to 1005 days; however, as seen in Figure 2, the majority of recalls were completed at regular 6-month intervals for the first 18 months.

Table 3. Distribution of Teeth

	Mx Right	Mx Left	Total (Mx)	Mn Right	Mn Left	Total (Mn)	TOTAL
1st Molar	69	75	**144**	116	98	**214**	**358**
2nd Molar	43	57	**100**	74	76	**150**	**250**
TOTAL	**112**	**132**	**244**	**190**	**174**	**364**	**608**

Figure 1. Distribution of Number of Teeth Treated per Patient

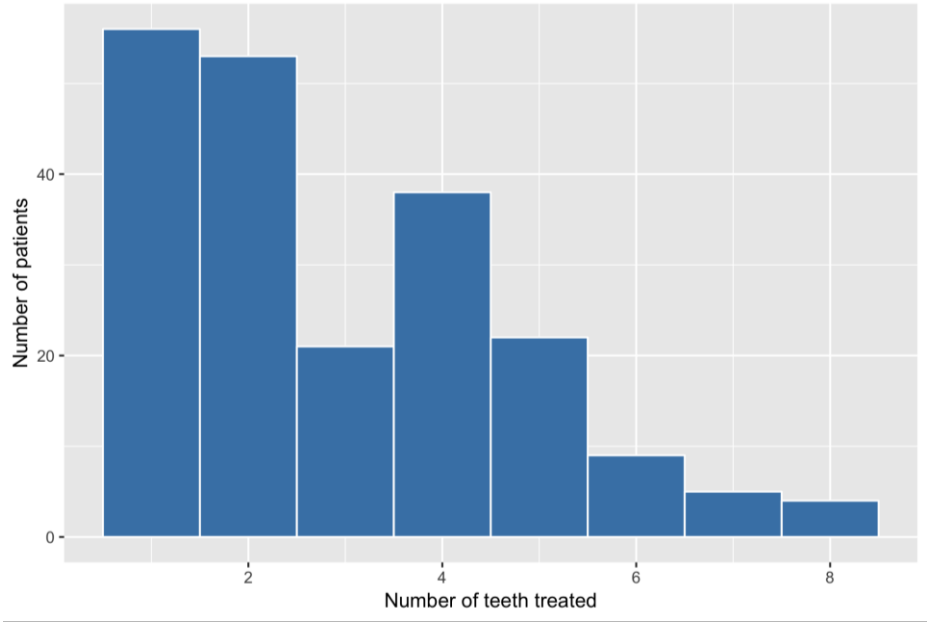
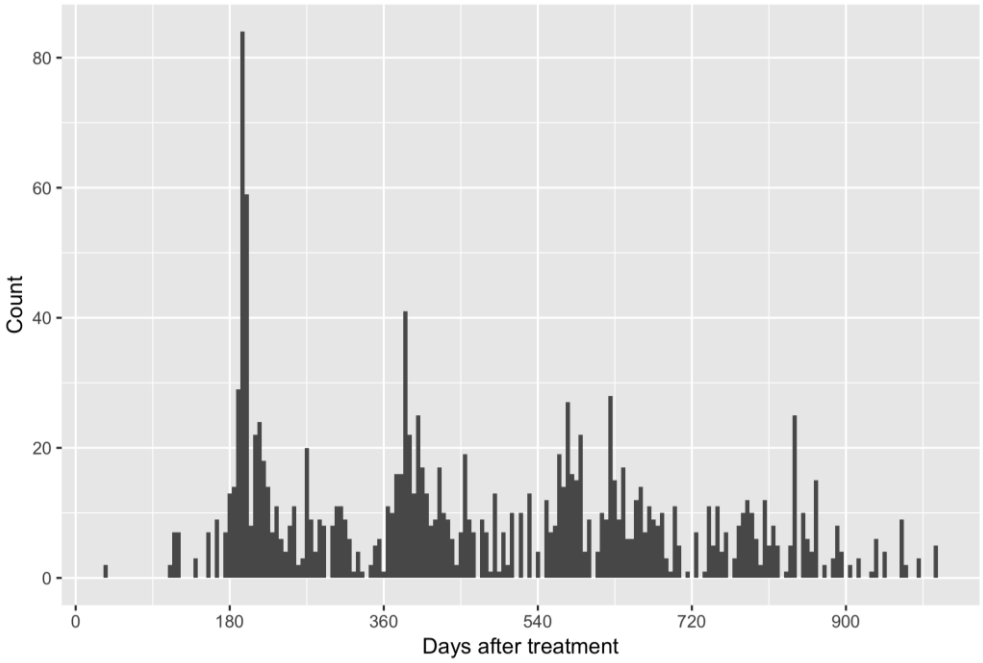


Figure 2. Distribution of Number of Teeth over Observation Time



4.1 Clinical Findings

Of the 608 individual teeth evaluated in this study, 599 teeth (98.5%) were clinically successful over 30 months. There are no observable differences in clinical outcomes when comparing 1st and 2nd primary molars. There are also no observable differences in clinical outcomes when comparing maxillary and mandibular teeth (Table 4).

Table 4. Distribution of Teeth with Clinical Success

	Mx Right	Mx Left	Total Mx	Mn Right	Mn Left	Total Mn	TOTAL
1st Molar (%)	69/69 (100)	75/75 (100)	**144/144 (100)**	113/116 (97.4)	97/98 (99.0)	**210/214 (98.1)**	**354/358 (98.9)**
2nd Molar (%)	41/43 (95.3)	55/57 (96.5)	**98/100 (98)**	73/74 (98.6)	76/76 (100)	**149/150 (99.3)**	**245/250 (98.0)**
TOTAL (%)	110/112 (98.2)	130/132 (98.5)	**240/244 (98.4)**	186/190 (97.9)	173/174 (99.4)	**359/364 (98.6)**	**599/608 (98.5)**

Of the 608 teeth assessed, there were 9 clinical failures observed over the period of the study, with 5 of the failures occurring within the first year. The 3 failures that occurred due to full coverage restoration loss occurred within the first 12 months. The 2 remaining failures presented with either pain or both pain and soft tissue pathology. Within 2 years follow-up, one tooth presented with both pain and pathologic mobility. Three more teeth presenting with clinical outcomes of pain were noted in the third year of follow up. These clinical failures were tabulated in Table 5 and Table 6.

Table 5. Distribution of Teeth with Clinical Failures

	Mx Right n=112	**Mx Left** n=132	**Total (Mx)** n=244	**Mn Right** n=190	**Mn Left** n=174	**Total (Mn)** n=364	**TOTAL** n=608
1st Molar	-	-	**0**	3	1	**4**	**4**
2nd Molar	2	2	**4**	1	-	**1**	**5**
TOTAL	2	2	**4**	4	1	**5**	**9**

Table 6. Type of Clinical Failures over Time

	0–6 mos n=46	**6–12 mos** n=453	**12–18 mos** n=364	**18–24 mos** n=356	**24–30 mos** n=208
Pain	1	2	-	1	3
Pathologic Mobility	-	-	-	1	-
Soft Tissue Pathology	-	2	-	-	-
Lost Restoration	-	3	-	-	-
Total Teeth	**1**	**4***	**0**	**1***	**3**

* Multiple clinical findings may have been observed in a single tooth

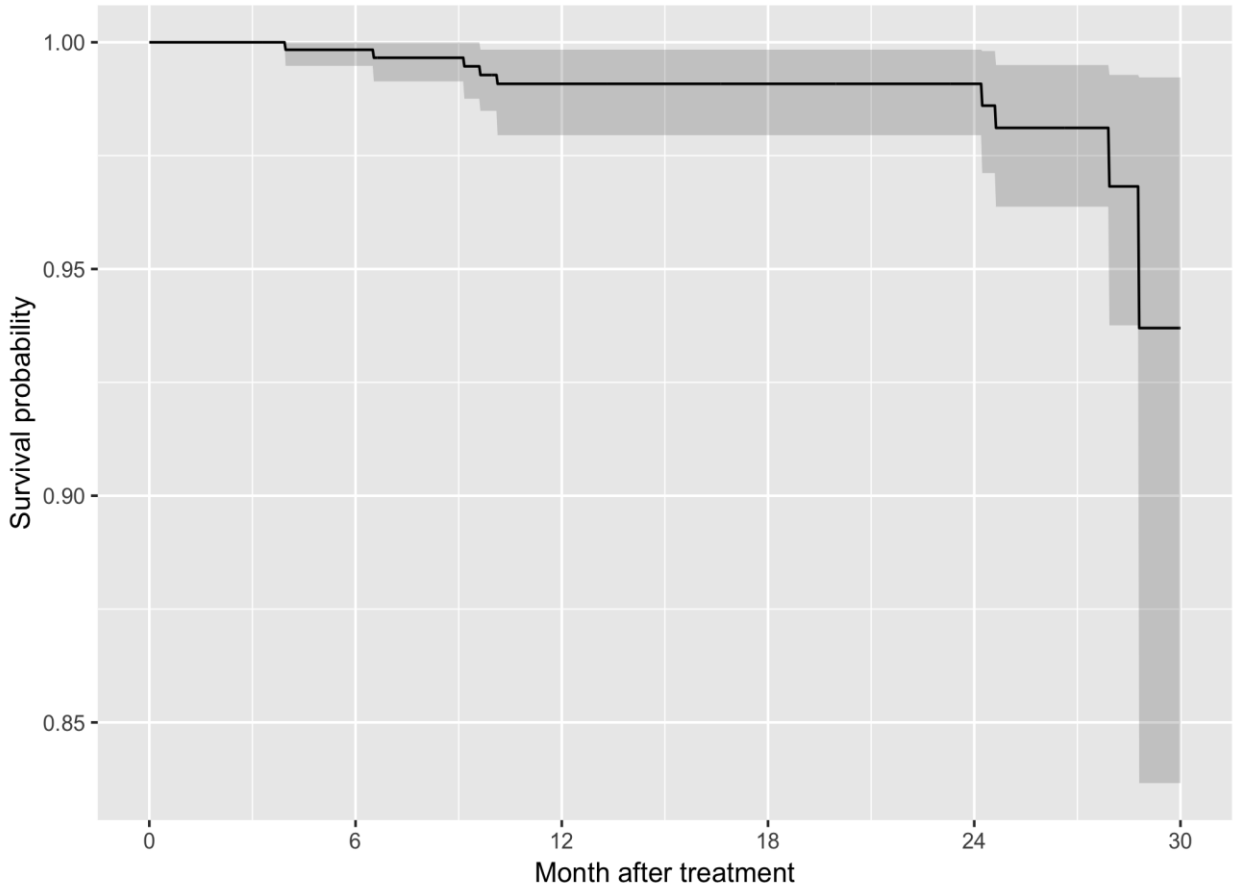
A survival analysis estimating the cumulative probability that any one tooth survived clinically with a 95% bootstrap confidence band is represented in Table 7. At 12 months, four hundred ninety-nine teeth were evaluated and the probability of survival was 99.1%. This

remained the same at the 24 months mark and dropped to 93.7% at 30 months. The survival analysis detailing the probability of clinical survival is plotted as a survival curve in Figure 3.

Table 7. Probability of Clinical Survival

Time (Months)	Probability of Survival (%)	95% Confidence Interval (%)
0	100.0	100.0 – 100.0
6	99.6	98.7 – 100.0
12	99.1	98.0 – 99.8
18	99.1	98.0 – 99.8
24	99.1	98.0 – 99.8
30	93.7	83.7 – 99.2

Figure 3. Clinical Survival Curve



4.2 Radiographic Findings

A total of 461 radiographs were evaluated of which 270 radiographs were determined to be diagnostic and included in this retrospective study. The total number of teeth assessed radiographically was 234 as some teeth were evaluated at multiple time points. Though there were 90 primary molars evaluated in the maxilla and 144 in the mandible, there were no observable differences in radiographic success rates between the teeth in the maxilla versus the mandible. A distribution of teeth observed to have radiographic success is shown in Table 8.

Table 8. Distribution of Teeth with Radiographic Success

	Mx Right	Mx Left	Total (Mx)	Mn Right	Mn Left	Total (Mn)	TOTAL
1st Molar (%)	30/30 (100)	23/25 (92)	**53/55 (96.4)**	45/50 (90.0)	39/39 (100.0)	**84/89 (94.4)**	**137/144 (95.1)**
2nd Molar (%)	15/16 (93.8)	16/19 (84.2)	**31/35 (88.6)**	25/29 (86.2)	24/26 (92.3)	**49/55 (89.1)**	**80/90 (88.9)**
TOTAL (%)	45/46 (97.8)	39/44 (88.6)	**84/90 (93.3)**	70/79 (88.6)	63/65 (96.9)	**133/144 (92.4)**	**217/234 (92.7)**

The overall radiographic success rate over 30 months was determined to be 217/234 (92.7%). Radiographic failures of pathologic radiolucency and pathologic root resorption were noted throughout the study observation period. Of the radiographic failures noted, five teeth presented with both pathologic radiolucency and pathologic root resorption. As seen in Table 9, the 13/17 (76.5%) of the radiographic failures, occurred within the first 18 months.

Inter-rater reliability was determined between 2 investigators by evaluating 51 radiographs – incorporating radiographs with successful and failed outcomes at a 2:1 ratio. Inter-rater agreement was 94.4% with a Fleiss' Kappa statistic of 0.870 which indicates a strong level of agreement (174). A selection of radiographs used for this inter-rater agreement test have been shows in Appendix B.

Table 9. Distribution of Teeth with Radiographic Failures

	Mx Right n=46	**Mx Left** n=44	**Total (Mx)** n=90	**Mn Right** n=80	**Mn Left** n=64	**Total (Mn)** n=144	**TOTAL n=234**
1st Molar	-	2	**2**	5	-	**5**	**7**
2nd Molar	1	3	**4**	4	2	**6**	**10**
TOTAL	1	5	**6**	9	2	**11**	**17**

Table 10. Type of Radiographic Failures over Time

	0 – 6 mos n=4	**6 – 12 mos** n=23	**12 – 18 mos** n=92	**18 – 24 mos** n= 78	**24 – 30 mos** n=61
Pathologic Radiolucency	1	4	1	2	1
Pathologic Root Resorption	-	4	6	1	2
Total Teeth	**1**	**6***	**6***	**2***	**2***

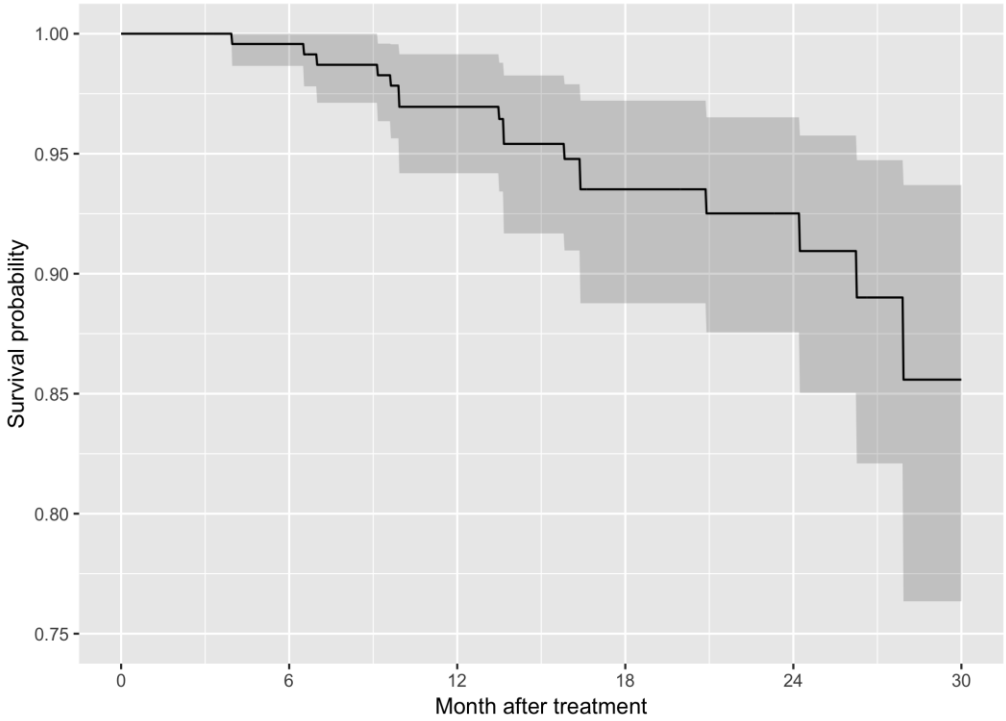
* Multiple radiographic findings may have been observed in a single tooth

From the diagnostic radiographs evaluated, a radiographic survival curve was estimated. The cumulative probability that any one tooth showed no signs of radiographic failure at one year was 97.0%. This probability remained the same through to the 30-month mark; however, due to the lower number of diagnostic radiographs after this time point, the confidence interval widened significantly. The data has been tabulated in Table 11 with the data points plotted on the survival curve in Figure 4.

Table 11. Probability of Radiographic Survival

Time (Months)	Probability of Survival (%)	95% Confidence Interval (%)
0	**100.0**	**100.0 – 100.0**
6	**99.6**	**98.7 – 100.0**
12	**97.0**	**94.2 – 99.1**
18	**93.5**	**88.8 – 97.0**
24	**92.5**	**87.6 – 96.5**
30	**85.6**	**76.3 – 93.7**

Figure 4. Radiographic Survival Curve



4.3 Clinical and Radiographic Outcomes

Radiographic and clinical outcomes were combined to give an overall success rate of 588/608 (96.7%) during the 30-month post-treatment period. There were 6 teeth that presented with both signs of clinical and radiographic failures. The remaining 14 failures were either a clinical failure or a radiographic failure – three were clinical failures, while eleven were radiographic failures exclusively. Of the 17 patients who experienced failed pulpotomy outcomes, five patients experienced two pulpotomy failures. The majority of failed Biodentine pulpotomies occurred between 6 to 18 months. Table 12 outlines the observed failures, arranged in chronological order post-treatment.

Table 12. List of Clinical and Radiographic Failures

Age at Tx	Tooth	Post-Tx Time (days)	Clinical Pathology	Radiographic Pathology
4 yrs, 10 mos	85	119	Pain	RL
6 yrs, 7 mos	84	196	Pain, ST Path	RL
4 yrs, 10 mos^{+}	65	210	--	RR
5 yrs, 4 mos	84	275	Pain, ST Path, Lost SSC	RL
5 yrs, 11 mos	65	289	Lost SSC	RL
3 yrs, 6 mos*	64	298	--	RL, RR
3 yrs, 6 mos*	84	298	--	RL, RR
5 yrs, 4 mos	55	304	Lost SSC	--
3 yrs, 7 mos	84	405	--	RL, RR
5 yrs, 8 mos^{++}	75	410	--	RR
5 yrs, 8 mos^{++}	85	410	--	RR
8 yrs, 10 mos	75	475	--	RR
6 yrs, 1 mo**	84	492	--	RR
6 yrs, 1 mo**	85	492	--	RR
6 yrs, 3 mos	85	627	--	RL, RR
4 yrs	65	727	Pain, Mob	RL
5 yrs, 6 mos$^{\wedge}$	84	739	Pain, Mob	--
4 yrs	64	788	--	RL, RR
4 yrs, 10 mos^{+}	55	838	Pain, Mob	RR
5 yrs, 6 mos$^{\wedge}$	74	864	Pain, Mob	--

$^{+, ++, *, **, \wedge}$ indicate same patient, **ST Path** = Soft tissue pathology, **Mob** = Pathologic mobility, **RL** = Radiolucency, **RR** = Root Resorption

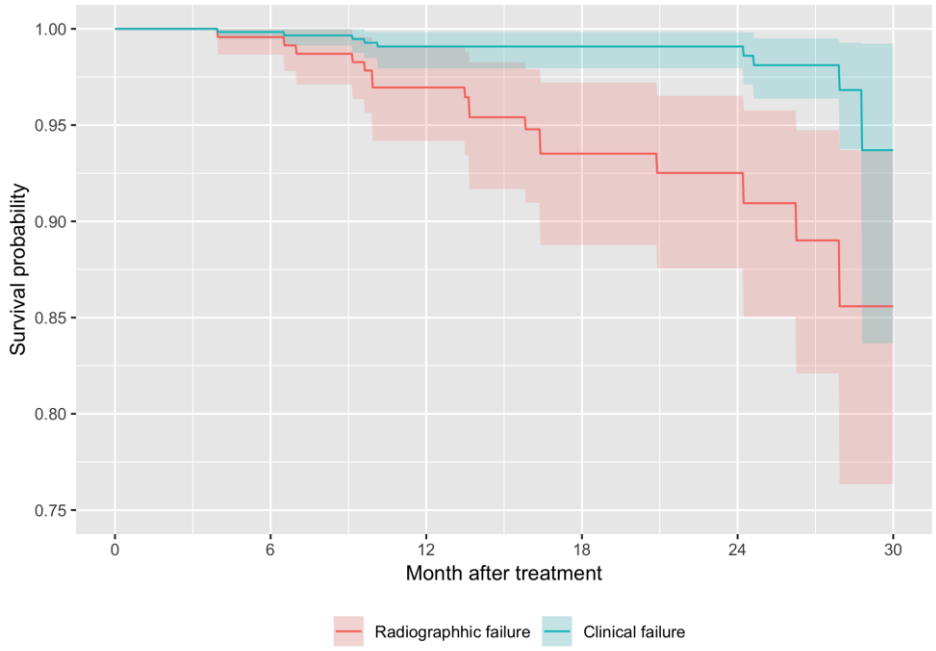
Table 13. Distribution of Teeth with Overall Failures

	Mx Right n=112	**Mx Left** n=132	**Total (Mx)** n=244	**Mn Right** n=190	**Mn Left** n=174	**Total (Mn)** n=364	**TOTAL** n=608
1st Molar	-	2	**2**	6	1	**7**	**9**
2nd Molar	2	3	**5**	4	2	**6**	**11**
TOTAL	2	5	**7**	10	3	**13**	**20**

Table 14. Distribution of Overall Failures over Time

	0–6 mos n=46	**6–12 mos n=453**	**12–18 mos n=364**	**18–24 mos n=356**	**24–30 mos n=208**	**Total**
Total Teeth	**1**	**7**	**6**	**2**	**4**	**20**

Figure 5. Clinical and Radiographic Survival Curves



Chapter 5: Discussion

5.1 Comparison to Results in the Literature

Use of Biodentine as a pulpotomy medicament resulted in a high overall cumulative success rate of 97.3% over the 30-month study period. Unlike traditional formocresol or ferric sulphate pulpotomies, which have been shown to have similar clinical and radiographic success rates of 92% and 74% respectively, this study's results compared favorably (79). Biodentine is one of the calcium silicate-based cements, which have noted excellent sealing abilities, biocompatibility and bioactive properties (154). Unlike formocresol and ferric sulfate, bioactive materials minimize the likelihood of radicular pulp inflammation, which is otherwise associated with pathological root resorption and subsequent pulpotomy failure (75). The results of this study are similar to other investigations of primary molar Biodentine pulpotomies. An 18 month retrospective review of two hundred primary molars with Biodentine pulpotomies demonstrated a success rate of 94% after 9 months, and 89.5% after 18 months (175). A recent review identified 8 studies reporting the clinical and radiographic success rates of Biodentine pulpotomies in primary molars (169). Five of the studies had one year or less of follow-up, samples sizes of 17-43 teeth, and reported success rates ranging from 88-100% (165,172,176,177). Three of the studies had up to 18 months of follow up and relatively small samples sizes of 15-32, with clinical and radiographic success rates of 95-100% (167,168,173). Comparatively, this investigation included 608 primary molars and observed a probability of clinical and radiographic survival at 30 months that was 94% (95% CI = 84-99%) and 86% (95% CI = 76-94%) respectively. These findings are similar to other published reports; however, this study has both a longer follow-up time and larger sample size than previously published literature.

The mechanisms of action for Biodentine and MTA are fundamentally similar, as both are biocompatible, non-cytotoxic, non-mutagenic calcium-silicate materials that can stimulate pulpal healing and regenerative mechanisms. A 24-month randomized trial comparing Biodentine and MTA found the two medicaments had similar clinical and radiographic results. A subsequent 2018 meta-analysis comparing primary teeth pulpotomies for MTA and Biodentine concluded that no superiority of one material over the other could be established (169). However, an advantage of Biodentine over MTA in a clinical environment is its setting time. Due to the addition of the calcium chloride accelerator in the liquid complement of Biodentine, the initial setting time is approximately 12 minutes, with a final setting time of 45 minutes (156,178). Comparatively, MTA takes 3 to 4 hours for final setting to be completed (136,148). This is of particular importance for restorative procedures where Biodentine is utilized as a layer under another restorative material, as is typical when performing direct or indirect pulp therapy. The clinically favorable results of this study provide support for the use of Biodentine as an alternative to MTA, especially for clinicians preferring a pulpotomy medicament with a shorter setting time. Furthermore, dye leakage studies show significantly better marginal sealing of Biodentine in comparison to MTA and glass ionomer cement (160). This could be partly attributable to Biodentine's interaction with dentinal tubules via mineral tags (161).

5.2 Clinical Outcomes

There were 9 clinical failures observed in the 608 teeth over the study period, resulting in a cumulative survival probability of 97.3%. Three of the 5 failures that occurred within the first year were attributed to loss of the full coverage restoration and the remaining 2 failures were children who presented with symptoms of pain and/or pathological mobility. In the second year,

an additional clinical failure was noted when a child returned with a pulpotomized tooth demonstrating symptoms of both pain and pathologic mobility. Three more teeth presenting with clinical outcomes of pain were noted in the third year of follow-up. Poor tooth selection, failure of the pulpotomy medicament, and failure of the restoration are all possible explanations for these failures. However, given the overall high success rate and minimal number of lost restorations, it is speculated that these clinical failures were most likely a consequence of poor tooth selection. Accurate diagnosis of pulpal vitality plays a critical role in the outcome of a pulpotomy; however, no reliable method exists by which an operator can determine accurate pulpal diagnosis at the time of pulpal exposure. The colour and volume of blood observed following pulp amputation are considered subjective in nature and are thus unreliable markers of pulp status (179). A recent investigation that measured the presence of inflammatory cytokine markers to assess the current standard of pulpal hemostasis as a measure of inflammation and indicator to proceed with a pulpotomy suggests there is no direct correlation between the achievement of hemostasis and the inflammatory status of the radicular pulp (179). Three clinical failures were attributed to loss of the full coverage restoration. Because of their low annual failure rates, full coverage stainless steel crown restorations are considered the standard of care after pulp therapy is performed on a primary tooth (180). In the present study, both stainless steel crowns (n=557) and zirconia (n=51) crowns were placed. To the best of our knowledge, there are currently no studies reporting long-term annual failure rates of zirconia crowns placed in deciduous molars. An interesting incidental observation of this study was that no failures were the consequence of loss of a zirconia crown, but the numbers were too small to draw any clinically or statistically significant conclusions from this finding. Ultimately, accurate pre-operative pulp vitality diagnosis, the choice of pulpotomy medicament, and the choice of

restorative material are all determinants that contribute the clinical success of pulpotomy procedures in the primary dentition.

5.3 Radiographic Outcomes

There were 17 radiographic failures observed in 234 teeth, with a radiographic survival probability of 86% over 30 months. These results are similar to previously reported success rates of Biodentine pulpotomies, which range from 87% to 94% over time periods up to 18 months (168,173,175,181). The outcome is also comparable to reported MTA radiographic outcomes of 87.1% (168). However, the study results are more favourable than radiographic success rates of formocresol and ferric sulphate pulpotomies, which can range from 78-90% and 70-97% respectively (79,81).

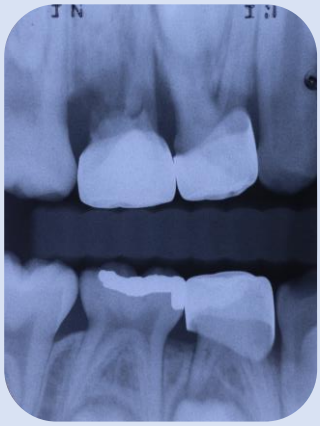
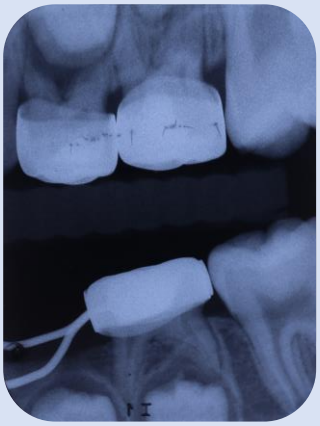
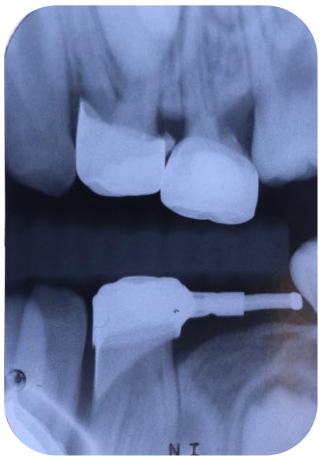
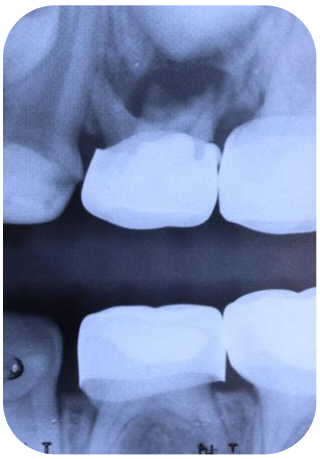
Reported success rates of primary tooth pulpotomies have been inconsistent, partly due to the variation in methodology and dissimilarities in the criteria defining what is considered successful (61). To address this limitation, two radiographic outcome variables identified as the most relevant in defining pulp therapy failure were utilized (78). Typically, evaluation of radiographic outcomes utilizes periapical radiographs to visualize the PDL space, and to assess for the presence or absence of periradicular or furcation radiolucencies (5). Although this study relied upon bitewing films taken at routine, recall evaluations, there are differences to take into consideration when performing radiographic evaluation of the primary dentition compared to the permanent dentition. Upon radiographic examination of a primary molar, a pathologic radiolucency secondary to a pulpal necrosis may not present periapically – a typical finding in the permanent dentition. Rather, primary molars have a high prevalence of furcal accessory

canals resulting in pathological furcation radiolucencies secondary to a necrotic pulp (14). The low radiographic failure rate of this study suggests that routine periapical radiographs of primary molars following a pulpotomy is not recommended. Further, the majority of the radiographic failures (76.5%, n=13) occurred within the first 18 months post-treatment, which additionally excludes the need for periapical radiographs to follow primary molars receiving pulpotomies until exfoliation. These results support the currently recommended radiographic intervals recommended by the American Dental Association (182).

The study results are consistent with previous pulp therapy studies in that the observed radiographic success rate was lower than the clinical success rate (165,168,173,175,183). This is partly attributable to radiographic failure not consistently correlating with signs or symptoms of clinical failure such as pain, pathologic mobility or soft tissue pathology. For example, a tooth with radiographic signs of internal root resorption, though considered a radiographic failure, may not present with any clinical signs of failure. In the current study, of the 17 radiographic failures, only 6 teeth also presented with correlating clinical symptoms. Radiographic interpretation can be difficult in the primary dentition as it may be challenging to discern between pathologic and physiologic processes due to the exfoliation process, which employ identical cellular mechanisms of resorption (184). For instance, in the current study, the root resorption noted on the distal roots of two maxillary primary second molars was also suggestive of first permanent molar ectopic eruption, a pathologic process that may have contributed to pulpotomy failure. Select radiographs demonstrating these confounding factors of ectopic eruption or physiologic resorption is presented in Figure 6. Consequently, an operator may endorse continual observation

of the tooth exhibiting signs of radiographic failure, yet ultimately opt for an extraction plan only if the tooth presents with pain, pathologic mobility, or soft tissue pathology.

Figure 6. Confounding Factors of Radiographic Interpretation

Ectopic Eruption?	Physiologic Resorption?
 **Tooth #55**	 **Tooth #64**
 **Tooth #65**	 **Tooth #64**

5.4 Strengths and Limitations

Unlike existing prospective clinical trials in the literature, a retrospective study design in the present investigation permitted for a larger sample size of Biodentine pulpotomies in primary molars to be evaluated. As pulpotomies are a routine procedure performed in a pediatric dental setting, this study gives a realistic clinical perspective as to the long-term outcomes of using Biodentine as a pulpotomy medicament. A retrospective study design also allows for minimal selection bias considering that all teeth treated within the elected study range were included. The results of this study are particularly valuable to the clinician who is exploring the current market for an ideal pulpotomy material, as the bulk of the existing literature are prospective clinical trials that involve significantly smaller sample sizes and shorter follow-up periods.

One of the major criticisms of pulpotomy studies in the literature revolve around the lack of consensus pertaining to the outcome variables that constitute clinical or radiographic failure. The decision to use a consistent set of outcome variables, as recommended by the authors of the 2013 Cochrane review on this topic, was made to allow easier comparisons to future pulpotomy studies (78). Moreover, the use of full coverage crowns to minimize restoration micro-leakage eliminates a potential confounding factor in the outcomes of this pulpotomy study.

Though it is important to recognize the advantages of retrospective studies, they are not without limitations, especially in the setting of this investigation. While in a prospective study, the outcome variables determining a clinical or radiographic failure are pre-determined and evaluated for every tooth. A retrospective study relies on the accuracy of the clinicians' notes which may not reflect the study's outcome variables of the pulpotomy treated tooth. Another

limitation of this investigation pertains to the study population: children treated under general anesthesia. There are many indications for treatment under general anesthesia in pediatric dentistry; however, uncooperative behavior is often the reason. Consequently, it would be reasonable to assume that a thorough clinical examination and radiographic examination may prove difficult in the sample population of this study. Moreover, in a pediatric specialty office where a large proportion of patients are seen on referral basis, these patients may return for limited follow-up appointments before returning to the referring provider. For this reason, statistical analysis was conducted as a survival analysis to accommodate for wide variability of patient follow-up.

5.5 Future Research

This investigation contributes to the amounting literature that supports the use of Biodentine as a pulpotomy agent in the primary dentition. Though some of the limitations of using a retrospective study could have been avoided with a prospective study design, the large sample size of this investigation provides a realistic perspective on Biodentine use for primary molar pulpotomies. Aside from the proven biocompatibility that Biodentine has on pulpal tissues, the ability for a clinician to use a material with ease in the pediatric population is just as important. With the advancements of pediatric dentistry, particularly the introduction of esthetic full-coverage zirconia crowns, future prospective clinical trials on Biodentine pulpotomies in primary molars restored with aforementioned restorations may prove an invaluable contribution to the literature.

Chapter 6: Conclusion

In this retrospective investigation, it was determined that pulpotomy procedures on primary molars utilizing Biodentine as a pulpal medicament had favourable clinical and radiographic results up to 30 months post-treatment. At 30 months, the determined probability of clinical survival was 93.7% (95% C.I. 83.7-99.2) and radiographic survival of 85.6% (95% C.I. 76.3-93.7).

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Appendices

Appendix A Recall Form

Chart #:_____ **Recall Form**

Dentist: _____
CDA: _____
Date: _____

Name:_____ Guardian Name:_____

Medical/Dental Health Update

1. Are there any dental problems you would like us to review since the last visit?
2. Is your child taking medications, prescription or non-prescription? What and Why?
3. List all changes in your child's medical history since the last visit.
4. Have there been any changes in the address, insurance, parental marital status or guardianship of the child? If yes, please be sure to let the receptionists know.

SIGNATURE _____ ☐ Fluoride Usage ☐ Diet ☐ Oral Habits ☐ Feeding Habits

Behaviour: ☐ 1 ☐ 2 ☐ 3 OHI: ☐ 1 ☐ 2 ☐ 3 Caries Risk: ☐ High ☐ Moderate ☐ Low

Examination

Extra Oral

Profile: ☐ Straight ☐ Convex ☐ Concave TMJ/TMD: ☐ WNL ☐ Other: _____

Head, Face, Perioral, Neck: ☐ WNL ☐ Lymph Nodes ☐ Scars ☐ Herpes simplex ☐ Other: _____

Comments: _____

Intra Oral Soft Tissue

Tongue, Lips, Frenum, Mucosa, Pharynx: ☐ WNL ☐ Canker sore ☐ Geographic tongue ☐ Abscess: _____
☐ High Attachment ☐ Large Tonsils ☐ Other: _____

Gingiva: ☐ WNL ☐ CMG(G)—mil/mod/sev ☐ CMG(L)—mil/mod/sev ☐ Pigmented ☐ Amalgam Tattoo
☐ Minimal Attached ☐ Recession ☐ Other: _____

Periodontium ☐ WNL ☐ Periodontitis—generalized/localized ☐ Calculus ☐ Other: _____

Comments: _____

Dentition

Type: ☐ Primary ☐ Mixed ☐ Permanent Midline: Max:Rt Lt ___ mm ☐ = ☐ NA Man: Rt Lt ___ mm ☐ = ☐ NA

Molar Relationships: **Rt -** • NA • EE • I • II • III **Lt -** • NA • EE • I • II • III

Cuspid Relationships: **Rt -** • NA • EE • I • II • III **Lt -** • NA • EE • I • II • III

Overbite_____% Overjet_____mm X-Bites: anterior: _____

Openbite_____mm Diastema_____mm posterior: _____

Space Deficient ☐ Max—A P ☐ Man—A P Space excess: ☐ Max—A P ☐ Man—A P

Other: ☐ Ectopic eruption ☐ Hypoplasia ☐ Congenital absence ☐ Supernumerary ☐ Sensitivity

☐ Ankylosis ☐ Fractures ☐ Stains—intrinsic/extrinsic ☐ Mobility ☐ Habits: _____

☐ Bruxism ☐ Fused ☐ Dens evaginatus ☐ Dens invaginatus ☐ Over retained ☐ Decalcification

Comments: _____

Home Care/Diet/Referral

Home Care/ Diet Recommendation: _____

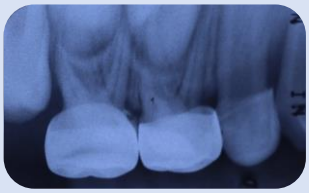
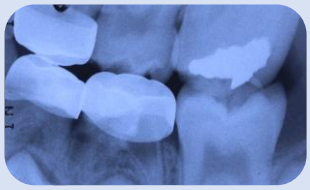
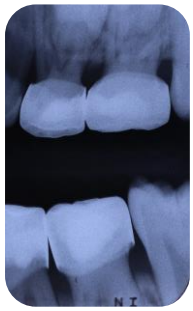
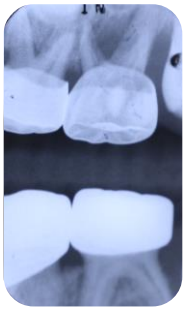
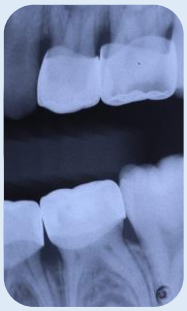
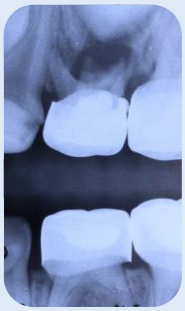
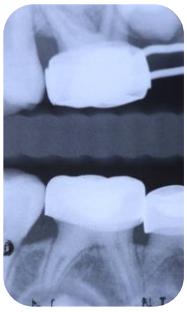
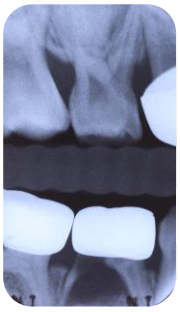
Referral: ☐ Ortho ☐ OS ☐ Perio ☐ OM ☐ Other: _____ Referral given to: _____

Comments: _____

Discussed/Brochures: ☐ Caries ☐ Diet ☐ Filling types ☐ Fissure Sealants ☐ Fluoride Supplements

☐ Sucking ☐ Pulpotomy ☐ InfantToddler OH ☐ Extraction(s) ☐ Space Maintainers ☐ Other: _____

Appendix B Select Radiographs from Inter-rater Reliability Test

Radiographic Success	Radiographic Failure
 **Tooth #55**	 **Tooth #64**
 **Tooth #65**	 **Tooth #65**
 **Tooth #75**	 **Tooth #64**
 **Tooth #85**	 **Tooth #84**