A COMPARISON OF TWO LINER MATERIALS FOR USE IN THE FERRIC SULFATE PULPOTOMY

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DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

Signature:.....

Date:.....4/02/2004.....

ABSTRACT

Pulp therapy in the primary dentition has always been a source of much controversy. Different pulpotomy techniques and medicaments have been covered extensively in the literature but due to the increasing awareness of the potential deleterious effects of some of these medicaments, a need has arisen in the dental profession to find safer, alternative pulpotomy agents. Ferric sulfate and calcium hydroxide have been suggested as possible, more biologically acceptable alternatives to formocresol, which is known for its toxic side effects. Ferric sulfate is one of the most recent agents used in vital pulp therapy and has enjoyed reasonable success.

Further controversy also exists in terms of the type of base which is placed over the amputated pulp. The choice of the base seems to determine the pulpal response. Two bases, calcium hydroxide (Dycal) and zinc oxide-eugenol (Kalzinol) have both been used in separate studies but have never been compared. The aim of this study is to compare the success rate obtained when applying one or the other of these two bases following a ferric sulfate pulpotomy. Presently it is unknown which base is best.

In this study, after haemostasis was achieved with damp cotton pellets, ferric sulfate was applied to the pulpal stumps. Half of the cases then received a Dycal base followed by a cured layer of Vitrebond and a permanent amalgam restoration. The other half of the cases received a base of zinc oxide-eugenol (Kalzinol) followed by an amalgam restoration. Overall, teeth treated with Dycal demonstrated a higher failure rate when compared with those that received the Kalzinol base. Abscess formation and internal resorption were the most common causes of failure. Even though the Kalzinol base demonstrated greater success, there were still quite a few failures.

This study demonstrates, that even with the use of a haemostatic agent, calcium hydroxide cannot be recommended as a medicament in primary tooth pulpotomies. It also highlights the need for alternative pulpotomy medicaments that are not irritating or harmful to the pulp.

ABSTRAK

Pulpaterapie in die primêre gebit was maar altyd 'n kontroversiële onderwerp. Verskeie pulpotomie tegnieke en medikamente is ekstensief in die literatuur gedek. Vandag is daar 'n toenemende bewustheid van die potensiële nadelige effekte van party van hierdie agente en daar is 'n behoefte om veiliger pulpotomie medikamente te identifiseer. Ferrisulfaat en kalsiumhidroksied is voorgestel as moontlike plaasvervangers vir formocresol wat bekend is vir sy toksiese newe-effekte. Ferrisulfaat is ook een van die mees onlangse pulpotomie agente wat goeie resultate behaal het in vitale pulpaterapie van primêre tande.

Die tipe basis materiaal wat oor die pulpastompe geplaas word is ook kontroversieel. Die basis blyk om die pulpale reaksie te bepaal. Twee basisse, kalsiumhidroksied (Dycal) en zink oksied-eugenol (Kalzinol) is albei in verskeie studies gebruik maar is nooit met mekaar vergelyk nie. Die doel van hierdie studie is om die sukses van die twee basisse te vergelyk nadat die standaard ferrisulfaat pulpotomie tegniek uitgevoer is. Huidiglik is dit onbekend watter een van die twee basisse die beste is.

In hierdie studie, is ferrisulfaat op die pulpastompe aangewend na hemostase bereik is met klam watteplusies. Die helfte van die gevalle het 'n Dycal basis ontvang gevolg deur die plasing van 'n gekuurde laag Vitrebond en 'n permanente amalgaam herstelling. In die ander helfte van die gevalle was 'n zink oksied-eugenol (Kalzinol) basis geplaas gevolg deur 'n amalgaam herstelling. Oor die algemeen het die tande wat die Dycal basis ontvang het meer dikwels gefaal. Absesformasie en interne resorpsie was die algemeenste oorsake hiervan. Alhoewel die Kalzinol basis meer suksesvol was, was daar nogsteeds heelwat mislukkings.

Hierdie studie demonstreer dat selfs met die gebruik van 'n hemostatiese agent, kalsiumhidroksied nie as 'n pulpotomie medikament in primêre tande aanbeveel kan word nie. Dit beklemtoon ook die behoefte om alternatiewe pulpotomie medikamente te vind wat nie skadelik of irriterend vir die pulpa is nie.

DEDICATION

To my students, past and present, for giving me the opportunity to experience the joy and privilege of teaching.

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TABLE OF CONTENTS

CHAPTER 1

INTRODUCTION

A major goal of paediatric dentistry is the maintenance of the primary dentition till the permanent teeth erupt. Carious primary teeth can lead to bacterial invasion of the coronal pulp which in turn results in pulpal inflammation. The resilience of injured pulpal tissue has been demonstrated by its ability to heal in the absence of adverse conditions. Thus, removal of affected tissue and placement of an appropriate dressing would encourage the pulp tissue to recover, provided the biological seal is maintained. It has been shown that dental pulp tissue has the ability to produce secondary, tertiary and reparative dentine after an injurious insult [1, 62, 65, 78].

Over the years, various techniques have been introduced to take advantage of this fact and try and preserve the vitality of teeth wherever possible [33, 48]. Primary and permanent teeth have been shown to react differently to different techniques and materials and factors such as the complex anatomy of primary teeth and the close proximity of the permanent tooth germs, further complicates pulp therapy in the primary dentition.

When treating vital primary teeth with carious exposures, the pulpotomy technique has been the procedure of choice across the decades. This procedure allows for the preservation of teeth which would normally be extracted, thereby maintaining the integrity of the dental arch and preventing the unwanted sequelae that would result from premature extraction of these carious teeth [1, 15, 41, 65].

In the deciduous dentition, a pulpotomy involves the removal or surgical excision of the affected coronal portion of a vital pulp and treatment of the remaining radicular pulp. Inflammatory and degenerative tissue at the entrance to the root canals is removed and a

medicament is usually placed in direct contact with the exposed pulp. In this way, the tooth is preserved as healing is promoted and normal physiologic development is allowed to continue [1, 2, 5, 10, 14, 50, 54].

Indications and contraindications for pulpotomies in the deciduous dentition [8, 9, 12, 14, 15, 16, 39, 80]

Indications include:

- Radiographic evidence of caries close to the pulp
- The tooth must be vital. In other words, normal, light red blood should be evident upon carious exposure of the pulp.
- Ideally, the tooth should be asymptomatic but a pulpotomy can still be performed on a tooth with slight symptoms. These symptoms can include cold or sweet sensitivity or pain caused by food impaction.

Contraindications include:

- Spontaneous pain
- Signs of non-vitality such as the presence of a sinus tract or swelling
- Mobility
- Tenderness to percussion
- Uncontrollable haemorhhage upon pulpal exposure
- Radiographic evidence of pathology
- Presence of internal and/ or external root resorption
- Presence of intra-radicular and/ or periapical bone destruction
- Signs of calcific pulpal degeneration
- A tooth which is not restorable due to gross caries

Ranly [6] stated that: " Ideal pulpotomy treatment should leave the radicular pulp vital, healthy and completely enclosed within an odontoblast-lined dental chamber". This would ensure that the normal physiological process continued until the time of

exfoliation. Thus, the main objective of this treatment procedure is to maintain vitality of the majority of the radicular pulp [14, 32].

A successful pulpotomy procedure can be summarised as follows:

- Most of the radicular pulp is vital.
- The patient has no clinical signs or symptoms such as sensitivity, pain or swelling or presence of a sinus or fistula.
- There is no radiographic evidence of pathology.
- No harm is caused to the permanent teeth [20].

Over the years, many different pharmacotherapeutic agents have been used in primary teeth when performing pulpotomies. These include formocresol, gluteraldehyde, ferric sulfate, mineral trioxide aggregate and calcium hydroxide to name but a few. Preparations containing corticosteroids, collagen solutions, freeze-dried bone, bone morphogenetic proteins and osteogenic proteins have also been cited as less toxic alternatives [4, 6, 7, 10, 27, 29]. Non-pharmacotherapeutic techniques include electrosurgical pulpotomies and the use of laser therapy [1, 7, 27]. Further controversy also exists in terms of the type of base that is placed over the amputated pulp. Zinc oxide-eugenol is the base that is most commonly used following formocresol and ferric sulfate pulpotomies .

According to Ranly [6], pulpotomy techniques can be grouped into 3 categories, namely:

1. Devitalisation, where vital tissue is destroyed and the pulp tissue is completely mummified (eg. where formocresol is used as a pulpotomy agent or where electrocautery has been performed). This procedure usually results in the destruction of vital tissue.
2. Preservation, where as much vital tissue is retained as possible, such as in cases where gluteraldehyde and ferric sulfate are used as pulpotomy agents. These agents are not capable of inducing reparative dentine formation.

3. Regeneration, where dentine bridge formation is induced. This is usually associated with the use of calcium hydroxide preparations and more recently, with bone morphogenetic proteins [4, 6, 14].

Concerns regarding the safety of these materials and/ or methods continue to this day and researchers are continually on a quest to find effective, biocompatible alternatives for use in such procedures.

The next section of this report is a literature review dealing with the different pulpotomy techniques that are practised, as well as the different materials and bases that are used in these procedures.

LITERATURE REVIEW

1.1. DEVITALISATION

1.1.1. Formocresol

Formocresol was first introduced by Buckley in 1904. Buckley's formocresol solution constitutes 19% formaldehyde, 35% tricresol, 15% glycerin and 31% water [1, 3, 18, 25, 28, 34, 36, 46, 80]. Today, most formulations of formocresol contain approximately 19% formaldehyde. Since its introduction, Buckley's formocresol has enjoyed varying degrees of success and there have been many different opinions as to its effectiveness. Over the years, this particular formulation has undergone a lengthy evolution to shorten its application time and reduce its concentration [1, 3, 9, 15, 17, 27, 31, 37]. Various dilutions have proven to be effective.

Ever since Sweet advocated its use in the 1930's, formocresol has been a popular choice of agent for use in pulpotomies in the primary dentition [4, 15, 20, 22, 31]. The formocresol pulpotomy is still the most universally taught procedure and has been considered to be 'the gold standard' for more than 60 years [16, 23, 46, 66, 86, 48]. In Scandinavian countries however, calcium hydroxide is the medicament of choice and this technique is taught in 70% of their dental schools [66].

Avram and Pulver [66] reported that worldwide, formocresol was the preferred pulpotomy medicament for pulpotomy procedures in vital primary teeth. Reasons for its popularity include ease of use and excellent clinical success [38, 39, 41, 47]. The rationale for using formocresol is not clear but Ranly [6] suggested that the only rationale for using formocresol in pulpotomies is that "it succeeds more often than it fails". Today however, formocresol is increasingly under the spotlight due to increasing concerns about its toxicity and potential carcinogenicity in humans [6, 20, 29]. There are specifically 3 areas of concern, namely:

1. Systemic distribution of formocresol from pulpotomy sites
2. Mutagenicity of formaldehyde
3. Cytotoxicity of formocresol

The toxicity of formocresol

Formocresol is a formaldehyde compound that has proven toxic properties and is believed to be potentially mutagenic and carcinogenic [25, 46, 70]. The active components of formocresol are formaldehyde and cresol. Formaldehyde has been shown to be toxic to the pulp and it is this component which is thought to be responsible for the harmful effects of formocresol on the dental pulp. It has been shown to elicit cellular and humoral immune responses. Formaldehyde is broken down in the liver but breakdown can also take place in red blood cells, the brain, kidney and muscle, ultimately resulting in liver and kidney changes [17, 24, 25, 28]. Because formaldehyde is a small molecule compared to other aldehydes, penetration into the surrounding tissues is easier and tissue damage may occur more readily [25].

The tricresol component of formocresol (generically known as cresol) is a caustic, lipophilic organic compound that has been shown to completely destroy cellular integrity by dissolving cell membranes [3, 4, 10, 15, 18, 19, 43, 46, 58, 70]. This loss of cellular definition has been proven histologically [47].

Formocresol was also shown to impair the microcirculation of the dental pulp [43]. It is a bactericidal agent which fixes affected and infected radicular tissue, replacing the initial acute inflammation with a chronic inflammatory response [4, 9, 27, 28, 50]. It devitalises damaged tissue and kills invading organisms [34, 70].

Evidence suggests that formocresol may not be solely confined to the radicular pulp. Numerous articles have documented the penetration of formocresol into the surrounding tissues (including pulp, dentine, periodontal ligament and periapical bone) after pulpotomy treatment of teeth [19, 22, 43]. This spread of formocresol is difficult to

control and this is therefore a major disadvantage [37]. Systemic distribution of formocresol from pulpotomy sites has been clearly demonstrated [9, 27, 28, 43]. The presence of formaldehyde in the blood has also been shown following experimental formocresol pulpotomy procedures. These toxic systemic effects would be more evident in general anaesthesia cases where several pulpotomies may be done during the same appointment, as circulating formaldehyde increases with the number of teeth treated [14, 17, 46].

Judd and Kenny [17] presume that the chances that toxic effects could result from pulpotomies are small, as the quantity of formocresol used in this procedure is negligible. However, formocresol in large quantities has been demonstrated to be very toxic. According to calculations by Ranly [46], "over 3000 pulpotomies would have to be performed at the same time in order for formocresol to reach such toxic levels". He does however concede that certain animal studies have demonstrated changes in liver and kidney tissues with as little as 16 pulpotomies.

Myers et al. [43] designed a study in order to determine if formaldehyde was systemically distributed following pulpotomy procedures with formocresol. The study was performed on rhesus monkeys. A radioactive marker, ^{14}C, was added to the formocresol, making it possible to identify the formaldehyde component of formocresol. Pulpotomies were performed and a formocresol-soaked pellet was applied for 5 minutes. A pellet was also sealed into a tooth for the duration of the experiment so that the effect of a longer application of formocresol could also be observed. Results indicated that systemic absorption of formaldehyde definitely takes place after pulpotomies with formocresol have been performed. Approximately 1% of the dose placed in the tooth was absorbed.

Little difference was however noted regarding the systemic distribution between the two different application times. In both cases, there was an initial period of rapid absorption which later seemed to level off. This suggested that the "absorption was self-limiting". It is thought that the initial exposure to formocresol causes vessel thrombosis which limits further systemic distribution. This could be the reason why a single 5-minute application

produced similar clinical and histological results as the multiple visit procedure. Concentrations of ^{14}C formaldehyde were detected in the periodontal ligament, bone, dentine and pulp, demonstrating that "materials placed on vital pulp tissue may be absorbed into the systemic circulation".

A similar study in rats [70] indicated that 30% of the formaldehyde was distributed systemically within 5 minutes. This percentage is higher than that reported by Myers [43]. Reasons for these differences could be due to the following:

- Differences in the anatomy of the root canals between the species
- Rats have a more active metabolic state than monkeys and dogs. Logically, it would seem that humans are far less likely to be as susceptible to the potential carcinogenic effects of formaldehyde than test rodents.
- Formaldehyde was applied with a pipette (and not a cotton pellet).
- Cresol was not part of the formulation applied to the pulp. This "caustic" component of formocresol is thought to "cauterize" tissue, thereby limiting its systemic distribution.

Magnusson [37] found that the diffusion of formocresol throughout the pulpal tissue was unpredictable and that the depth of penetration was difficult to determine histologically.

Most of the studies demonstrating toxicity and systemic distribution have been performed on animal models and these studies often do not take the differences in species into account. There is however no evidence in the literature of these harmful side effects following formocresol pulpotomies in humans [17, 18]. Lewis [19] stressed that it is clear that "formaldehyde poses a carcinogenic risk in humans" and it should therefore be treated as such.

The evolution of the formocresol pulpotomy technique

Due to the increasing awareness of the deleterious effects of formocresol amongst dental professionals, the formocresol pulpotomy has undergone many modifications over the years especially where the concentration of formocresol in formulations is concerned as well as the period of application and the incorporation of formocresol into the subbase.

Studies by Sweet led to this technique becoming widely accepted. It was a multiple visit procedure that was designed to completely mummify the pulp tissue. This technique can therefore be classified as a devitalisation pulpotomy [6, 31, 50, 86]. Sweet's technique consisted of 4 appointments, spanning a period of about 8 days. A formocresol-soaked pellet was left in contact with the pulp tissue for a combined period of about 6 days. The pellet was replaced once during this six-day period. At the final visit, a creamy mixture of zinc oxide-eugenol was placed into the pulp chamber before the tooth was permanently restored [6, 17, 31, 46]. This technique has been refined somewhat over the years and some variations have crept in. The application time of formocresol has progressed from several days, to two-appointment procedures and eventually, to application for a few minutes only.

Doyle et al. [47] evaluated a two-visit procedure in their study. After the utilization of a 5-minute formocresol protocol in later studies by Spedding et al. and Redig (as quoted by Ranly[6]), this technique gained popularity. In a study conducted by Magnusson [37], no differences were noted between the amount of tissue that was fixed when a 3 to 5 day formocresol application was compared with a 5-minute application. Thus, he concluded that there seems to be "little advantage in a two-appointment technique". Myers et al. [43] and Doyle et al. [47] corroborated this theory. In other words, the time of application (of formocresol) was insignificant as similar clinical and histological results were obtained.

Today, this 5- minute protocol is still being practised but this shorter treatment time means that mummification is incomplete and the pulp tissue is only partially devitalised.

Approximately one third of the coronal tissue in the pulp canals is mummified [50]. Incomplete mummification has a disadvantage in that the chronically inflamed pulpal tissue that remains, is more susceptible to abscess formation, and internal root resorption is therefore more prevalent. Ultimately, fixation or mummification also leads to disinfection. Thus, the elimination of pulp infection can be achieved by complete mummification of the pulp [6, 25, 46].

A survey done in the United States to ascertain the techniques taught in predoctoral paediatric dental programmes revealed that a 1 in 5 dilution of formocresol placed in the pulp chamber for 5 minutes is the most popular formocresol technique being practised [23]. Ranly and Garcia-Godoy (as quoted by Primosch et al. [23]) pointed out that " while the 1 in 5 dilution was routinely accepted, this dilution level was arrived at arbitrarily" [39]. They suspected that because this formulation had to be individually prepared and there was no diluted solution commercially available, this formulation was not used as often as previously thought. Lewis [19] stated that dilutions were difficult to standardise and also speculated that these formulations are arbitrary even today. According to him, these formulas have never been standardised and "the common dose of formocresol has been shown to be many times greater than the minimum dose needed for effect".

Morawa et al. [34] tested the efficacy of a 1 in 5 dilution of formocresol and compared it to a full strength formulation. They found that the results from their study corroborated results from previous studies [1] which concluded that the 1 in 5 concentration was just as effective as full strength formocresol, if not better [4, 34]. Histologically, there also seemed to be fewer cytotoxic effects with less destruction of vital tissue. Due to the obvious toxic nature of formocresol, minimizing the concentration used would also minimize the potential local and systemic effects [4, 17, 18, 36, 39]. The 1 in 5 dilution therefore represented a safer alternative to the full strength version. Ketley and Goodman [18] suggested that this particular formulation be used in the meantime while alternative pulpotomy agents are being investigated. They do however recommend that formocresol not be included in the zinc oxide-eugenol sublining.

The use of zinc oxide-eugenol as a subbase in formocresol pulpotomies

Various techniques for the formocresol pulpotomy have been described in the literature. These include:

1. application of a formocresol-soaked pellet onto the pulpal stumps followed by the placement of a base constituting a pure mixture of zinc oxide-eugenol;
2. placement of a zinc oxide-eugenol base containing equal amounts of eugenol and formocresol (usually one drop of each) without prior application of a formocresol-soaked pellet [35, 36, 38, 50, 80] and
3. application of a formocresol-soaked pellet prior to the placement of a zinc oxide-eugenol base into which formocresol has been incorporated. The rationale behind this is to prolong the action of formocresol [18, 35, 80] but controversy exists as to whether this incorporation of formocresol into the subbase is warranted.

Mansukani (as quoted by Ranly et al. [35]) could find very little difference in pulpal reactions between teeth where formocresol was applied with a pellet and those where a zinc oxide-eugenol base containing formocresol was applied without prior application of a formocresol-soaked pellet. Research by Garcia-Godoy [41] and Hicks et al. [72] tend to substantiate these findings. A favourable success rate of 93.8% was obtained in Hicks' study. This is comparable to that of previous studies.

According to Schwartz [36], a base of pure zinc oxide powder mixed with one drop of eugenol and one drop of formocresol "does not appear to have any clinical significance on the success of the pulpotomy". Ranly et al. [35] designed an experiment aimed at determining whether formaldehyde leached from the zinc oxide-eugenol subbase. Their study proved conclusively that formaldehyde was definitely lost from this base. They showed that in vitro, up to 80% of the ^{3}H-formaldehyde is lost from the zinc oxide-eugenol cement. Thus, they concluded that the additional application of a formocresol-soaked pellet could very well be redundant. This is in agreement with Beaver et al. [80] who found that the pulpal reactions were the same, irrespective of whether formocresol

was included in the subbase or not. Thus, after application of a formocresol-soaked pellet, it seems unnecessary to incorporate formocresol into the subbase as well.

Berger [50] conducted a study in order to determine the pulpal response to a zinc oxide-eugenol base. A formocresol-soaked pellet was placed into the pulp chamber for 5 minutes in pulpotomised teeth, followed by the placement of a base constituting zinc oxide powder and one drop each of eugenol and formocresol. This group was compared to pulpotomised teeth in which a pellet soaked with aqueous glycerine solution was applied to the pulpal stumps (instead of formocresol) for 5 minutes. A mixture of zinc oxide powder, one drop of eugenol and one drop of the aqueous glycerine solution was then placed over the pulpal stumps. Thus, it was possible to evaluate the pulpal response to a zinc oxide-eugenol base (without the influence of formocresol).

Radiographic success rates were 97% and 58% for the formocresol and zinc oxide-eugenol groups respectively. Although all teeth were clinically asymptomatic, histologically, necrotic changes were seen in the formocresol-treated teeth within three weeks following treatment, and acute persistent inflammatory reactions were observed in teeth where the zinc oxide-eugenol base was applied. None of the teeth in the zinc oxide-eugenol group had a good prognosis histologically and therefore, Berger concluded that more satisfactory long-term results could be obtained by excluding this base from the pulpotomy technique.

The success of formocresol pulpotomies in general

Formocresol pulpotomies on the whole have been very successful. The clinical and radiographic success has often been shown to exceed 90% [6, 24, 27, 29, 34, 47, 50]. Waterhouse et al. [1] demonstrated that Buckley's formocresol solution applied to the radicular pulpal stumps of primary teeth for 5 minutes, yielded clinical success rates of between 55 to 98% over periods ranging from 1 to 87 months. Different studies use different criteria and this could be one of the reasons for this variation in clinical success rates. Even though healing did not occur in formocresol pulpotomies, Doyle et al. [47]

attributed the clinical success of formocresol to its germicidal properties and its ability to fix pulp tissue [47, 50].

Despite these clinical successes, histological results have varied considerably. On the whole, the histological picture has been very discouraging.

Myers et al. [43] suggested that damage caused to the microcirculation of the pulp could be a possible reason for the varying histological findings. Histological results show coronal inflammation that progresses in an apical direction [85]. Variations in formocresol concentrations could also result in these histological discrepancies [34]. These variations can possibly be attributed to other factors such as different pre-operative conditions, different observation periods and variations in techniques. A one-treatment technique may present with a slightly different histological picture to a multiple appointment technique [49, 50].

Inflammation and necrosis have often been demonstrated by various authors (especially with full strength formocresol formulations) [24, 39, 49]. According to Berger [50], this pulpal inflammation could possibly be attributed to the zinc oxide-eugenol base which is commonly placed after the application of formocresol. In formocresol pulpotomies, mild inflammation is observed in the area of amputation but the use of a zinc oxide-eugenol subbase elicits a moderate to severe inflammatory response [38]. Histological signs of necrosis are often visible within three weeks of the pulpotomy procedure [50].

In Magnusson's study [37], varying numbers of inflammatory cells were present in the zone adjacent to the tissue that was fixed by the formocresol. Most of the coronal tissue in the root canals was totally necrotised by the formocresol. Histological observations have also shown that formocresol does not promote pulpal healing and often causes chronic irritation in the residual tissue [18, 32, 37, 46, 85]. None of the teeth in Magnusson's study [37] demonstrated any healing. A study by Doyle et al. [46] confirmed that formocresol did not stimulate a healing response. This is contrary to the calcium hydroxide pulpotomy where the potential for healing is greater, albeit only in a

low percentage of cases. In general, calcium hydroxide pulpotomies showed a lower incidence of necrosis in the residual tissue than in formocresol pulpotomies [37, 53].

Overall, the histological picture of formocresolized pulps does not seem to improve at any time after treatment [49]. Rølling and Lambjerg-Hansen [49] investigated the state of the pulp 3 to 5 years after formocresol pulpotomies had been performed. Even though these teeth were regarded as clinical and radiographic successes, histologically all teeth exhibited pulpal changes which included inflammation and/ or necrosis. Thus, it has been shown that a clinically successful pulpotomy can still display signs of chronic inflammation and partial necrosis [46, 49].

Clinically, where the formocresol pulpotomy is concerned, there are conflicting views in the literature with regards to:

- The occurrence of enamel defects on permanent teeth following pulpotomy procedures of their primary successors and
- The rate at which pulpotomized teeth exfoliate.

Even though it cannot be stated with absolute certainty that formocresol produces definite changes in permanent teeth, the accessory canals in the furcation areas of primary molars could serve as possible conduits through which formocresol escapes, thereby affecting the enamel of the permanent successor. Enamel defects, defined as any abnormality in surface morphology or colour (including hypoplasia and hypocalcification) have clearly been demonstrated by Pruhs et al. [52] in permanent teeth, following formocresol pulpotomies of their primary predecessors [17, 28, 52].

There is general acceptance in the literature that pulpotomised teeth tend to show accelerated exfoliation [17, 32, 34, 48]. Farooq et al. [54] showed that teeth that received formocresol pulpotomies often exhibited this phenomenon. Even when formocresol was not applied to the pulpal stumps but incorporated into the zinc oxide-eugenol lining, earlier exfoliation still took place in 45% of cases documented by Hicks et al. [72]. It is speculated that this could be attributed to leaching of formocresol from the pulpotomy

site to the surrounding tissue. A chronic inflammatory response is initiated, thereby leading to accelerated resorption [72].

Despite the reported toxic, mutagenic and carcinogenic properties of formocresol, this pulpotomy technique remains popular. A possible reason for this could be that current research on alternative medicaments is not sufficient to convince the majority of paediatric dentists and teaching institutions currently using formocresol, that a safer, more effective alternative has been developed. Rølling and Lambjerg-Hansen [49] advise that "the formocresol method should be considered only as a means to keep primary teeth with pulpal exposures functioning for a limited period of time".

However, there can be no doubt that formocresol is no longer regarded as the ideal pulpotomy medicament due to its potential harmful effects and research has proven that the replacement of formocresol has become imperative [14, 15, 19, 28, 29, 30, 43, 66].

1.1.2.Electrosurgery

Non-pharmacological devitalization pulpotomy procedures have also gained popularity in recent years due to their ease of use. These procedures eliminate bacterial contamination and denature pulp tissue.

Usually a low output current is applied for a brief period. The terms electrosurgery, electrocautery and electrofulguration have all been used in the literature. These terms could also be indicative of variations in electrical current [29, 24]. A surgical current is a high frequency current that is used to amputate the coronal pulp. A coagulation current can then be applied to the remaining pulpal stumps and results in a superficial zone of coagulation necrosis. It is speculated that this coagulation layer might limit the irritating effect that zinc oxide-eugenol has on the pulp. Fulguration is a dehydrating current. In this case, the electrode usually does not make contact with the tissue but instead, a spark jumps from the electrode causing charring of the tissue. These non-pharmacological techniques can also be used to promote pulpal haemostasis [4, 20, 24, 29, 30].

In the literature, there have been conflicting results regarding the success of these procedures. Success rates reported for electrosurgical pulpotomies have varied from very low [24] to very high [20].

Reumping et al. (as quoted by Ranly [6] and Mack et al. [20]) demonstrated that results of the electrosurgical pulpotomy compared favourably with that of conventional pulpotomies utilising formocresol. In contrast, a similar study done by Schulman et al. (as quoted by Mack et al. [20]) produced less favourable results with evidence of root resorption. This poor result was attributed to excessive heat production.

Mack and Dean [20] undertook a retrospective study in order to compare the clinical and radiographic success of electrosurgical pulpotomies in primary molars (where a zinc oxide-eugenol dressing was placed) with that of formocresol. A 99.4 % success rate for

the electrosurgical pulpotomy was observed in this study which was significantly higher than that of formocresol [20, 29].

Ranly [6] found this high success rate surprising as there is no explanation why "burned tissue is tolerated by the residual vital pulp".

Another study by Mack et al. [30] (which also compared electrosurgical pulpotomies with formocresol) showed there were "no statistically significant differences" between the success rates for these two groups. However, the radiographic failure rate for the electrosurgical pulpotomies was shown to be twice that of formocresol, but according to the authors, this difference was not statistically significant.

Fishman et al. [24] compared a zinc oxide-eugenol base to a calcium hydroxide base after electrofulguration pulpotomies were performed. The clinical success rate of the zinc oxide-eugenol and calcium hydroxide bases was found to be 77% and 81% respectively (after 6 months) while the radiographic success was documented as 55% and 57% respectively. Their study did not support the use of the electrosurgical pulpotomy technique for primary teeth with carious pulpal exposures as the results that were obtained did not compare favourably with those of previous clinical trials (in which caries–free teeth were used). They therefore feel that further studies are warranted before this procedure can be recommended in the treatment of cariously exposed primary teeth. Mack et al. [30] stated that this conclusion reached by Fishman et al. [24] could have been inappropriate as their study was designed to compare two different pulpotomy medicaments and not the success of two different pulpotomy techniques.

The advantages of electrosurgery [20] can be summed up as follows:

- It can be performed quickly (reduced operative time).
- No topical materials or agents are used which could produce undesirable effects locally or systemically.

The disadvantages of electrosurgery [6, 20] include:

- It has been shown to induce pathologic root resorption and periapical and/ or furcal pathology. Fibrosis, necrosis, oedema and acute and chronic inflammation have also been noted.
- This procedure is more technique-sensitive.

As mentioned above, electrosurgery seems to paint a bleak histologic picture even though clinical results compare favourably with those of formocresol. Ranly [6] stated that the only advantage of electrosurgery over the formocresol pulpotomy was the fact that the use of chemical agents was avoided. Pathological findings could be due to the application of different bases over the amputated pulp. Variations in electrical currents and techniques of pulp amputation could also be a reason for the conflicting results, making them difficult to interpret [6, 20, 24].

Ranly and Garcia-Godoy [75] state that the " argument in favour of electrosurgery is convenience and not the preservation of vital tissue".

1.1.3. Lasers

It has been suggested that lasers might have a more beneficial effect on pulpal tissue than electrosurgery. Ranly [6] speculates that laser irradiation could create a superficial zone of coagulation necrosis that is compatible with the underlying tissue, and that this could separate the pulp from the irritating effects of the subbase.

A study conducted on mongrel dogs evaluated the effect of irradiation with carbon dioxide laser on dental pulp tissue [88]. The treated teeth were subjected to histological evaluation immediately after irradiation. The amount of energy emitted per unit area and the wavelength of the laser beam determines the width of the coagulated layer. This study revealed that more coagulation necrosis occurs in pulp tissue when compared with skin and mucosa. This is explained by the fact that the hard tissue surrounding the pulp chamber restricts diffusion of the laser beams, increasing heat production. Using a defocused beam was found to be the most effective method for performing pulpotomy procedures. The length of laser irradiation seemed to have a greater effect on pulpal injury than the energy output of the laser beam.

Elliot et al. [82] conducted a study in which the carbon dioxide laser was compared with formocresol as an agent in pulpotomies of primary teeth. Pulpotomies were performed on healthy primary canines that were destined for orthodontic extraction. Comparable results were obtained in this study. But, as is the case with electrosurgical pulpotomies, the main reason for implementing this treatment is the avoidance of the toxic effects of formocresol.

Carbon dioxide lasers have advantages over other lasers in that:

- they allow incisions to be made without the occurrence of bleeding
- only a thin layer of necrotic material covers the irradiated tissue
- there is no mechanical contact with the tissue, ensuring no tissue damage
- aseptic conditions are guaranteed

These positive factors could possibly increase the success of vital pulpotomy procedures [88].

Shoji et al. [88] stated that "if we could determine the optimal irradiation procedure, we would be able to sever the coronal pulp with minimal damage to the remaining radicular pulp. The carbon dioxide laser has the potential to attain this objective".

More research is needed to determine the effectiveness of lasers in pulp therapy and also the type of laser that would be best suited to this procedure.

1.2. PRESERVATION

1.2.1. Gluteraldehyde

In the 1980's, gluteraldehyde was suggested as a possible replacement for formocresol and at one stage, it was a popular alternative in paediatric pulp therapy [3, 4, 19, 25, 28, 32, 84]. Gluteraldehyde is a disinfectant with effective sterilizing properties, which is also used as a fixative. Thus, its effect is thought to be similar to that of formocresol [32]. It was shown to have better fixative properties than formocresol and is apparently also less toxic [18, 25, 27, 32]. Due to its larger molecular size and its ability to form cross-linkages more rapidly, gluteraldehyde does not diffuse as readily to the periapical tissues [25, 27, 66, 71, 74, 84]. This could also be the reason for its reduced antigenicity [6, 74].

This would seem to indicate that gluteraldehyde is more biologically acceptable than formocresol for pulpotomies in primary teeth [3, 18, 25, 22]. However, there is disparity in this regard. Based on results from their study, Lekka et al. [71] stated categorically that diffusion of gluteraldehyde from teeth was much less than that of formaldehyde. They therefore recommended gluteraldehyde as an acceptable alternative to formocresol.

On the other hand, research done by Feigal et al. [22] concluded that gluteraldehyde was not as safe as it was originally thought to be. Feigal [22] stated that "both formocresol and gluteraldehyde are distributed systemically from pulpotomy sites in small but measurable amounts". They also examined the cytotoxicity and mutagenicity of both these agents and though research has produced conflicting results, the conclusion was drawn that ultimately, the mutagenic potential of gluteraldehyde was not markedly less than formaldehyde, which is a component of formocresol. Their studies showed that gluteraldehyde was only slightly less toxic than formaldehyde. However, the fact that a higher gluteraldehyde concentration and longer exposure time was required to achieve the same degree of fixation as formocresol, meant that any advantage associated with a slightly lower toxicity of gluteraldehyde would be lost. Feigal et al. stated that there therefore seems to be a "limited rationale for considering gluteraldehyde as an alternative

to formocresol" as there is limited clinical evidence to indicate that there is a higher pulpotomy success rate with gluteraldehyde [18, 22].

Waterhouse [3] also showed that the histological effect of gluteraldehyde was similar to that of formocresol. This was contradicted by Kopel et al. [74] who found that the histological picture of gluteraldehyde was different to that of formocresol. As was the case with formocresol, gluteraldehyde did not exhibit an inflammatory layer that decreases in intensity towards the apical region. Normal pulp tissue was found under the fixed region. Very little underlying inflammation was evident [74, 6]. Based on these histological findings and also their clinical observations, Kopel et al. are of the opinion that 2% aqueous gluteraldehyde "is more biologically acceptable for pulpotomies in primary teeth than formocresol". This is in agreement with ś-Gravenmade [25], who was the first to suggest gluteraldehyde as an alternative to formocresol.

Studies which have been done to determine the efficacy of gluteraldehyde have shown conflicting results, with success rates ranging from 82% to 98% [1, 3, 22, 39]. Other studies [32] were not as promising. When compared with calcium hydroxide, gluteraldehyde showed better success as a pulpotomy agent, but overall success rates were not as high as those reported for the formocresol pulpotomy [3, 18, 27].

Garcia-Godoy [39] evaluated gluteraldehyde pulpotomies where a 2% unbuffered gluteraldehyde solution was applied to the pulpal stumps for 1 to 3 minutes. A zinc oxide-eugenol base was then placed. A 98% clinical and radiographical success rate was achieved in this study, proving that this technique was effective. The author concluded that the 1 to 3 minute application proved to be just as effective as the standard 5-minute application of gluteraldehyde.

Fuks et al. [32] studied the efficacy of a 2% buffered gluteraldehyde solution as a pulp dressing in cariously exposed primary molars. After amputation of the coronal pulp, a cotton pellet soaked in gluteraldehyde was applied to the pulpal stumps for 5 minutes. The cotton pellet was removed and a zinc oxide-eugenol base was placed. Results

showed evidence of internal resorption, periapical and interradicular pathology and interradicular radiolucencies in various teeth. Pulp canal obliteration was also observed but these cases were not regarded as failures. Because of the high failure rate observed in this study, the authors do not recommend a 2% buffered gluteraldehyde solution as a substitute for formocresol.

Ranly and Garcia-Godoy [76] speculated that the reason for the high failure rate reported in Fuks' study could be due to the fact that the gluteraldehyde-soaked pellet was squeezed dry as opposed to just being blotted. The drier the cotton pellet, the less fixing agent it contains, resulting in unfixed pulpal tissue coming into direct contact with the zinc oxide-eugenol base, known for its ability to elicit an inflammatory response.

As mentioned previously in the section on formocresol, on the whole, pulpotomised teeth have been shown to exfoliate faster than their healthy antimeres [17, 32, 34]. Teeth where gluteraldehyde pulpotomies were performed showed slower exfoliation rates compared with formocresol. This could possibly be due to the limited fixative properties of gluteraldehyde [32] .

Controversy seems to exist regarding gluteraldehyde. The effects of gluteraldehyde have not been studied as extensively as those of formocresol. There have been no recent publications and it has fallen into disfavour amongst dental professionals. Research is still needed in terms of the ideal concentration and application time of gluteraldehyde as well as the type of base that would be best suited to this type of pulpotomy. Davis et al. [84] also suggested that the optimal pH of the solution be determined as an alkaline pH is more bactericidal. Stronger evidence is also required regarding the efficacy and safety of gluteraldehyde before it becomes a replacement for formocresol. Gluteraldehyde should be subjected to the same scrutiny as formocresol where factors such as systemic distribution from pulpotomy sites, cytotoxicity and mutagenicity are concerned. It will have to be proven that gluteraldehyde is a safer alternative with clinical success rates equivalent to those of formocresol before it can be accepted as an alternative medicament [18, 22].

1.2.2. Ferric Sulfate

Ferric sulfate (previously known as Monsel's solution) is a non-aldehyde, haemostatic compound which is commonly used (in conjunction with gingival retraction cord) to obtain haemostasis prior to impression taking for crown and bridge work. [6, 9,15, 27, 61, 86]. It has also been accepted as a soft tissue haemostatic in dermatology [61]. Today, ferric sulfate is thought to be more 'tissue-friendly' and less toxic than haemostatic agents such as aluminium chloride. It is available as a 15.5% solution [15, 27] and is also known commercially as Astringedent.

Ferric sulfate is currently enjoying a lot of attention in the quest for alternative pulpotomy agents, without the toxic side effects of formocresol [15]. According to a survey done by Primosch et al. [23], evidence suggests increased support for this technique. It was originally developed as a haemostatic agent for calcium hydroxide pulpotomies. Ferric sulfate is not a fixative agent, nor is it bactericidal and it does not mummify the pulp like formocresol does [59]. Because of this fact, the type of base placed in direct contact with the pulp may play an important role when it comes to healing. On the contrary, the fixative properties of formocresol make the pulp tissue less susceptible to the effects of the base that is placed over it.

Ferric sulfate was proposed as a pulpotomy agent on the basis of its action [9, 14]. The mechanism of action is still not fully understood but it is thought that ferric sulfate reacts chemically with blood proteins, causing agglutination. A metal ion-protein complex is then formed at the surface of the pulpal stump. The membrane of this complex seals the cut blood vessels mechanically, producing haemostasis and preventing blood clot formation [7, 14, 15, 28, 61]. Haemostasis is achieved by applying a pellet soaked with ferric sulfate onto the pulpal stumps with continuous friction for 10 to15 seconds and then rinsing it [7, 14, 15]. Ranly [6] proposed that the plug which is formed also acts as a (passive) barrier between the pulp and potential irritating components of the subbase which is placed over it [6, 14].

The use of Astringedent to control bleeding and produce haemostasis could increase the chances of success of calcium hydroxide pulpotomies, as failure has often been ascribed to the presence of a blood clot between the pulp tissue and the medicament [8]. However, even with stringent measures taken to avoid clotting, internal resorption of primary teeth was still observed [4, 9].

When used as a pulpotomy agent, the toxic potential of ferric sulfate is questionable. Its effect on osseous healing was tested when it was used to control haemorrhage during surgery. It was found that ferric sulfate can damage bone and delay healing when used in maximum amounts and left in situ [61]. In an animal study performed on swine, Shaw et al. [87] demonstrated that application of the commercial preparation of ferric sulfate (Astringedent) to the gingival sulcus produced changes in connective tissue within 30 minutes of application. However, the damage was reversible and the tissue returned to normal within two weeks.

Whether these facts would have any bearing on its use as a haemostatic agent in pulp therapy is not known. Larson (1988) and Epstein (1989), as quoted by Lemon et al. [61] stated that: "Ferric sulfate solution is known to be cytotoxic and to cause tissue necrosis, but systemic absorption of ferric sulfate is unlikely since the coagulum isolates it from the vascular supply". This fact is a plus for ferric sulfate. However, more research definitely needs to be done in this regard.

The clinical technique employed for ferric sulfate pulpotomies is similar to zinc oxide-eugenol pulpotomies, except that ferric sulfate is applied to the pulpal stumps prior to the placement of a zinc oxide-eugenol subbase [7, 15].

Clinical studies

The ferric sulfate pulpotomy has demonstrated comparable outcomes to that of the formocresol pulpotomy [7, 9, 14, 15]. Ibricevic and Al-Jame [14] demonstrated clinical and radiographic success rates of 97.2% with both ferric sulfate and full strength

formocresol. They concluded that ferric sulfate compared favourably with formocresol as a pulpotomy medicament in primary teeth.

A similar study by Fei et al. [9], which also compared ferric sulfate and formocresol (1:5 dilution), showed a slightly higher clinical and radiographic success rate for ferric sulfate pulpotomies after a one year recall period, even though there were no significant differences between the two groups at the 3 and 6 monthly recall intervals. However, the small sample size (29 teeth in the ferric sulfate group and 27 teeth in the formocresol group) should be taken into account as one tooth could make a huge difference to the results. Results of this study suggest that ferric sulfate could be recommended as a successful pulpotomy medicament in primary teeth.

A long-term human study on carious primary teeth by Fuks et al. [7] found comparable success rates between dilute (20%) formocresol and ferric sulfate pulpotomies. Success rates were 92.7% and 84% respectively. They found no differences in the resorption rates between the pulpotomized teeth and their healthy antimeres. The permanent successors also exhibited no developmental defects. Smith et al. [15] also noted the absence of defects on permanent teeth where ferric sulfate pulpotomies were performed on their predecessors [7, 15].

In a retrospective review of ferric sulfate pulpotomies where zinc oxide-eugenol subbases were placed, Smith et al. [15] reported a success rate comparable with that of the 1 in 5 dilution, 5-minute formocresol pulpotomy. The overall success rate of ferric sulfate pulpotomies was however found to be lower than those in previous literature studies [9, 14]. Radiographically, calcific metamorphosis and internal resorption were noted. It was speculated that this could be due to pulpal inflammation caused by the irritating effects of the zinc oxide-eugenol subbase. Observation of these radiographic failures showed that areas of resorption tended to recalcify when left undisturbed for a couple of months. Studies by Magnusson [21, 37] (involving pulpotomies with zinc oxide-eugenol) demonstrated similar findings.

Burnett and Walker [28] compared the success rates of ferric sulfate pulpotomies with formocresol pulpotomies in a community in Arizona over a period that spanned about 15 years (from 1987). A search of the records revealed that most dentists used either ferric sulfate or formocresol. However, there were a small percentage of dentists who used a combination of both techniques. The latter method was favoured in cases where the tooth had a questionable prognosis. Ferric sulfate was first applied in order to achieve haemostasis, after which a dilute (20%) formocresol solution was applied to the pulpal stumps for 5 minutes. The rationale behind this was that some dentists thought the ferric sulfate would constrict the blood vessels, thereby limiting the uptake of formocresol into the bloodstream and the bactericidal characteristics of formocresol would be an added benefit. Overall long-term results revealed that formocresol pulpotomies were more successful than the ferric sulfate pulpotomies and the combination pulpotomies showed the worst prognosis. A possible reason for this high failure rate could be the fact that the latter procedure was generally reserved for those teeth that were diagnosed as having the poorer prognosis.

A recent study by Casas et al. [90], compared the ferric sulfate pulpotomy to root canal therapy in cariously exposed, vital primary molars after a two-year period. The success rate for the ferric sulfate pulpotomy in this study was lower than that reported in previous studies. Teeth that received root canal treatment demonstrated a more favourable outcome after two years, with a lower incidence of periapical radiolucencies and widened periodontal ligament space. The clinical examination revealed a 96% and 98% success rate for the ferric sulfate and root canal treated teeth respectively but radiographically, only 61% of ferric sulfate molars yielded favourable outcomes as opposed to 91% in the root canal treated teeth. The authors concluded that both the ferric sulfate pulpotomy procedure and root canal therapy are acceptable alternatives to pulpotomy procedures where aldehydes or other potentially toxic medicaments are used in the treatment of primary molars with carious exposures.

Histological studies

On the whole, histological results were less favourable than clinical results. In another study conducted by Fuks and colleagues [86], the pulpal response to ferric sulfate and formocresol in primary baboon teeth was evaluated. Both agents produced similar results after eight weeks. Approximately 60% of teeth in both groups presented with normal pulps. The authors therefore suggested that further clinical trials with longer observation periods be conducted before ferric sulfate could be recommended as a pulpotomy agent. One should also bear in mind that even though baboons are often used in pulpotomy studies due to their similarity with humans, it is perhaps not the most ideal model.

Cotes et al. [85] conducted an animal study (using rats) to compare the histological pictures obtained after formocresol and ferric sulfate pulpotomies were performed. The effect of two different base materials, namely, polycarboxylate cement (Durelon) and zinc oxide-eugenol was also investigated. It was found that ferric sulfate did not exhibit a reduced inflammatory response when compared with that elicited by formocresol. The use of polycarboxylate cement also did not improve the pulpal response as it provided a poor marginal seal, with resultant microleakage. The formocresol group where a zinc oxide-eugenol lining was placed, demonstrated the least inflammation, possibly due to the fixative nature of formocresol.

Landau and Johnsen [59] observed only slight inflammatory changes in the pulps of Aephipos monkeys, 7 days after the ferric sulfate pulpotomy procedure was performed. When compared with teeth in which calcium hydroxide was used as a pulpotomy agent, secondary dentine and partial bridge formation was more often observed in teeth in which ferric sulfate pulpotomies were performed. The authors therefore felt that ferric sulfate was "a promising medicament for teeth indicated for pulpotomies".

Ibricevic and Al-Jame [14] also recommend ferric sulfate as a satisfactory substitute for formocresol as its effect on primary molars is similar to that of formocresol, without the toxic side effects. Another advantage of ferric sulfate is that it is easy to use and its

application time is only 15 seconds as opposed to the 5-minute formocresol application. Yet, their success rates are the same [9, 14].

Despite the promising findings, this is a relatively new technique and it has been suggested that further research be done to establish the long-term effects of ferric sulfate as a pulpotomy agent. Clinical trials should also be done to determine the pulpal response to ferric sulfate as well as its potential effects on the permanent successors in humans, as animal models are often not ideal. Ranly [6] states that it still has to be proven that "heavy metal coagulation with ferric sulfate is somehow able to subdue the pulp when a high pH-coagulation of calcium hydroxide cannot".

1.2.3. Zinc oxide-eugenol

Zinc oxide-eugenol has been used in dentistry for many years as a temporary filling material and as a permanent lining or base. Kalzinol is an example of a zinc oxide-eugenol cement. Zinc oxide-eugenol was the first agent to be used for preservation and is one of the most widely used base materials in pulpotomies today. It is reported to have bactericidal properties [10, 64, 69, 80, 85].

Conflicting opinions exist about the effect of zinc oxide-eugenol on pulpal tissue. On the one hand, it has been considered to be one of the best pulpotomy dressings and was first introduced as a therapeutic, sedative dressing to be placed over formocresol-treated pulps [10, 27, 34, 69]. It has however been shown that the eugenol component of zinc oxide-eugenol also possesses destructive properties especially when placed directly onto vital pulp tissue, as it causes a moderate to severe inflammatory response with resulting chronic inflammation and necrosis [6, 15, 21, 64, 38, 80].

Zinc oxide-eugenol was found to have therapeutic effects when placed over intact carious dentine, showing signs of suppressed inflammation and increased local blood flow. A toxic effect was however exhibited when it was brought into contact with soft tissue [69].

Kalzinol was tested in germ-free rat molar teeth and its effect on exposed pulp tissue was observed [64]. Localized chronic pulpal inflammation and necrosis (without calcific repair) was evident where the Kalzinol came into direct contact with the pulp, but in instances where dentine particles separated the Kalzinol from the pulp, calcific repair was noted with the absence of inflammation and necrosis.

Preparations of zinc oxide-eugenol have been shown to produce an acute or chronic inflammatory response with associated degeneration of odontoblasts and it has therefore been suggested that this base only be placed after most of the inflammation has subsided [10]. Because of these findings, its "therapeutic" nature as well as its suitability as a dressing in primary tooth pulpotomies has been increasingly questioned [38, 50, 85].

The use of zinc oxide-eugenol as a base in pulpotomies

Croll and Killian [75] claim to have performed successful pulpotomies using only pure zinc oxide-eugenol for more than a decade. Unfortunately, these claims were not supported by statistics.

Chien et al. [27] compared pulpotomies where a thick mix of zinc oxide-eugenol paste was placed into the pulp chamber after controlling bleeding with only the use of sterile cotton pellets, with those where haemostasis was achieved with the help of ferric sulfate. Both methods yielded a 100% success rate after a 3-month follow-up period. These results corroborated their theory that there was no need for the use of fixatives in pulpotomies due to the good tissue response noted in this instance. Zinc oxide-eugenol was not only cheaper than ferric sulfate, but proved to be equally effective as well. Through this study, the authors concluded that both 15.5% ferric sulfate and zinc oxide-eugenol could be regarded as good alternative medicaments to formocresol and gluteraldehyde. However, it should be borne in mind that this was a short-term study.

Magnussen [21] showed that zinc oxide-eugenol causes inflammation and internal resorption when placed directly over the amputated pulp. It therefore seems to be an unsuitable dressing for pulpotomised primary molars. Studies by Smith et al. [15], Fuks et al. [7] and other investigations where zinc oxide-eugenol was used as a subbase or pulpotomy agent, also showed evidence of internal resorption and calcific metamorphosis. This seemed to be a common finding [50]. This could also be the reason why internal resorption is sometimes observed in ferric sulfate pulpotomies where a zinc oxide-eugenol base has been placed over the amputated pulp [7, 15, 64].

Garcia- Godoy [38] conducted a study of 5-minute formocresol pulpotomies where a pure zinc oxide-eugenol base was compared with a polycarboxylate cement base. The zinc oxide-eugenol group elicited a moderate to severe inflammatory response while the polycarboxylate cement base showed only slight inflammation in the amputation site. In

instances where pulps were not treated with formocresol prior to the placement of a zinc oxide-eugenol base, the inflammatory response was found to be more severe. Formocresol fixes the pulp tissue, making it less susceptible to the irritating effects of the base. The conclusion was therefore reached that in formocresol pulpotomies, most of the inflammation can be attributed to the eugenol component of the zinc oxide-eugenol base. In the light of these findings, Garcia Godoy stated that: "zinc oxide-eugenol should be critically evaluated as a dressing for formocresol pulpotomies".

In pulpotomies utilising mineral trioxide aggregate (MTA), the zinc oxide-eugenol base is separated from the pulp by a layer of MTA, thus preventing the irritating effect of the zinc oxide-eugenol on the pulp. This could be a possible explanation why teeth treated with MTA as pulpotomy agent showed no signs of internal resorption [16].

Comparison between zinc oxide-eugenol and calcium hydroxide

A high frequency of internal resorption has also been observed in cases where calcium hydroxide has been used as a pulpotomy agent. When Magnussen [21] compared the frequency and extent of internal root resorption between teeth treated with calcium hydroxide and those where a layer of zinc oxide-eugenol was placed directly over the amputated pulp as a wound dressing, he found the severity of resorption under the zinc oxide-eugenol bases to be more serious. It also appeared to have a greater risk of associated periradicular spread. This contradicted previous suggestions that the degree of internal resorption was more severe when calcium hydroxide bases were used.

Alternative base materials

Because of the inflammatory pulpal response which is routinely elicited by zinc oxide-eugenol bases in pulpotomies, alternative base materials have been proposed. Researchers started incorporating corticosteroids and antibiotics into pulpal dressings in an effort to reduce inflammation and relieve pain [60].

Ranly [6] reported that even though there was a reduction in inflammation and internal resorption, a study by Hansen et al. (1971) showed a success rate of only 79% when corticosteroids were incorporated into pulpal dressing when compared with zinc oxide-eugenol.

After calcium hydroxide pulpotomies were performed, Heilig et al. [5] used a temporary filling material, Cavit, instead of a zinc oxide-eugenol base and achieved favourable results.

The advantages of Cavit above other materials include the following:

- it does not contain eugenol
- it has excellent sealing properties and
- its consistency and handling properties permit a gentle placement technique.

Even though there is disparity as to the effect of zinc oxide-eugenol on pulpal tissue, the negative reports outweigh the positive. It therefore seems as though its use in primary tooth pulpotomies could eventually be phased out in favour of non-eugenol containing bases which are kinder to the pulp. By eliminating the irritating effect of the zinc oxide-eugenol base, success rates of these procedures are likely to be better.

1.3. REGENERATION

1.3.1. Calcium Hydroxide

Calcium hydroxide has been used in dentistry for many years, mainly because of its antibacterial properties (which is probably due to its high pH) [1, 55, 57]. It is known for its capacity to induce the regeneration of reparative dentine and stimulate tissue repair (as has been demonstrated in the case of direct pulp capping procedures). It is a well-known fact that calcium hydroxide promotes pulpal healing and calcific bridge formation, especially in permanent teeth [4, 40, 42, 44, 47, 77].

The mutagenicity and carcinogenicity of calcium hydroxide is questionable as conflicting opinions exist in the literature. Pure calcium hydroxide preparations have been shown to destroy tissue when placed in direct contact with the pulp [48]. Alacam et al. (1993) as quoted by Waterhouse [3], found that calcium hydroxide powder had a destructive effect on cell cultures. Dunham et al. [83] demonstrated that repeatedly treating hamster cheek pouches (which have a similar structure to the lining of the oral cavity) with calcium hydroxide, resulted in cellular atypia in 11% of cases but none of the cases showed neoplastic changes. These effects of calcium hydroxide need to be investigated further.

The purpose of using calcium hydroxide in pulpotomies is to try and stimulate the pulp to produce dentine on the surface of the wound or exposure site. After studying the effect of calcium hydroxide on pulpal tissue, Zander [51] noted the formation of an "amorphous layer of calcium on the cut surface of the pulp" which "formed the matrix for the regular dentine formation". This resulted in the formation of a bridge over the exposed pulp tissue. Because calcium hydroxide is used routinely for pulpotomy procedures of the permanent dentition and because it is less harsh on pulp tissue than formocresol, it was thought that it could turn out to be the material of choice for pulpotomies in primary teeth [2, 18].

The use of calcium hydroxide in the primary dentition

Waterhouse et al. [1] suggested that calcium hydroxide in its pure form was "a clinically acceptable alternative to the 1:5 dilution of Buckley's formocresol". Other articles have also suggested calcium hydroxide as a possible substitute for formocresol [3, 18, 28].

Procedures such as direct pulp capping and partial pulpotomies with calcium hydroxide which have proven to be effective in the permanent dentition, have not been as successful in primary teeth. Where frequency of healing (clinically and histologically) is high in the permanent dentition, this is not the case in primary teeth. Consequently, the failure rate of these procedures in the primary dentition is very high [37, 40, 42, 47]. Where calcium hydroxide stimulates dentinal bridge formation on the one hand, it has also been proven to have destructive effects on the other [2, 48]. Magnusson's study [53] showed that more often than not, this delicate balance is tilted towards the destructive pathway.

Numerous studies have been done where calcium hydroxide has been used as an agent in vital pulpotomies of primary teeth. The success rates varied considerably from 22% to 75%, to nearly 100% [2, 3, 6, 24]. However, radiographic successes seldom exceeded 60% [8, 53]. Although there was evidence of calcific bridge formation and complete healing of the pulp in certain cases, other cases showed evidence of chronic pulpal inflammation, fistulae formation and internal resorption— an unwanted outcome of vital pulp treatment with calcium hydroxide [3, 6, 10, 37, 39, 56]. The cause of internal resorption in calcium hydroxide pulpotomies is still not clear. A thesis by Brown in 1947 (as quoted by Via [42]) indicated that " 68.9% of the total teeth on which treatment had failed showed internal resorption". Because of these documented side effects, the popularity of calcium hydroxide as a pulpotomy agent in primary teeth has waned.

Internal resorption is a sign of chronic inflammation of the residual pulp and is the most common cause of failure of calcium hydroxide pulpotomies, especially in the primary dentition [28, 37, 40 42, 47, 53]. This chronic inflammation is either present before treatment or it can be induced by the treatment [2].

Internal resorption was particularly evident in the study conducted by Magnusson [53]. He demonstrated that this phenomenon was radiologically detectable in 81% of all primary molars that he examined, even as early as six months after the procedure. The degree of resorption varied considerably.

Histological findings were also discouraging. Healing (defined as the formation of a complete dentine bridge and absence of inflammation in the residual pulp) took place in only 12% of cases. Other cases showed varying degrees of inflammation. Abscess formation often accompanied the accumulation of inflammatory cells in the coronal part of the residual pulp. Absence of radiographic changes was demonstrated in only one fifth of all the cases that he studied [53].

In the above-mentioned study [53], the initial exposure was capped with calcium hydroxide and the actual pulpotomy procedure (where the coronal portion of the pulp was removed and re-covered with calcium hydroxide) was performed a few days later. It is unclear whether this delay in treatment could have affected the outcome and further studies will have to be done to determine this.

A clinical and radiographic success rate of 67% was obtained after one year in a study done by Schröder [8] where calcium hydroxide pulpotomies were performed, followed by the placement of a zinc oxide-eugenol base. This figure dropped to approximately 59% after two years. Schröder found that it was difficult to avoid the formation of a blood clot on the wound surface but extra diligence in this regard could result in greater success. This could account for the lower percentage (21%, counted per root canal) of internal resorption seen in this study as opposed to previous studies. In most cases, internal resorption occurred within six months of treatment.

A definite link has been established between the inflammatory response elicited and the formation of a hard tissue barrier [2]. Schröder's study [2] indicated that chronic inflammation became less in an apical direction. Bridging occurred more frequently when the inflammatory response was slight and hard tissue formation near the amputation site

showed bone-like characteristics. Cvek et al. [73] agree that barrier formation is stimulated in the presence of any low-grade irritation, irrespective of the capping agent used. Chronic inflammation and necrosis resulted when materials were ineffective in promoting wound healing [60].

There are many theories as to why calcium hydroxide pulpotomies fail [2, 3, 7, 8]. Schröder et al. [2] concluded that blood clot formation between the amputation site and the calcium hydroxide was one of the major reasons for the failure of calcium hydroxide pulpotomies. Their studies showed evidence of a "structureless eosinophilic mass" above the amputation site, believed to be an extra-pulpal blood clot. It is thought that this blood clot acts as a bacterial substrate, attracting micro-organisms to the area and exacerbating infection [2, 60]. The blood clot also prevents the calcium hydroxide from coming into contact with the residual pulp and interferes with healing, resulting in chronic inflammation of the residual pulp. This in turn leads to internal dentine resorption. Partial and complete hard tissue bridge formation was noted in some specimens and this was believed to be due to the fact that the calcium hydroxide came into contact with the pulp tissue. Thus, the conclusion was reached that preventing or minimizing the formation of a blood clot might reduce the chances for chronic inflammation and internal resorption in pulpotomies with calcium hydroxide and improve the chances for clinical success [24, 29, 45].

Schröder substantiated this theory with another study [45]. When a blood clot was intentionally allowed to form on the wound surface before the application of calcium hydroxide, healing was impaired even though conditions for healing were ideal. The pulps of the teeth used in this study were healthy and pulp amputation was performed under aseptic conditions with the minimum amount of trauma. Only 22% of cases in this study showed signs of healing (defined as the formation of a hard tissue barrier without the infiltration of inflammatory cells in the residual pulp) and in 72% of cases, healing was poor or non-existent. It was therefore proven that the presence of a clot on the wound surface definitely impaired healing under otherwise optimal conditions. Similar conclusions were reached in an animal study by Masterton [33].

Adequately controlling pulpal haemorrhage (before placement of the medicament) could prevent clot formation and possibly ensure good contact between the medicament and the pulpal tissue [1, 2, 29]. Haemostatic agents such as aluminium chloride (in earlier studies) and ferric sulfate (more recently) were introduced. Heilig et al. [5] studied cases where aluminium chloride was used as a haemostatic agent prior to the application of calcium hydroxide. Aluminium chloride produced more rapid haemostasis when compared with the control group where sterile water was used to obtain haemostasis. After nine months, the aluminium chloride group had a higher success rate. Radiographic findings were also more favourable in this group. Although these calcium hydroxide pulpotomies demonstrated favourable results, it should be remembered that the sample size was small (a total of 17 primary molars) and that this was a relatively short-term study with a maximum follow-up period of nine months.

Waterhouse et al. [1, 78] found that the time taken to obtain haemostasis did not influence the outcome of the procedure. Even if bleeding occurred after the placement of the medicament, success rates were not affected. When compared with formocresol, fewer cases of post-placement bleeding were reported in instances where pure calcium hydroxide powder was used. This is explained by the fact that the powder soaked up the blood.

Non-pharmacological techniques such as electrosurgery have also been tried as a means of controlling pulpal bleeding [20, 24, 29]. Sasaki et al. [29] documented a study in which electrocoagulation was used to obtain haemostasis in calcium hydroxide pulpotomies where pulpal haemostasis could not be obtained solely with the use of moist cotton pellets and applied pressure. After haemostasis was obtained (either with or without the aid of electrocoagulation), the pulp was covered with calcium hydroxide. Results indicated no significant differences in the success rates between the teeth that received electrocoagulation treatment and those that did not.

Comparison of different preparations of calcium hydroxide

Calxyl was one of the first calcium hydroxide preparations to be used in earlier studies [32, 33, 47, 48, 51]. Different formulations of calcium hydroxide used in pulpotomies have shown varying tissue reactions and results [1, 3, 4, 5]. This could be due to factors such as differences in pH, the amounts of calcium available and the rates at which hydroxyl and calcium ions are released [60]. The wide range of preparations in use and the different techniques employed, makes it difficult to compare different studies utilizing calcium hydroxide.

Both Schröder [60] and Ranly [6] suggested that necrosis caused by the high pH of calcium hydroxide (pH =12) leads to slight irritation of the dental pulp. This in turn stimulates the pulp cells to "defense and repair" or in other words, hard tissue formation. However, it is thought that hard-setting calcium hydroxide preparations such as Dycal (which has been one of the most popular pulp capping agents for many years) may stimulate reparative dentine more directly because of its lower pH, thereby avoiding major tissue damage [48, 60]. Its reduced alkalinity tends to have a more favourable effect on the pulp [40, 48, 60]. Stanley [48] verified that the newer calcium hydroxide preparations caused less tissue damage. In more recent studies [5, 6], hard-setting calcium hydroxide showed a better success rate than the inorganic compound. Heilig et al. [5] demonstrated that the commercial calcium hydroxide preparation, Life, was a successful pulpotomy agent in primary teeth.

A study by Turner et al. [40] corroborated Stanley's results. They evaluated the effect of different calcium hydroxide preparations on the exposed dental pulp in primary canines. It should be stressed that the exposures were mechanically caused in teeth with healthy pulps that were destined for orthodontic extraction. A standard calcium hydroxide-saline paste was compared with three commercially available preparations, namely, Dycal, Life and Nu-Cap. Overall short and long-term results indicated that inflammation was more pronounced in teeth where the standard calcium hydroxide-saline paste was utilized. This base also showed a wide zone of mummification, and bridge formation was evident in the

deeper lying areas. The commercial preparations on the other hand exhibited less inflammation, limited mummification and bridge formation closer to the amputation site. Increased inflammation (for all preparations) was however observed in instances where dentinal chips were impacted or where the medicament was incorporated deep in the pulpal tissues during initial preparation of the teeth. These chips apparently prevented good bridge formation and inflammatory cells accumulated in this area, resulting in pulpal necrosis and continued pulpal inflammation [40, 48].

This is a contentious issue. Stanley [48] stated that the newer calcium hydroxide preparations stimulated dentinal bridge formation irrespective of the presence of these dentinal chips. According to him, reparative dentine formation is initiated around these chips and they eventually join together to form a bridge on the pulp surface.

Turner et al. [40] reported no internal resorption in their study. The authors feel that this could be due to the fact that it was a relatively short-term study and it should be borne in mind that this study was not conducted on cariously exposed primary teeth. The conclusion was reached that non-inflamed pulps responded to all preparations of calcium hydroxide by the formation of reparative dentine. The authors therefore feel that hard-setting, calcium hydroxide preparations could be used in primary teeth for procedures such as direct pulp capping and pulpotomies where the remaining pulp tissue is not inflamed. However, more research still needs to be done in this regard.

Hard-setting preparations also have a high early compressive strength which is an added advantage, especially where the embolization of calcium hydroxide particles is concerned [4, 5, 6]. It is speculated that the high incidence of internal resorption in calcium hydroxide pulpotomies could be due to these particles of calcium hydroxide breaking off and then being transported via dilated blood vessels in the exposure site. These particles can then get lodged, causing coagulation necrosis and inflammation in the radicular pulp [5, 48]. It is thought that hard-setting preparations could reduce this phenomenon [4, 5, 6].

Pure calcium hydroxide preparations mixed with saline and ordinary tap water respectively, showed comparable results to the hard-setting variety [57]. It is thought that the high pH of calcium hydroxide could possibly destroy the bacteria present in tap water.

The use of different base materials in calcium hydroxide pulpotomies

A study done by Fishman et al. [24] compared a zinc oxide-eugenol base with a calcium hydroxide base placed after electrofulguration pulpotomies were performed. There were no notable differences in success between the two bases.

Gruythuysen and Weerheijm [57] studied calcium hydroxide pulpotomies (in primary molars) utilizing a light-cured glass ionomer lining instead of the regular zinc oxide-eugenol base, over a two-year period. Haemorrhage control was achieved by means of a damp cotton pellet. A layer of calcium hydroxide was then placed, followed by a Vitrebond lining and a permanent restoration. This study yielded good results with a clinical and radiographic success rates of 87.7% after one year and 80.4% at the two-year follow-up. Teeth that received a stainless steel crown showed a higher success rate as opposed to those with an amalgam restoration. Despite these impressive statistics, the authors concede that there were some cases that presented with "severe abscesses".

Because the floor of the pulp chamber has many accessory canals, it is prone to microleakage in the furcation area. The authors therefore recommend that calcium hydroxide only be placed on the wound surface and not the entire floor of the pulp chamber. This would possibly result in greater success [57]. However, this technique needs to be investigated further.

Comparison between calcium hydroxide and formocresol pulpotomies

On the whole, calcium hydroxide pulpotomies have not compared favourably with those of formocresol. Its success in primary tooth pulpotomies in some instances has been found to be nearly half those of formocresol [28, 29]. There have however been studies such as those by Waterhouse et al. [1, 78] which showed comparable success rates between pulpotomies where a 1:5 dilution of formocresol was used as opposed to pure calcium hydroxide in powder form. It should be noted that more failures were recorded in the calcium hydroxide group but it was deemed to be statistically insignificant. When combined with strict selection criteria, this preparation of calcium hydroxide was judged to be an acceptable alternative to formocresol as the powder ensured good contact with the pulp tissue. The authors do however encourage further research to substantiate their findings before calcium hydroxide powder is recommended as a pulpotomy agent in primary teeth.

Doyle et al. [47] compared the effect of these two pulpotomy agents (calcium hydroxide and formocresol) on healthy, uninfected dental pulps. Zinc oxide-eugenol was used as a subbase. The calcium hydroxide pulpotomies showed a 64% radiographical success rate as opposed to 93% for the formocresol group. Dentine bridge formation occurred in only half of the calcium hydroxide pulpotomies and those which failed exhibited signs of inflammation and internal dentine resorption. The formocresol pulpotomy was judged to be the superior of the two techniques.

Factors influencing the success of calcium hydroxide pulpotomies

It has been suggested in numerous articles that the success of calcium hydroxide pulpotomies largely depends on the clinician's ability to assess the condition of the pulp [5, 8, 10, 14, 19, 32]. However, as demonstrated in Doyle's study [47], there were still a large number of failures even though pulpotomies were performed on healthy, uninfected teeth. Thus, Doyle and colleagues [47] came to the conclusion that since this procedure did not succeed in healthy teeth, it "is difficult to believe that this treatment could

succeed in infected teeth". Cariously exposed pulps with more pronounced inflammation have not shown positive reaction to calcium hydroxide. Therefore, Schröder [60] recommended that calcium hydroxide should be used only in instances where the pulp is not chronically inflamed.

This is contrary to the statement made by Zander nearly thirty years previously [51]. Zander believed that dentine formation took place not only in healthy pulps but in the presence of inflammation as well. Despite this fact, he found that vital pulp amputation using calcium hydroxide resulted in more than one failure that could not be explained. He speculated that it was possibly due to the condition of the pulp at the time of amputation or the technique which was employed.

In Brown's thesis (as quoted by Via [42]), the conclusion was reached that factors such as the amount of bleeding, maintaining an aseptic field and size of the exposed pulp, did not influence the outcome of the treatment. The high failure rate exhibited in this study was also speculated to be due to incorrect diagnosis of the condition of the pulp.

Heilig et al. [5] attributed the high success rate achieved in their study to "controlling such variables of treatment as pulpotomy technique, calcium hydroxide compound, cavity sealing material, and final restoration". The control of pulpal bleeding was also considered a very important variable.

In general, calcium hydroxide pulpotomies have been proven to be less successful than formocresol. Because of its limited clinical success, it is often not a recommended dressing for pulpotomies in the primary dentition [14, 56]. These less than satisfactory results could be the reason why the popularity of calcium hydroxide has waned (especially when it comes to the treatment of primary teeth) despite its potential to initiate dentine bridge formation.

According to Magnusson [53], this particular technique appears to have a "temporary character" and could possibly be indicated only in emergency cases or as an interim measure to postpone potential extractions. He also stated that it is important to follow-up

all pulpotomy procedures in primary teeth where calcium hydroxide has been used as a dressing.

Ranly [6] stated that calcium hydroxide "is considered a safe drug relative to formocresol, but, other than that, there are no strong arguments for its use".

1.3.2. Mineral Trioxide Aggregate (MTA)

Mineral trioxide aggregate is a new material that has only recently been introduced for use in pulp therapy. It is said to be biocompatible, prevents microleakage and has a sealing ability that is superior to that of amalgam or zinc oxide-eugenol. Its cytotoxicity is also reported to be less than that of other materials currently used in pulp therapy [26, 16, 58, 63].

According to the manufacturers, this material can be used for pulpotomy procedures in primary teeth. Its pH of 12.5 and mechanism of action are reported to be similar to that of calcium hydroxide [79]. MTA was also shown to have the ability to actively stimulate hard tissue formation by stimulating cytokine release from bone cells. It has an inductive effect on cementoblasts and studies have reported it to be superior to calcium hydroxide [58, 63, 79].

Faraco and Holland [79] compared calcium hydroxide (Dycal) and MTA when used as pulp capping materials in primary teeth of dogs. Two months after treatment, dentinal bridge formation was evident in all the MTA cases as opposed to only five of the calcium hydroxide specimens. The results from this study showed that MTA was superior to calcium hydroxide when used in pulp capping procedures.

Eidelman et al. [16] compared MTA to formocresol when used as a pulpotomy agent in primary teeth. In teeth where MTA was used as a pulpotomy agent, the coronal pulp was removed with a round bur, haemostasis was achieved and MTA paste was placed directly over the pulpal stumps. This paste consists of MTA powder that is mixed with sterile saline in the ratio of 3:1 [16, 58]. The tooth in question was then restored with IRM and a stainless steel crown. In the other half of the teeth, formocresol was placed onto the pulpal stumps for 5 minutes with a cotton pellet and then covered with a zinc oxide-eugenol base. No signs of clinical or radiographic pathology were found in any of the MTA-treated teeth. Teeth treated with MTA also demonstrated dentine bridge formation. Pulp canal obliteration was noted in 28% of all teeth treated. This was usually evident

around twelve months after treatment. However, this phenomenon was not regarded as a failure of the pulpotomy procedure. Even though follow-up times ranging between 6 and 30 months demonstrated good results, the efficacy of MTA over longer periods must still be evaluated. The small sample size (15 in the MTA group and 17 in the formocresol group) used in this study should also be kept in mind.

It was suggested that MTA could make an ideal replacement for the zinc oxide-eugenol base in ferric sulfate pulpotomies. Because ferric sulfate does not fix the pulpal tissue as in the case of formocresol, the zinc oxide-eugenol base, which has been shown to induce pulpal irritation, could be effectively separated from the pulpal tissue by a layer of MTA. A zinc oxide-eugenol base used in the formocresol pulpotomy would not be as crucial because the fixative properties of formocresol limits the effect of this base on the pulpal tissue. [16, 28]

This "barrier effect" could be the reason why internal resorption was not noted in MTA-treated teeth in the study conducted by Eidelman et al. [16]. However, the authors concur that because this was a relatively short-term study, internal resorption might still become evident with longer observation periods.

Mineral trioxide aggregate appears to be a promising, more biologically sound alternative to formocresol and calcium hydroxide. Treatment time is also reduced using MTA. Since this material is relatively new, it still has to be subjected to further scrutiny before definite conclusions can be made regarding its place in pulp therapy for the deciduous dentition.

1.3.3. The Way Forward

With new advances in the biological sciences, especially regarding recombinant DNA technology, the future of pulp therapy seems very bright. Experiments with growth factors that induce bone and dentine formation have yielded promising results. Even though this research is still in the experimental stage, the truly biologic pulpotomy that eliminates the use of harmful chemicals and promotes healing could be within reach. A summary of the recent advances in pulp therapy follows.

Bone morphogenetic proteins (BMP's) and osteogenic proteins

This has been suggested to be the future of pulp therapy for both primary and permanent teeth. Bone morphogenetic proteins are growth factors which have been advocated as possible agents for use in pulpotomies due to their ability to induce bone and dentine formation [4, 6]. This can therefore be classified as the so-called "reparative pulpotomy".

Bone morphogenetic proteins are non-collagenous proteins which have been renamed the DVR (decapentaplegic-Vg-related) family. Bone morphogenetic proteins have different functions, depending on where they are expressed in the body. Huggins (1931), as quoted by Ranly [6] showed the formation of bone after urinary tract epithelium was implanted into muscle. This was attributed to the bone morphogenetic proteins that are expressed in the kidneys and bladder.

Because bovine preparations are not suitable for human teeth and bone morphogenetic proteins are difficult to isolate from human bone, recent advances in molecular biology and recombinant DNA technology have eliminated this problem, making these proteins more readily available.

Nakashima [89] investigated the effect of bone morphogenetic protein on the formation of reparative dentine in dogs. Crude canine bone morphogenetic protein was placed into the pulp chamber after pulp amputation. It was found that "the formation of osteodentine

was localized to the amputated surface in which bone morphogenetic protein had been implanted". It is speculated that this osteodentine plays a role in the differentiation of odontoblasts. Nakashima stated that bone morphogenetic protein exhibited the properties of a good pulp- capping agent, namely:

- It was completely absorbed
- It produced large amounts of reparative dentine on the surface of the amputated pulp
- The root canals remained unaffected
- It did not demonstrate any adverse effects

Rutherford et al. [62], showed that recombinant human osteogenic protein-1, which is equivalent to BMP-7 [6], was capable of inducing reparative dentine formation in experiments done on molar and premolar pulps in monkeys. Three preparations (used as pulp capping agents) were compared namely:

1. Osteogenic protein combined with collagen matrix
2. Calcium hydroxide
3. Collagen matrix only

After pulp exposure, haemostasis was achieved and the pulps were capped. Results demonstrated that the collagen matrix on its own was inactive but when used in conjunction with osteogenic protein, pulp vitality was preserved and the formation of a dentine bridge took place. The osteogenic protein/ collagen formulation was easy to place and showed excellent haemostatic properties as bleeding was immediately brought under control when it was placed on the exposed pulp tissue.

Reparative dentine was evident in all cases treated with the osteogenic protein/ collagen formulation. This was superior to results obtained with calcium hydroxide. The pattern of bridge formation also differed. The amount of reparative dentine formed was proportional to the amount of osteogenic protein/ collagen placed and the type of reparative dentine seemed similar to patterns of bone formation. Collagen without the bone morphogenetic protein component has no osteogenic potential and is resorbed [62, 6].

Results have been promising and this formulation therefore seems clinically effective as a pulp capping agent.

This is the area of pulp therapy where the most advances are likely to occur in future. Clinical trials will be undertaken as soon as recombinant bone morphogenetic proteins become available commercially.

Freeze-dried bone

In recent years, freeze-dried bone has been suggested as a possible, more biologically compatible alternative to primary tooth pulpotomy agents such as formocresol and calcium hydroxide which are currently in use. It is thought that its action is similar to that of calcium hydroxide, inducing calcific barrier formation.

Fadavi and Anderson [56] found freeze-dried bone to be biologically compatible with pulpal tissue. In another study, they compared the pulpal response to freeze-dried bone with that of calcium hydroxide and zinc oxide-eugenol (IRM) over a six-month period. The study was performed in cynomolgus monkeys because the life cycle of the primary teeth, root development of the permanent teeth and pattern and nature of the pulp is reported to be identical to that of humans. After haemorrhage was controlled, the various bases were applied over the pulpal stumps. Freeze-dried bone was mixed with saline to form a paste.

Freeze-dried bone showed very promising results. 100% and 83.3% of teeth treated with freeze-dried bone were vital after 6 weeks and 6 months respectively compared with calcium hydroxide which demonstrated a 75% success rate after 6 weeks. In the calcium hydroxide and zinc oxide-eugenol groups, all the teeth showed pulpal necrosis after 6 months. At the 6-month follow-up, dentine bridge formation was evident in all cases where freeze-dried bone was used compared with 50% of teeth in the calcium hydroxide group. In teeth treated with freeze-dried bone, the inflammatory cell infiltrate was mild to

non-existent whereas all teeth treated with calcium hydroxide exhibited moderate to severe inflammation. Freeze-dried bone exhibited superior results when compared with the calcium hydroxide and zinc oxide-eugenol groups, with the "absence of periapical, furcal and necrotic involvement" [56].

It was found that freeze-dried bone promoted healing in pulpal tissue and did not appear to be toxic like formocresol, nor did it demonstrate systemic distribution. It induces calcific bridge formation without the unwanted side effects of internal resorption which is often associated with calcium hydroxide. The use of this material in pulp therapy in animals seems very promising. More research is however needed, especially in human subjects.

1.4. OVERALL CLINICAL, RADIOGRAPHIC AND PATHOLOGICAL FINDINGS

Most articles listed the clinical signs of failure as follows:

- Pain
- Tenderness to percussion
- Swelling
- Sinus tract
- Mobility

The majority of studies [14, 15, 16, 44, 49, 54] considered treatment to be a radiographic failure if one or more of the following signs were present:

- Internal root resorption [8]
- External root resorption
- Furcation and/ or
- Periapical/ interradicular bone destruction [2, 7]
- Radiographic evidence of pathology/ radiolucencies
- Widening of the periodontal ligament space—this can be the first sign of peri-radicular osteitis [2].

A retrospective study of ferric sulfate pulpotomies suggested new guidelines for determining radiographic success rates [15]. Distinction should be made between dental changes and osseous changes. In this study, the authors only classified the osseous changes as radiographic failures. These included interradicular and periapical bone destruction and/ or external root resorption. Osseous resorptive changes could lead to the development of sinus tracts, cellulitis, pain and/ or mobility. Internal resorption, calcific metamorphosis, uneven root resorption (compared to the contralateral tooth) and early eruption (compared to the contralateral tooth) were not listed as failures. The latter were not associated with osseous change and therefore posed no risk to the permanent

successors. As long as the permanent tooth is not affected, the authors feel that the traditional criteria that indicate radiographic failure may not be that important. Where internal resorption was classified as a sign of failure in most studies, this study proposed that as long as it was confined to the tooth, internal resorption should not be classified as a failure. This is in agreement with Casas et al. [90]. Casas et al. [90] stated that it makes more sense to classify outcomes as acceptable (normal or minor pathology present) or unacceptable (presence of severe pathology) because the clinical diagnosis is clearer as opposed to when terms such as 'normal' versus 'pathological' and 'successful' versus 'unsuccessful' are used.

This long-term study [15] made it possible to track the progression of radiographic lesions. A tooth which presented with internal resorption at 7 months showed evidence of calcification at the 15 month and 19 month follow-up visits. This phenomenon where new formation of reparative hard tissue occurs in areas of previous resorption was also demonstrated in studies by Magnusson [21] involving zinc oxide-eugenol pulpotomies, as well as calcium hydroxide [53]. This reparative process should however not be regarded as a sign of healing of inflamed tissue [53]. Other studies where the periradicular structures appeared normal and internal root resorption was repaired by bone or calcified tissue, were also classified as successes [42].

Fuks et al. [32] stated that "the potential risk for internal resorption is increased in teeth where the predentin is lacking". Massler et al. [65] speculated that the much higher resorption potential of primary teeth was the reason why inflammation seems to be more pronounced in the primary dentition. Inflammation in primary teeth also had a tendency to be more "diffuse".

In many studies, pulp canal obliteration or calcific metamorphosis was not seen as a sign of failure [7, 16, 32, 67]. Narrowing of the pulp canals was taken as a sign of success in formocresol pulpotomies performed by Farooq et al. [54].

Formation of a reparative dentine bridge is usually indicative of healing [53, 77]. Cvek et al. [73] reported that more often than not, the presence of a low-grade irritation leads to the formation of a hard tissue barrier, irrespective of the material placed in contact with the pulp [4, 73]. Even though the development of a dentine bridge is considered to be desirable, its absence did not necessarily indicate failure either [5]. Law (1956) as quoted by Boller [10] stated that the "presence of a hard tissue bridge does not guarantee success nor does its absence necessarily imply failure and pulp degeneration".

Calcium hydroxide pulpotomies

In the literature, other signs of failure such as those reported in calcium hydroxide pulpotomies (as summarized by Via [42]) included:

- Radiographic evidence of loss of periradicular bone
- Absence of dentinal bridge formation (radiographically)

Successful calcium hydroxide pulpotomies would therefore exhibit the following signs:

- Normal lamina dura and periodontal membrane width
- Radiographic evidence of dentinal bridge formation
- No evidence of internal root resorption.

Histological results have varied from calcific bridge formation to signs of inflammation and internal resorption. The latter is said to be a result of chronic inflammation and is most frequently observed in pulpotomies with calcium hydroxide [1, 2, 42]. More often than not, internal resorption was noted a short distance from the amputation site [2]. Extensive internal resorption below the level of amputation was a common finding in calcium hydroxide pulpotomies of primary teeth [8, 9, 53].

Mineral Trioxide Aggregate pulpotomies

Pulp canal obliteration was evident in 41% of cases treated with MTA but this was not regarded as a failure [16].

Ferric sulfate pulpotomies

Interradicular radiolucency was the most common sign of failure [9]. Pulp canal obliteration was also noted in these pulpotomies but this was not regarded as a sign of failure [15,16, 90]. In Casas' study [90], 71% of molars demonstrated this finding. This particular study also revealed internal resorption in 55% of ferric sulfate pulpotomies. Other studies [7, 14, 15] also reported signs of internal resorption.

Formocresol pulpotomies

Willard [67] found that pulp canal obliteration or calcific metamorphosis was one of the most common post-operative radiographic findings in formocresol pulpotomies [32, 67]. This phenomenon was evident in 60% of cases in Hicks' study [72]. Increased calcification of the root canal walls appears uniformly throughout the canals, leading to almost complete obliteration. Calcification could be indicative of increased activity of the odontoblasts, suggesting that formocresol does not cause complete loss of pulp vitality. Normal root resorption, periapical and furcation pathology and internal and external root resorption were also radiographically observed.

Hicks et al. [72] demonstrated internal resorption in over 10% of cases where formocresol was incorporated into the zinc oxide-eugenol base without prior application of a formocresol-soaked pellet. External resorption was also accelerated. Strangely enough, radiographic evidence of internal resorption in formocresol pulpotomies has rarely been demonstrated in earlier studies [10, 37, 65, 47].

Magnusson [37] conducted a clinical study which involved two different application times of formocresol. In about half of the cases, a formocresol pellet was applied for a period of 3 to 5 days and in the other half, it was only applied for 5 minutes before the tooth was permanently restored. Overall, he reported periradicular osteitis in 10% of teeth and internal resorption in 37% of the cases. He found that the application time made no difference to the type and frequency of internal resorption observed. Upper molars were more readily affected. Farooq et al. [54] contradicted this finding. Mandibular first primary molars were more prone to failure in her study. Magnusson's study [37] also

confirmed that, compared with pulpotomy techniques where zinc oxide-eugenol and calcium hydroxide were applied, internal resorption was not as common or as severe in formocresol pulpotomies.

Intraradicular radiolucency was also found to be indicative of failure in formocresol pulpotomies [9]. It was noted that formocresol pulpotomies that demonstrated signs of underlying radiographic pathology at the time of pulp amputation, invariably ended up as failures [54].

Gluteraldehyde pulpotomies

Internal resorption, periapical and interradicular pathology, interradicular radiolucency and pulp canal obliteration have been observed. The latter finding was however not considered to be a radiographic failure by Fuks et al. [32].

Zinc oxide-eugenol base

This base was shown to elicit an acute, persistent inflammatory reaction. Beaver et al. [80] are of the opinion that "histologically, an inflammatory reaction should not be considered a failure", as pulpal inflammation is often reversible. The presence of internal resorption was consistently found in pulpotomies where a zinc oxide-eugenol base was placed over the amputated pulp (without the prior application of any kind of medicament) [50].

Radiographic failures tend to be significantly higher than clinical failures [28, 72]. Even if a tooth is clinically sound, radiographic evidence might indicate signs of pathology. Clinical failures can be evident radiographically but not all radiographic failures have associated clinical signs and symptoms [53, 65, 72, 86, 90].

In a study by Casas et al. [90], a 96% and 98% clinical success rate for ferric sulfate pulpotomies and root canal therapy dropped to 61% and 91% respectively upon radiographic examination. The authors therefore suggested that in teeth that have received some form of pulp therapy, radiographs be taken at follow-up visits as "the post-

operative clinical appearance of pulp-treated molars may not be representative of its actual status".

Success should be determined on a histological as well as a radiographical basis. It should however be borne in mind that histological results have been subjected to varying interpretations.

Magnusson [53] demonstrated in his study of calcium hydroxide pulpotomies that teeth which appeared normal radiographically showed signs of severe inflammatory changes histologically. Fuks et al. [86] stated that even if the pulps appeared normal histologically, it did not necessarily mean that it would result in clinical success.

Eidelman et al. [16] stated: " Pulpotomy cannot be regarded as successful if it presents internal resorption or any other pathologic consequence of the treatment, even if the permanent successor erupts into its proper location and presents no enamel defects".

It is up to the clinician to decide whether a tooth with radiographically demonstrable pathology should be retained and monitored on a regular basis or whether it should be extracted and a space maintainer placed.

1.5. DETERMINANTS OF PULPOTOMY SUCCESS

The success of pulpotomy procedures is determined by variables such as:

1. The condition of the pulp at the time of treatment

Proper case selection and diagnosis is a crucial factor that could determine the success of the pulpotomy procedure. As there is no clinical method for accurately assessing the status of the radicular pulp, and therefore the degree of pulpal inflammation present, diagnosis is very difficult [14, 19, 78].

A major reason for failure of pulpotomy procedures was considered by some to lie in the ability of the operator to determine whether the pulp has passed into an irreversible state of degeneration. This factor will most likely determine the long-term clinical outcome. Healing is dependent on the degree of pulpal inflammation present. No known pulpal medicament, including calcium hydroxide, is able to induce healing in chronically inflamed pulpal tissue [8, 12, 18, 81] and teeth affected by caries are usually in a state of acute inflammation. Pulpotomies on such teeth therefore tend to have a less favourable outcome [1, 5, 8, 10,12, 32, 65, 77]. It should also be borne in mind that poor results were reported in some studies involving healthy teeth [47].

Calcium hydroxide relies on the ability of the pulp to heal. Thus, the success of these pulpotomies may depend greatly on the condition of the radicular pulp. Calcium hydroxide pulpotomies may therefore be more technique sensitive than formocresol. Because formocresol devitalizes and fixes the pulp, the state of the pulp in formocresol pulpotomies might not be such a crucial factor when determining the outcome [1].

Schröder [81] demonstrated that there was an 81% correlation between clinical and histological diagnosis. He showed that in cases where normal light red blood is evident upon pulpal exposure, inflammation is limited to the coronal pulp.

Recent research has investigated the role of Prostaglandin E_2 as a possible quantitative indicator of pulpal inflammation [78]. A definite correlation was found between the levels of Prostaglandin E_2 in blood (obtained from pulpal exposures in carious primary molars) and the radiological picture after pulp therapy. The authors therefore suggest that Prostaglandin E_2 could turn out to be a useful marker to predict the outcome of treatment in the future. Further research is needed in this regard.

Factors such as history and symptoms exhibited, together with critical evaluation of the exposure site should all be taken into account when making a diagnosis.

2. The pulpotomy technique itself [54, 57]

A gentle amputation technique is thought to be one of the factors needed for a successful pulpotomy (in the absence of pathology) [2, 8, 12, 32, 60, 88].

Amputating the pulp by means of a high-speed handpiece with continuous water cooling was shown to minimize trauma when removing the coronal portion of the pulp [5].

3. Control of haemorrhage and prevention of blood clot formation [2, 8]

Adequate control of bleeding after pulpal exposure and prevention of a blood clot is said to yield more favourable results [1, 2, 5, 55, 45, 24]. This seems to be the most important factor in determining the successful outcome of calcium hydroxide pulpotomies. The failure rate increased with the presence of a blood clot on the wound surface and the incidence of internal resorption was also higher in these cases [1].

It has been speculated that the more inflamed the pulp, the longer it will take to bring the bleeding under control. However, Waterhouse et al. [1, 78] investigated this and found that the time required to bring bleeding under control was statistically insignificant where success rates were concerned. Even if bleeding occurs after placement of the medicament, the outcome is not affected [1, 78].

In the literature, various solutions have been used to control pulpal bleeding. These include a sterile cotton pellet soaked in:

- A solution of calcium hydroxide in water [2]
- Haemostatic agents such as aluminium chloride [5] and ferric sulfate [7]
- Sterile water
- Sodium hypochlorite [55]

Prevention of a blood clot has been proven to be an important factor in determining success because it ensures good contact between the medicament and the pulp tissue [2, 8].

4. Type of calcium hydroxide preparation used

The use of different calcium hydroxide preparations could result in different outcomes. Hard setting calcium hydroxide preparations tend to be more successful in general [5, 6, 60].

5. Differences in cavity sealing materials and final restorative materials [5, 54, 57]

The capacity of materials to prevent microleakage plays a role in the outcome [1, 58, 64]. Marginal leakage of a restoration could result in bacterial invasion and pulp irritation, thereby accounting for a high failure rate [54, 65]. An adequate coronal seal is therefore very important [77].

Formocresol pulpotomies where an immediate stainless steel crown was placed showed a higher success rate compared with the placement of temporary restorations (which were later replaced by stainless steel crowns) since temporary restorations are more prone to marginal breakdown [54, 65, 75]. Stainless steel crowns have also shown more favourable results compared with amalgam restorations [57].

6. Period of observation

The longer the observation period, the greater the chances that more failures will be evident [65]. Degenerative changes appear more pronounced with longer observation

periods [2]. In a study of ferric sulfate pulpotomies [15], fewer normal pulps were observed as time wore on.

7. Contamination

Maintaining asepsis during the pulpotomy procedure is very important. Prevention of bacterial contamination leads to a more favourable pulp response [4, 88]. It is thought that improving debridement of cariously exposed teeth prior to the application of a medicament might improve their prognosis. Sodium hypochlorite has been suggested as an irrigant, as it has been shown to dissolve debris [4, 55].

CHAPTER 2
MATERIALS AND METHODS

A COMPARISON OF TWO LINER MATERIALS FOR USE IN THE FERRIC SULFATE PULPOTOMY

2.1. OBJECTIVES OF THIS STUDY

Because ferric sulfate does not fix pulp tissue like formocresol, the base placed over the pulp could play a significant role in the outcome of the pulpotomy procedure. This is not the case in formocresol pulpotomies as the pulp tissue is fixed, making it less susceptible to the effect of the base. The pulpal response to different base materials following the ferric sulfate pulpotomy has not been compared in the literature.

The objective of this study was to compare the clinical and radiographic outcomes of the basic ferric sulfate (Astringedent) pulpotomy technique where a Dycal base placed over the amputated pulp is compared with a Kalzinol base.

The Research Committee of the University of Stellenbosch's School of Oral Health Sciences approved the protocol for this study.

2.2. INCLUSION CRITERIA

The aim of this study was to include approximately 20 to 30 children in each group. The children are regular patients at the Paediatric Dentistry Division at the University of Stellenbosch's School for Oral Health Sciences. For a child to be included in the study, the following criteria had to be met:

1. The parent had to have signed a consent form. This is a routine requirement for any person wishing to be treated as a patient at the University of Stellenbosch's School of Oral Health Sciences.
2. Good patient cooperation.
3. Absence of any medical condition that would be a contra-indication for pulp therapy.
4. Absence of clinical signs of non-vitality such as an abscess, soft tissue swelling, mobility or tenderness to percussion. In other words, the tooth had to be vital.
5. The patient should not have had a history of spontaneous pain (teeth with slight symptoms or asymptomatic teeth only).
6. Absence of radiographic signs of pulpal necrosis such as apical or furcal radiolucencies, internal resorption or pulpal calcifications.
7. There had to be radiographic evidence of caries close to the pulp or involving the pulp horns.

2.3. THE CLINICAL TECHNIQUE

The clinical procedure was performed by the author or by a student under the direct supervision of the author. Depending on the situation, treatment was either performed under general anaesthesia or using local anaesthetic. The standard ferric sulfate pulpotomy as described by Fuks et al. [7] and Ibricevic et al. [14],was used in this study. The clinical technique involved the following:

1. The cavity was prepared with a fast handpiece with continuous water cooling.
2. After the removal of all caries, the roof of the pulp chamber was removed.
3. The coronal pulp was then amputated using either a large, sterile caries bur in a slow handpiece or an excavator. Teeth had to be vital, in other words, normal, light red blood had to be evident upon exposure of the pulp [50].
4. Bleeding was brought under control with the aid of damp cotton pellets.

5. 15.5% Ferric sulfate (Astringedent, Ultradent Products) was applied with a cotton pellet for 15 seconds (with continuous friction). Haemorrhage control was assessed and ferric sulfate was re-applied if bleeding did not cease.
6. The tooth was gently rinsed to remove the ferric sulfate and any remaining debris.
7. Every alternate patient (i.e. one half of the cases) had a calcium hydroxide base placed over the amputated pulp. Dycal (Dentsply Caulk) was used in this instance. If haemorrhage occurred after the placement of the medicament, it was gently blotted with sterile cotton pellets. A glassionomer lining, Vitrebond (3M Dental Products) was mixed according to the manufacturer's instructions and then placed over the Dycal layer and cured for 20 seconds. This was followed by the placement of a permanent amalgam (Dispersalloy, Dentsply Caulk) restoration.
8. In the other half of the cases, a zinc oxide-eugenol base, Kalzinol (Dentsply De Trey) was mixed according to manufacturer's instructions till it could be rolled between the fingers without sticking. It was placed over the amputated pulp with the aid of a damp cotton pellet. This was then followed by the placement of a permanent amalgam restoration.
9. In patients that required more than one pulpotomy procedure, both techniques were employed, but in different teeth.
10. Occlusion was checked and relieved where necessary.

2.4. THE FOLLOW-UP EXAMINATION

With the follow-up examination, it was not known beforehand which pulpotomy agents were used. Conclusions were drawn without this prior knowledge, ensuring an unbiased view. Where possible, the cases were followed up every 6 months for 1 year (i.e. 2 follow-up visits) or until the teeth exfoliated. Radiographs were taken at each follow-up visit.

The patients were examined and the pulpotomized teeth were evaluated for the presence or absence of the following findings:

Clinically

1. Signs of a defective restoration or secondary caries.
2. Symptoms related to the treated tooth reported by the child or the parent (spontaneous pain or pain initiated by stimuli).
3. Signs of mobility, soft tissue swelling, sinus formation, tenderness to percussion.
4. Signs that the treated tooth was starting to exfoliate or that the successor was starting to erupt. It was also noted whether exfoliation appeared advanced, delayed or normal when compared with the contralateral tooth.
5. The presence of enamel or other defects on permanent teeth, where pulpotomies were performed on their predecessors.

Clinical signs of failure included:

- presence of a draining sinus or swelling
- reports of pain
- mobility (not due to the exfoliation process)

Radiologically

1. Whether the restoration was still intact.
2. Whether there were signs of recurrent caries.
3. Whether there were signs of pathology such as radiolucencies in the periapical and/ or furcal areas.
4. Presence of pathological resorption (internal and/ or external)
5. Whether there were signs of normal physiologic root resorption, indicating that the tooth was starting to exfoliate.
6. Signs of calcifications (intra-canal calcifications).

Radiographic signs of failure included:

- recurrent caries
- evidence of pathology such as periapical and/ or furcal radiolucencies
- signs of internal and/ or external resorption

Pulp canal obliteration was not regarded as a failure as this has been shown to be a result of increased activity of the odontoblasts, thereby indicating that the pulp has retained some degree of vitality.

If a pulpotomy failed, the tooth was either subjected to root canal treatment or it was extracted.

The clinical and radiographic findings observed in this study will be discussed in the section that follows.

CHAPTER 3
RESULTS

3.1. GENERAL REMARKS

In this study, the clinical and radiographic outcomes of the traditional ferric sulfate (Astringedent) pulpotomy procedure where different base materials were placed over the amputated pulp were compared. A zinc oxide-eugenol base (Kalzinol) was compared with a calcium hydroxide base (Dycal), which was followed by the placement of a glass ionomer lining (Vitrebond).

3.2. SAMPLE DETAILS

The sample was divided into two groups namely:

1. Ferric sulfate was placed over the amputated pulp followed by the placement of a zinc oxide-eugenol (Kalzinol) layer and a permanent amalgam restoration.
2. Ferric sulfate was placed over the amputated pulp followed by the placement of a layer of hard-setting calcium hydroxide (Dycal) and a cured Vitrebond lining. A permanent amalgam restoration was then placed.

In this study, a total of 38 teeth were treated. Nearly 50% of the cases were performed under general anaesthesia and the rest were completed using local anaesthetic. The children ranged in age from 3 to 10 years with a mean age of 5.9 years. 52% of the subjects were female.

3.3. DETAILS OF TEETH TREATED

A total of 22 teeth received a Kalzinol base and 16 received the Dycal and Vitrebond base. 21 pulpotomies were performed on first primary molars and 17 were performed on second primary molars. All the teeth had radiographic evidence of caries close to the pulp or involving the pulp horns. There was no history of spontaneous pain and normal bright red blood was evident upon pulpal exposure.

3.4. OUTCOME OF TREATMENT

The statistical analysis involved the use of binary data and comparisons of the two groups at a given time of follow-up was carried out in terms of proportions of successes, Chi-squared and Fisher exact tests of significance.

In the tables that follow, variables Dycal=1 and Kalzinol=2.

Table 1: Pain at 6 months

Other variables: Pain= NO=1

Pain= YES=2

Frequency Percent	Dycal 1	Kalzinol 2	Total
N= 0	8 25.00 30.77 61.54	18 56.25 69.23 94.74	26 81.25
Y= 1	5 15.63 83.33 38.46	1 3.13 16.67 5.26	6 18.75
Total	13 40.63	19 59.38	32 100.00

In this table, 94.74% of patients who received the Kalzinol base indicated NO (meaning they experienced no pain) and 61.54% of patients who received the Dycal base indicated NO. The difference is significant; P (Exact) =0.029.

Statistic	DF	Value	Prob
Chi-Square	1	5.584	0.018

Fisher's Exact Test

Two-sided Pr <= P	0.029

Table 2: Sinus formation at 6 months

Frequency Percent	Dycal 1	Kalzinol 2	Total
N= 0	7 21.88 28.00 53.85	18 56.25 72.00 94.74	25 78.13
Y= 1	6 18.75 85.71 46.15	1 3.13 14.29 5.26	7 21.88
Total	13 40.63	19 59.38	32 100.00

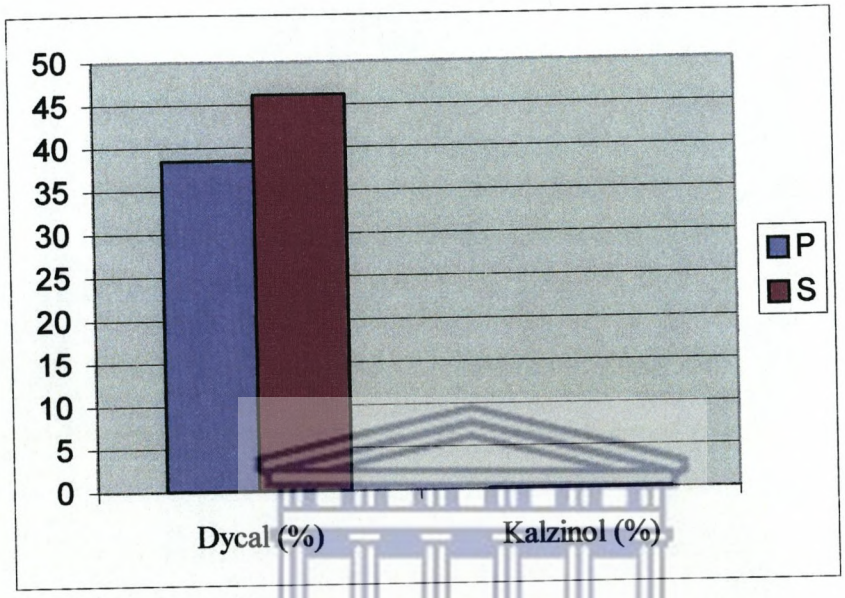
In this table, 94.74% of patients who received the Kalzinol base indicated NO (meaning there was no sinus present) while 53.85% of patients who received the Dycal base indicated NO. The difference is significant; P (Exact) =0.010.

Statistic	DF	Value	Prob
Chi-Square	1	7.552	0.006

Fisher's Exact Test

Two-sided Pr <= P	0.010

Figure 1: Percentage of patients who presented with pain and sinus formation at the 6-month follow-up visit



P= PAIN
S= SINUS FORMATION

Table 3: Clinical success at 6 months

Frequency Percent	Dycal 1	Kalzinol 2	Total
N	6 46.15	1 5.26	7
Y	7 53.85	18 94.74	25
Total	13	19	32

This table shows a 53.85% success rate for the Dycal pulpotomy and a 94.74% success rate for the Kalzinol pulpotomy after 6 months. The difference is significant; P (Exact) =0.006.

Statistic	DF	Value	Prob
Chi-Square	1	7.552	0.006

Fisher's Exact Test	
Two-sided Pr <= P	0.010

Figure 2: Summary of clinical success rates after 6 months

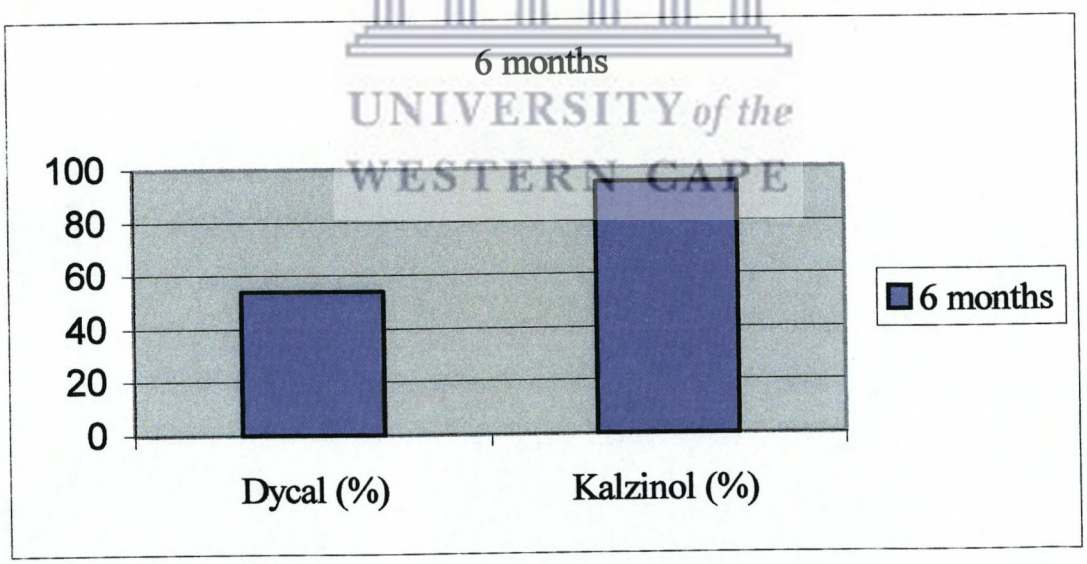


Table 4: Radiographic success at 6 months

Frequency Percent	Dycal 1	Kalzinol 2	Total
N	4 50.00	3 18.75	7
Y	4 50.00	13 81.25	17
Total	8	16	24

This table shows a 50% radiographic success rate for the Dycal pulpotomy and an 81.25% radiographic success rate for the Kalzinol pulpotomy after 6 months. At first glance, the results appear to indicate that there is a significant difference between the two materials. However, one should bear in mind that the small sample size could influence the results. This is especially relevant in the Dycal group. The reason for this is that it was not possible to take follow-up x-rays in many of the patients due to poor cooperation.

Statistic	DF	Value	Prob
Chi-Square	1	02.521	0.112

Fisher's Exact Test

Two-sided Pr <= P	0.167

Figure 3: Summary of radiographic success rates after 6 months

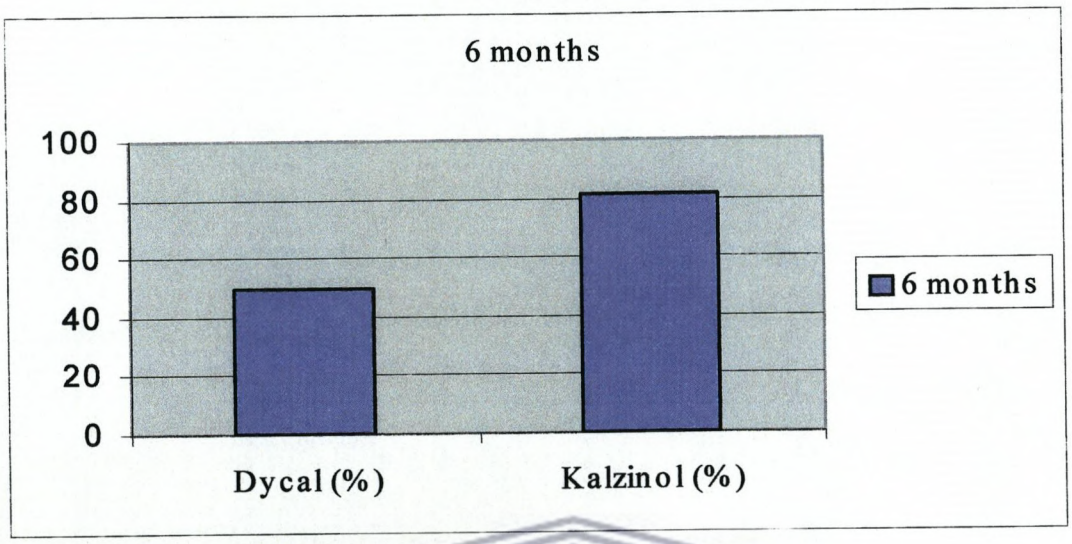


Table 5 : Incidence of resorption at 6 months

Other variables: Internal resorption= A

External resorption= B

Normal physiologic resorption= C

No resorption evident= N

Frequency Percent	Dycal 1	Kalzinol 2	Total
A	3 37.50	0 0.00	3
B	1 12.50	0 0.00	1
B, C	0 0.00	2 12.50	2
N	4 50.00	14 87.50	18
Total	8	16	24

Once again, the small sample in the Dycal group is due to the fact that x-rays could not be taken in some of the children.

Statistic	DF	Value	Prob
Chi-Square	3	10.000	0.019

Table 6 : Incidence of other radiolucent lesions at 6 months

Other variables: Furcal radiolucency= D

Periapical radiolucency= E

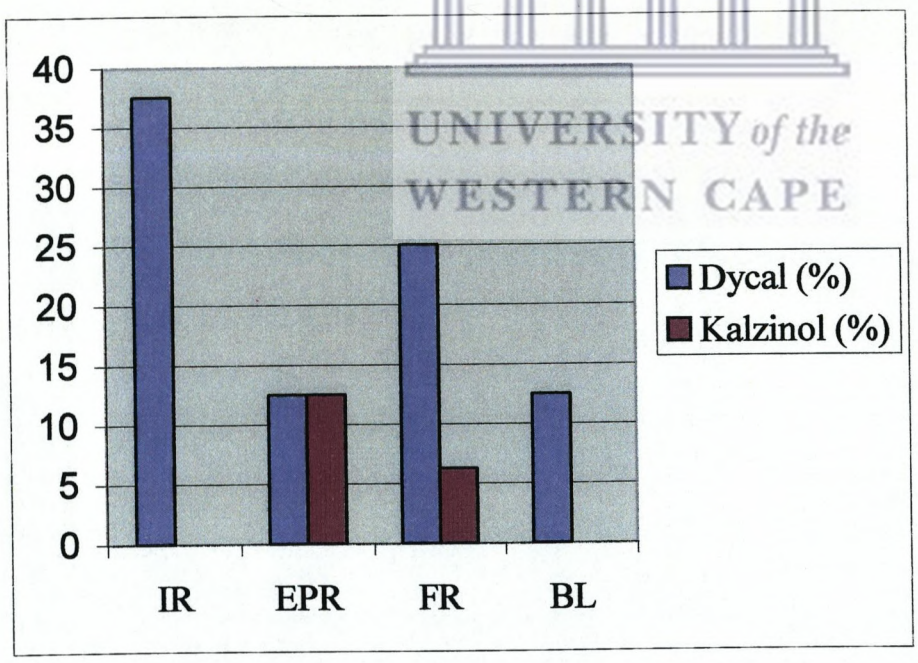
No radiolucency evident= N

Frequency Percent	Dycal 1	Kalzinol 2	Total
D	2 25.00	1 6.25	3
E	1 12.50	0 0.00	1
N	5 62.50	15 93.75	20
Total	8	16	24

Statistic	DF	Value	Prob
Chi-Square	2	4.125	0.127

Fisher's Exact Test	
Two-sided Pr <= P	0.091

Figure 4: Incidence of radiographically demonstrable pathology at 6 months



IR= INTERNAL RESORPTION
EPR= EXTERNAL PATHOLOGIC RESORPTION
FR= FURCAL RADIOLUCENCY
BL= BONE LOSS

Figure 5: Patient compliance

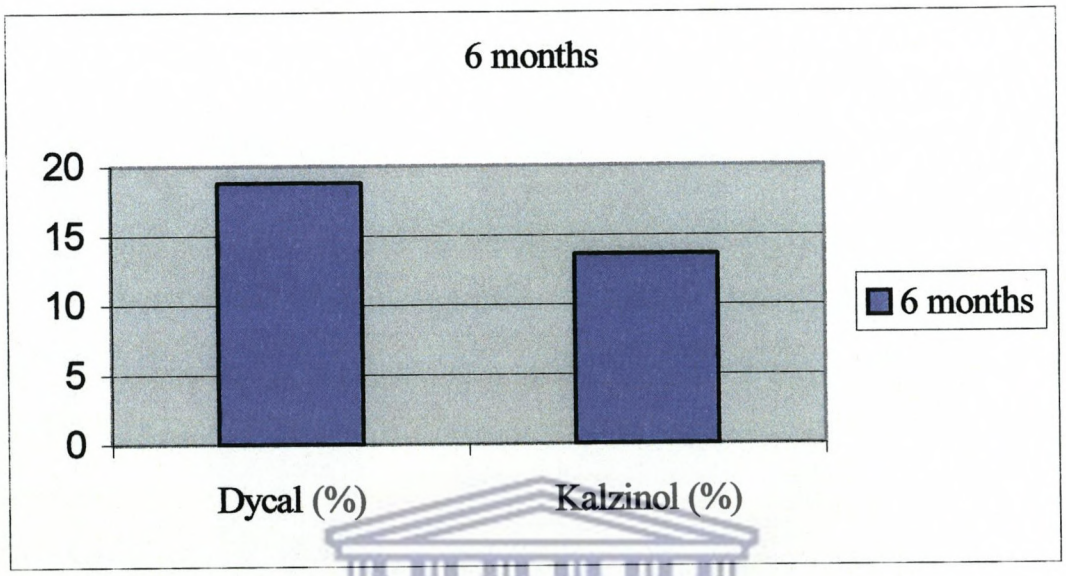
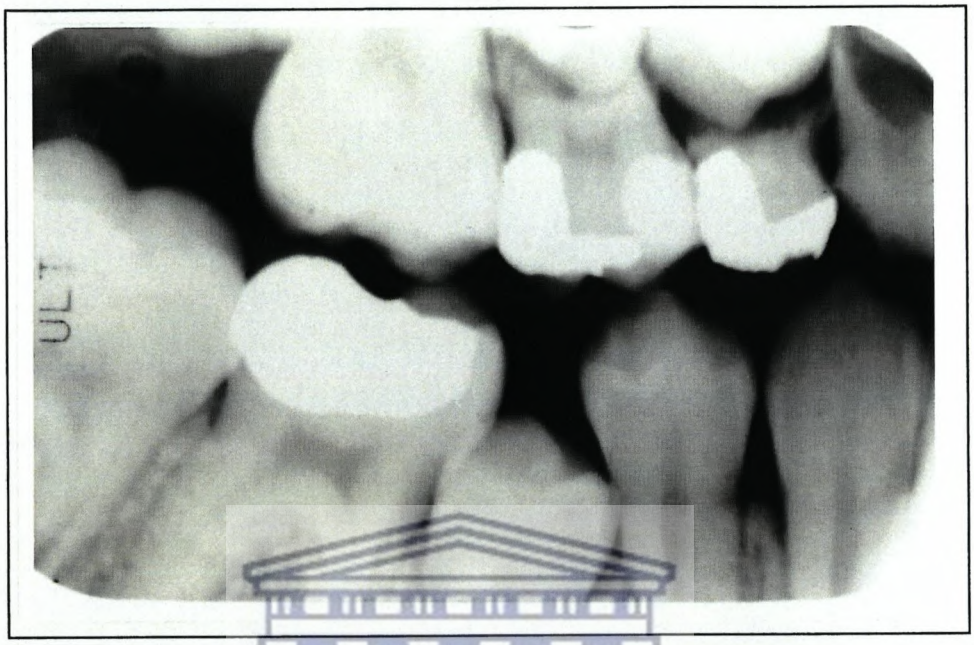


Figure 5 (above) indicates the percentage of patients who failed to keep appointments. This was one of the stumbling blocks encountered in this study.

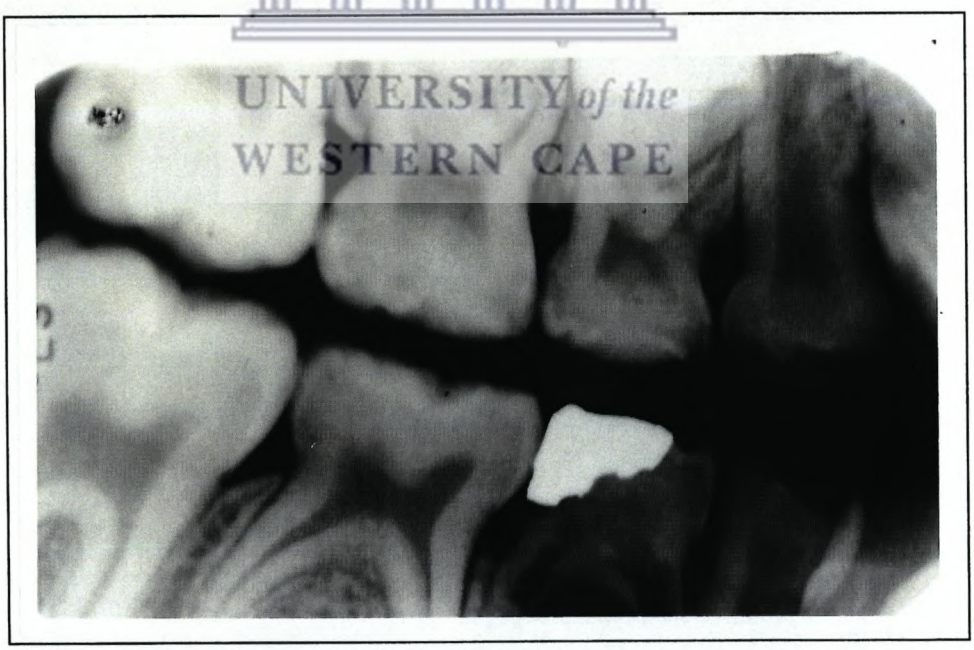
The statistical results presented in this section will be discussed in the chapter that follows.

EXAMPLES OF PATIENT CASES

Ferric sulfate pulpotomy utilising a Dycal/ calcium hydroxide base I

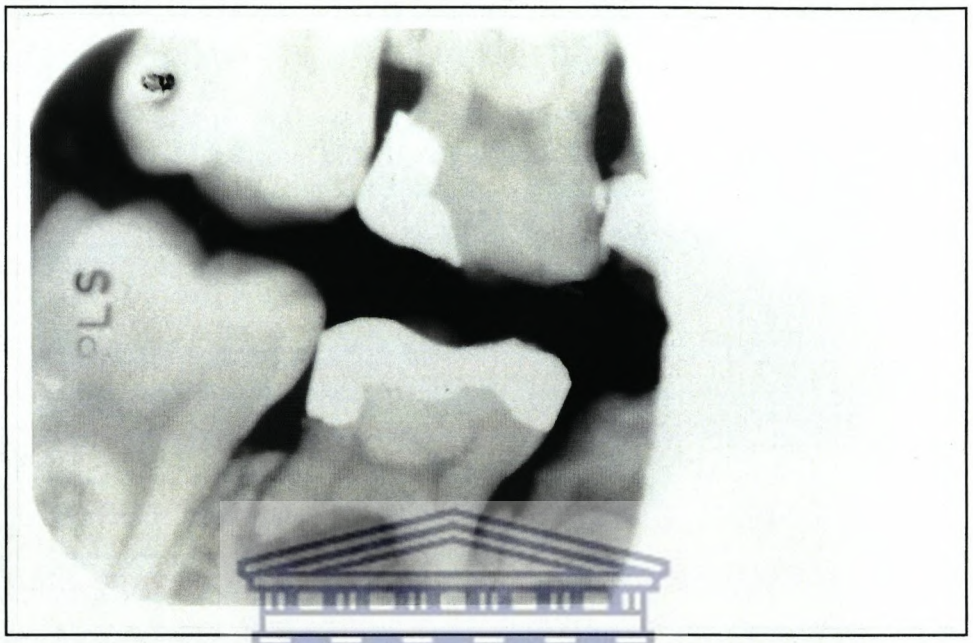


PATIENT A (tooth 54): Clinical and radiographic success at 6 months. At the time of the 12-month follow-up visit, the tooth had already exfoliated.

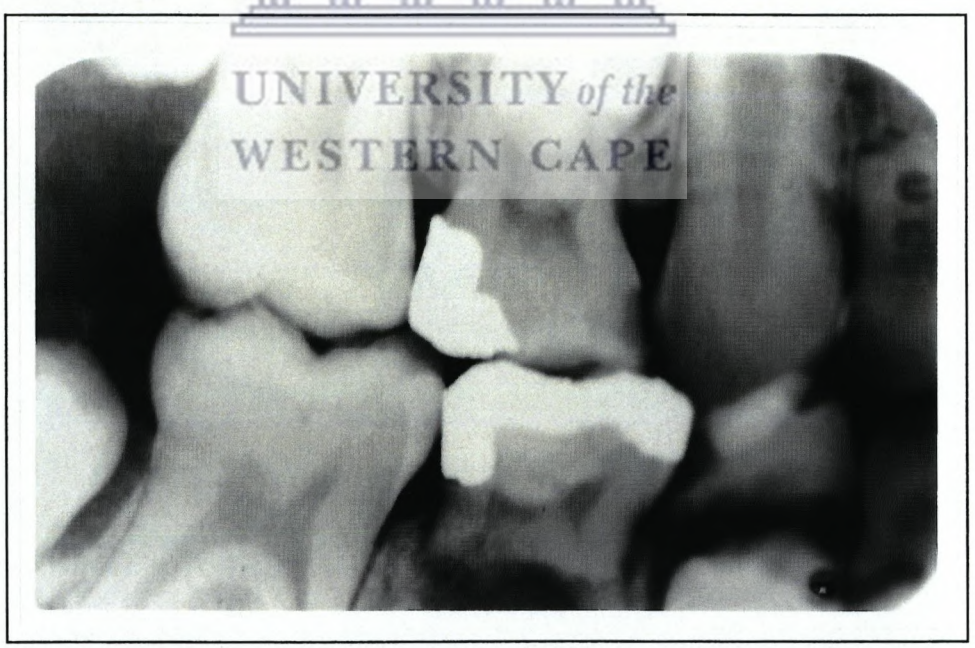


PATIENT B (tooth 84): At 6 months, the tooth exhibited signs of internal resorption and a furcal radiolucency was also visible on the x-ray. The patient presented with no pain and did not return for more than a year. When she eventually returned, the tooth had exfoliated without incident and there were no defects visible on the permanent successor.

Ferric sulfate pulpotomy utilising a Dycal/ calcium hydroxide base II(a)



PATIENT C (tooth 85): Follow-up visit 1 (at 6 months)



PATIENT C: Follow-up visit 2 (after more than a year)

Ferric sulfate pulpotomy utilising a Dycal/ calcium hydroxide II(b)

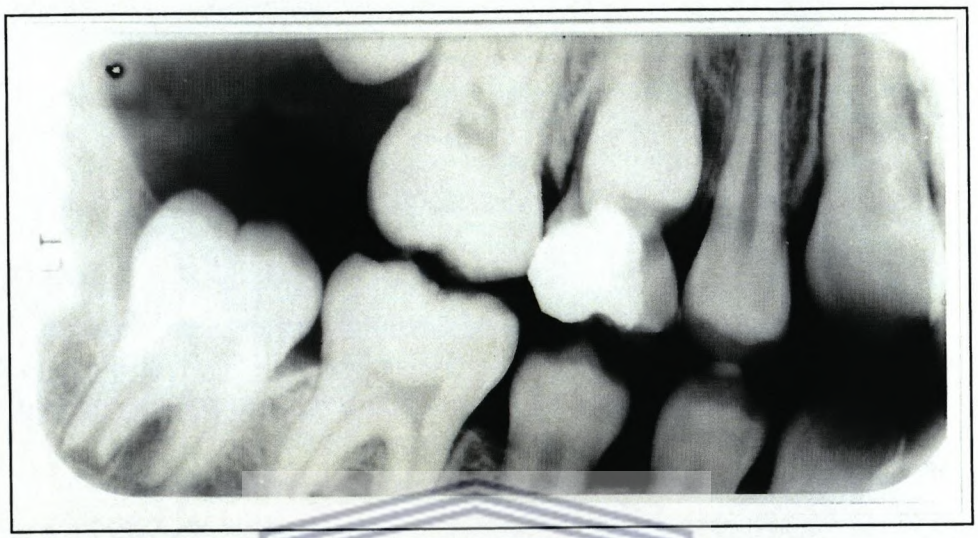
PATIENT C: At a later visit

At 6 months (as can be seen on page 91), resorption was already evident on the 85 in 9-year-old patient C. He presented with no pain. He failed to return for subsequent appointments and when he eventually did return, the external resorption had worsened. A periapical readiolucency was visible and bone loss was also evident. He still presented with no pain but an extraction was indicated. The patient failed to return for the extraction. Some time later, he arrived for a "check-up". The final x-ray (above) was taken at that visit. The periapical radiolucency had grown progressively worse.

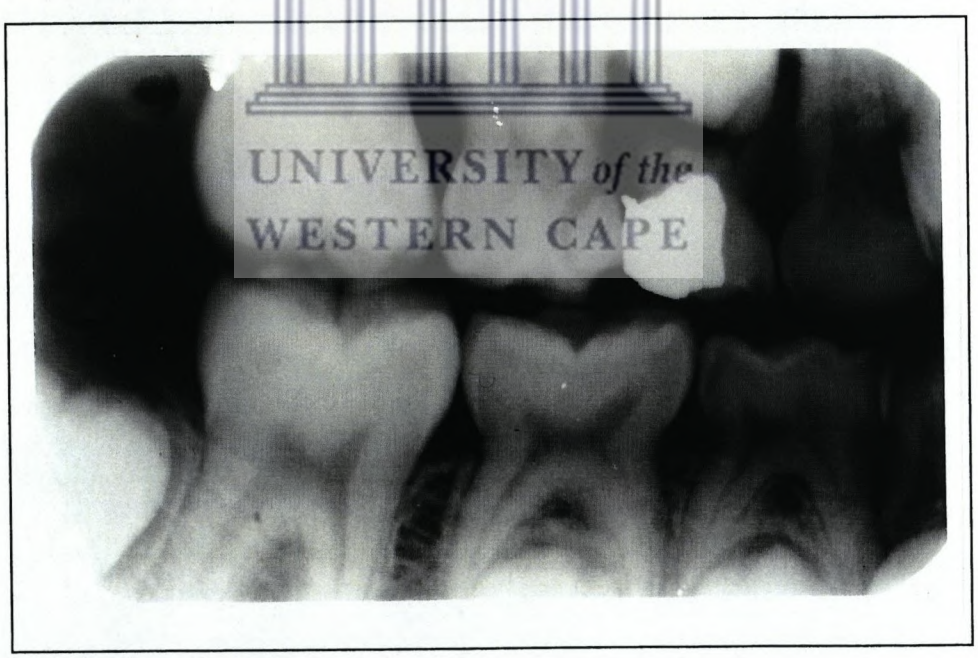
In this case, the patient's failure to return for the scheduled extraction made it possible to track the progress of the 85 which received a Dycal base and Vitrebond lining after the standard ferric sulfate pulpotomy was performed.

Thus, the long-term outcome of this pulpotomy procedure proved to be unsuccessful.

Ferric sulfate pulpotomy utilising a Dycal/ calcium hydroxide base III



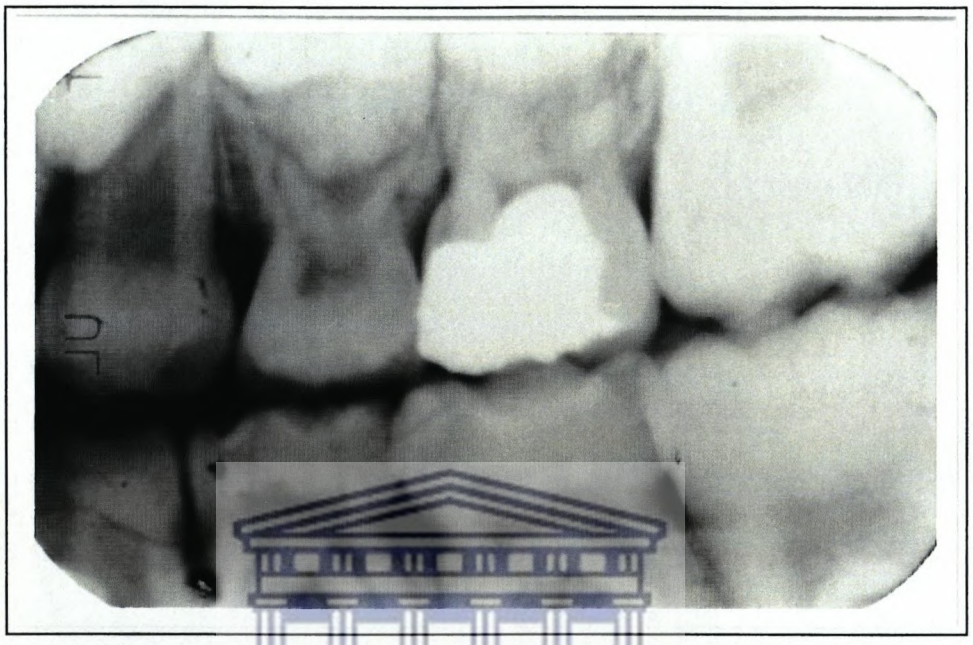
PATIENT D (tooth 55): Follow-up visit 2 (at 12 months)



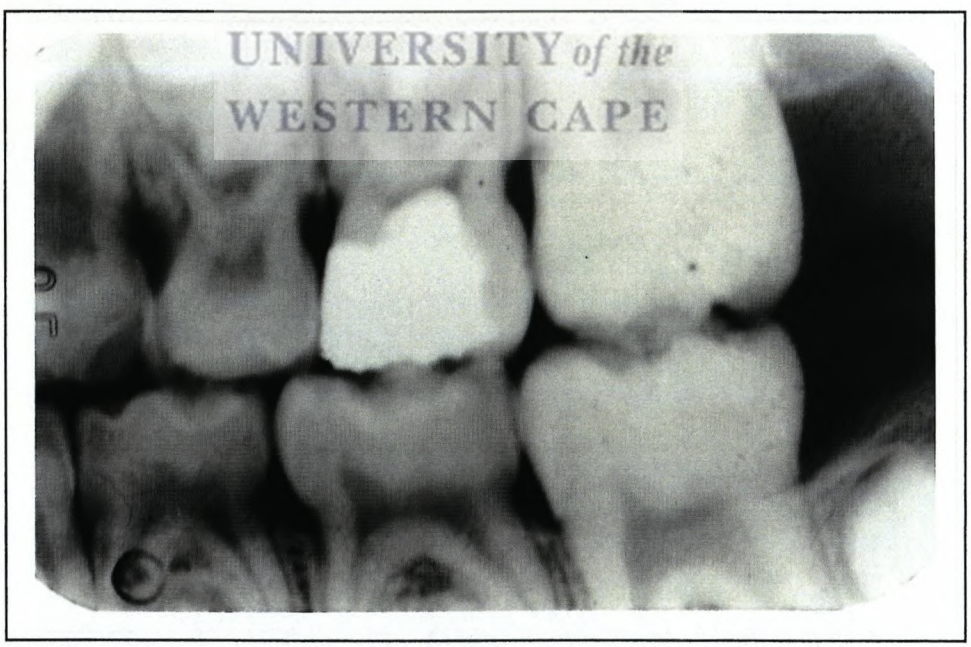
PATIENT E (tooth 54): Follow-up visit 2 (at 12 months)

Patients D and E (above) are both examples of successful pulpotomies where a Dycal base was used. Both cases are undergoing normal physiologic resorption.

Ferric sulfate pulpotomy utilising a zinc oxide-eugenol/ Kalzinol base I

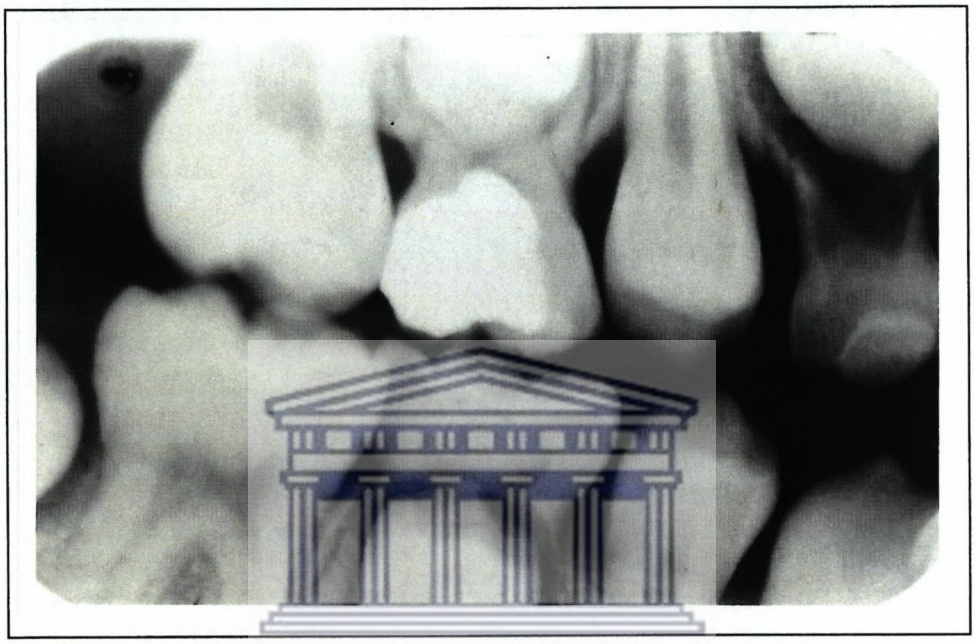


PATIENT F (tooth 65): At 6 months



PATIENT F: At 12 months

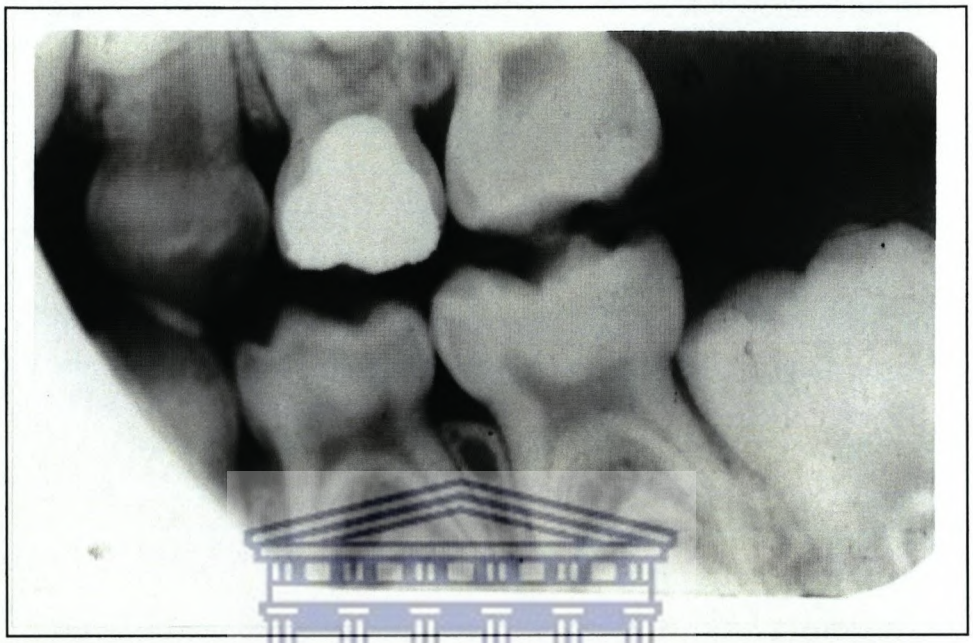
Ferric sulfate pulpotomy utilising a zinc oxide-eugenol/ Kalzinol base II



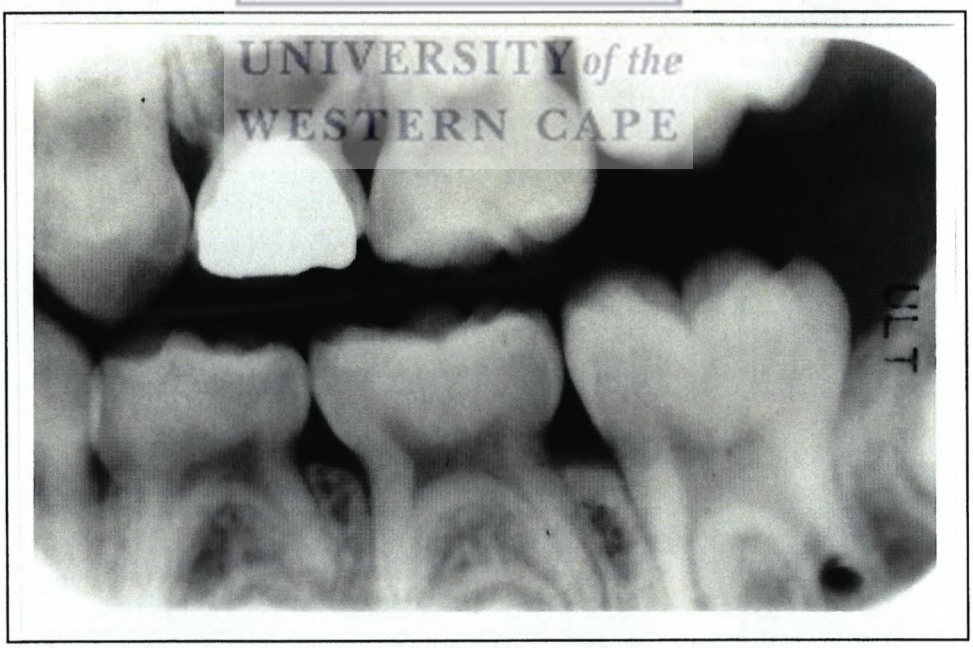
PATIENT G (tooth 55)

Patients F (as seen on page 94) and G (above) are both examples of successful pulpotomies where a zinc oxide-eugenol/ Kalzinol base was placed after a ferric sulfate pulpotomy was performed. Neither of the patients presented with any pain and the restorations were all intact. These cases were therefore clinical and radiographic successes at the 6 and 12-month follow-up periods.

Ferric sulfate pulpotomy utilising a zinc oxide-eugenol/ Kalzinol base III

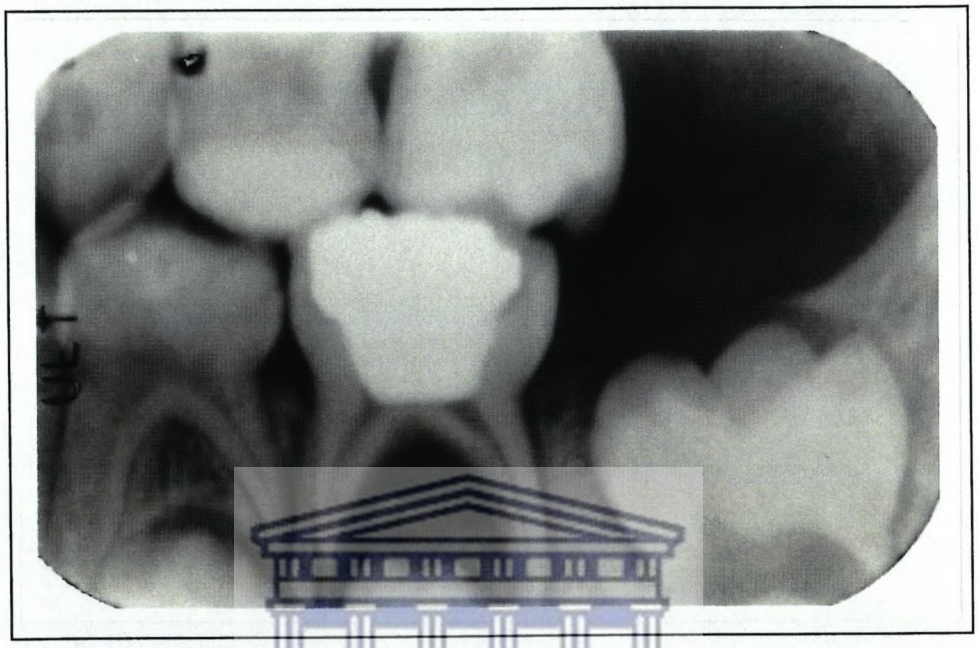


PATIENT H (tooth 64): At the 12-month follow-up visit. The pulpotomy was classified as a clinical and radiographic success.

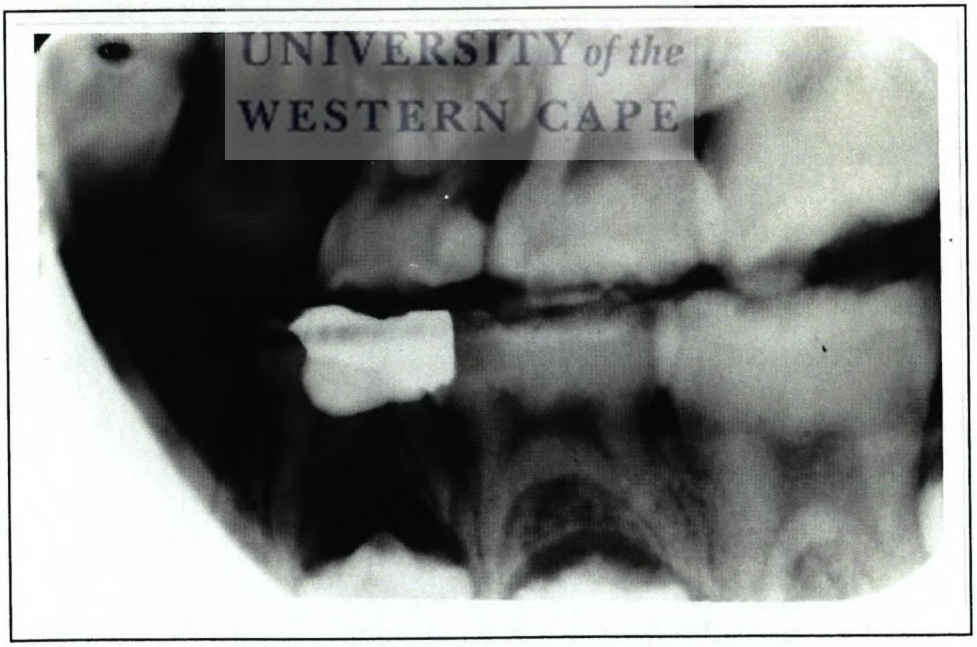


PATIENT H: Seen one year later— a furcal radiolucency is clearly evident on the x-ray. The tooth was still however clinically sound and the patient presented with no pain. From this situation it is clear, that clinical success does not necessarily indicate radiographic success.

Ferric sulfate pulpotomy utilising a zinc oxide-eugenol/ Kalzinol base IV



PATIENT I (tooth 75): At the 12-month follow-up visit. A furcal radiolucency is clearly visible despite the fact that the tooth is asymptomatic. This tooth, as well as the one below (Patient J), was therefore classified as a clinical success but a radiographic failure.



PATIENT J (tooth 74): As is the case in Patient I, a furcal radiolucency was also visible at the 12-month follow-up visit. This case however appears to be worse. The reason for this could be the fact that the tooth is starting to exfoliate. The permanent successor is visible on the x-ray.

CHAPTER 4
DISCUSSION

4.1. DISCUSSION

Until recently, the standard pulpotomy treatment was the 5-minute formocresol devitalisation pulpotomy which partially mummified the pulp tissue. This technique replaced the initial multiple visit technique, which resulted in complete mummification of the pulp tissue. However, due to the proven toxicity of formocresol, the popularity of this technique has waned [6, 3, 7, 4, 1, 19].

Ferric sulfate has been suggested as a less toxic pulpotomy agent and it is gaining popularity worldwide. A number of studies have confirmed the success of this method [6, 7, 4, 14, 15]. Success rates of the ferric sulfate pulpotomy were similar to those achieved with the formocresol pulpotomy [6, 9, 4].

Ferric sulfate was originally developed for a calcium hydroxide base as it was thought that the prevention of clot formation with the aid of ferric sulfate would increase the chances of success of this type of pulpotomy. It is also thought that the metal protein clot which is formed over the pulpal stumps protects the pulp from the irritating effects of the base which is placed over it [15].

In pulpotomy procedures, zinc oxide-eugenol cement is the most commonly used base material. It has however been shown to cause a moderate to severe inflammatory response with resulting chronic inflammation and necrosis [6, 15, 21, 64, 38, 80].

The choice of base is thought to influence the pulpal response. Calcium hydroxide and zinc oxide-eugenol have both been used in separate studies but have never been compared. The purpose of the present study is to compare the success rate obtained when

applying one or the other of these two bases following a ferric sulfate pulpotomy. Kalzinol is an example of a zinc oxide-eugenol cement which was used in this study and Dycal is the calcium hydroxide preparation which was used.

Instead of the usual zinc oxide-eugenol base, Vitrebond was used as a lining over the calcium hydroxide. The reason behind this was to eliminate the potential irritating effect of the zinc oxide-eugenol, making it possible to compare a Dycal base to a Kalzinol base. Vitrebond is a light-cured glassionomer base with good properties. It can be easily applied and could serve to seal the pulp, thereby preventing microleakage and stimulating reparative dentine formation.

4.1.1. Observations

Ferric sulfate pulpotomies utilising a zinc oxide-eugenol (Kalzinol) base

The putty-like consistency of Kalzinol made it easy to manipulate and easy to place. It could be compressed gently into the pulp chamber with the aid of a damp cotton pellet. The technique was quick and this was an added advantage, especially in the treatment of difficult children. Thus, in children who displayed poor cooperation, this placement technique was favoured. It was also favoured in cases where access and visibility was limited.

Ferric sulfate pulpotomies utilising a calcium hydroxide (Dycal) base with a Vitrebond lining.

The pulpotomy procedure in which Dycal was used, was more labour intensive and technique sensitive. Dycal adhered with difficulty to the exposed pulp and it was generally more difficult to place. The procedure took much longer because the Dycal did not stay where it was placed and often had to be re-applied. Bleeding often re-occurred, making another application of ferric sulfate necessary. This resulted in increased trauma to the pulpal tissue. The longer treatment time also meant that there was a greater chance of bacterial and/ or saliva contamination.

Vitrebond was chosen over Vitremer (3M Dental Products) as the glassionomer lining because it is not as viscous as Vitremer and is easier to place. Vitremer has a thick, sticky consistency and is difficult to handle.

The Vitrebond layer which was placed over the Dycal took up a lot of space, often leaving little room for the amalgam. This was especially difficult in the smaller teeth. This could possibly make the amalgam restoration more susceptible to fracture.

On the whole, the calcium hydroxide pulpotomies were more demanding. This was also a finding in the literature [4].

4.1.2. Radiographic findings

Pulpotomies with a Dycal base.

Internal and external resorption as well as furcal radiolucencies were the most common radiographic findings indicative of pulp pathology. One case (Patient C as seen on pages 78 and 79) presented with severe bone loss. As is thought in many studies [1, 5, 8, 10, 12, 32, 65, 77], this severe reaction could have been due to the questionable prognosis of the pulp at the time of pulp amputation. Pulp canal obliteration was seen in one case but this has been regarded as a sign of success by many authors [7, 16, 32, 67].

Pulpotomies with a Kalzinol base.

Furcal radiolucencies and external resorption were the most common pathological changes observed on the radiographs. The radiographic success for the Kalzinol group was 81.25% after 6 months. This success rate is higher than for the Dycal group which demonstrated a radiographic success rate of 50% after 6 months. As was demonstrated in other studies [8, 53], the radiographic successes of the calcium hydroxide pulpotomy procedure seldom exceeded 60%.

4.1.3. Clinical findings

Pulpotomies with a Dycal base.

More often than not, these pulpotomies failed within 6 months of the initial procedure. This is in agreement with Sawusch [44] who noted that most calcium hydroxide pulpotomies failed within a 6 to 12-month follow-up period. A large number of patients presented with pain and sinus formation was very common. Sinus formation was evident in 46.15% of these patients at the 6-month follow-up visit and 38.46% presented with pain. These symptoms invariably meant that the pulpotomised tooth would be destined for either root canal treatment or extraction.

Pulpotomies with a Kalzinol base.

Besides the occasional gumboil, these pulpotomies were generally more successful than pulpotomies in which a Dycal base was placed. The clinical success rate for the Kalzinol group was 94.74% at the first follow-up visit. At 6 months, the Kalzinol pulpotomy performed considerably better than the Dycal pulpotomy which demonstrated a 53.58% success rate.

As discussed previously in section 1.4, clinical success does not necessarily indicate radiographic success.

In this study, patients were to be followed up every 6 months for a period of a year (ie. 2 follow-up visits) or until the treated teeth exfoliated. After 12 months, a large number of the teeth had exfoliated and many patients failed to return for their follow-up appointments. Cases that failed after 6 months were also excluded from the study. This meant that the sample that remained was not large enough to be subjected to a meaningful statistical analysis.

In cases where the pulpotomised teeth had exfoliated, no enamel defects were visible on the permanent successors. Of the patients who did return after 12 months, a greater number of successes were recorded in the Kalzinol group.

4.1.4. Reasons for failure of pulpotomies

- The pulpotomy procedures in which Dycal was used were generally more difficult to execute.
- Poor patient cooperation.
- Poor moisture control.
- Dycal does not permit a gentle pulpotomy technique.
- Teeth often had a questionable prognosis.

4.1.5. Difficulties encountered in this study

The suggested sample size (protocol) was not achieved in this study due to various reasons. These included:

- The time-period over which the patients had to be followed up was one year. It takes a long time to get a sample size that is reliable and that can be followed up regularly.
- Patient unreliability with regards to keeping appointments.
- A large number of patients could not be tracked down, either due to a change of address and/ or telephone numbers and quite a few patients were not interested in further treatment.
- Poor patient pool: The patients who seek dental care at the University of Stellenbosch's School of Oral Health Sciences are often not the ideal patients for pulpotomy procedures as most patients come when they have an emergency or the teeth are often too far gone and cannot be saved. The patient compliance with regards to oral hygiene is also poor and relapse after treatment (including treatment under general anaesthesia) is common.
- Patients tend not to return for treatment once the pain has been relieved.
- On the whole, patients in this study were very young. Even if x-rays could be taken in theatre, they often did not comply when x-rays had to be taken at the follow-up visits.

These factors threw out the follow-up period completely and since radiographic evaluation was part of the protocol, results were influenced.

4.2. CONCLUSION

As was demonstrated in other studies [4, 9], calcium hydroxide pulpotomies in general are not very successful, even when haemostatic agents like ferric sulfate are used to try and prevent clot formation. Ranly [6] also suggested that the passive barrier formed by the ferric sulfate could possibly protect the pulp from the irritating effect of the subbase placed over it. However, this assumption was not supported by the results of this study.

Unlike formocresol, ferric sulfate does not have fixative properties and the base placed over the pulpal tissue seems to play an important role in the outcome of this type of pulpotomy procedure. Overall, success rates were higher in teeth that received a Kalzinol base as opposed to those in which Dycal was used.

The ferric sulfate pulpotomy technique described in this thesis using a Dycal base and Vitrebond lining cannot be recommended for the treatment of cariously exposed primary teeth. Even though the zinc oxide-eugenol base is also not ideal due to its irritating effect on pulpal tissue, it is still preferable to a Dycal base covered by a Vitrebond lining.

The success of pulpotomy procedures can be improved by:

- using a gentle placement technique (amputation and application of the medicament) and
- maintaining an aseptic field (which is not always possible in children).

Casas et al. [90] stated that: "Future investigations of the ferric sulfate pulpotomy would benefit from the use of alternative base materials that do not stimulate internal resorption."

Ideally, materials should not interfere with the exfoliation of primary teeth nor should they adversely affect the eruption of the permanent successors. An effective pulpotomy medicament must be physiologically compatible with both the pulp and the surrounding tissues and must result in clinical and radiographic success.

At present, it seems as though the ideal pulpotomy dressing material has still not been found and pulp therapy is likely to remain a contentious issue for many years to come. The quest continues.....

APPENDIX A

SIFTINGSVORM / SIFTING FORM

SLEGS VIR KANTOOR GEBRUIK / FOR OFFICE USE ONLY

Hou vir: | Brief | | Afspraak |

1. Hoofklagte.....

2. BEHANDELINGSKLASSIFIKASIE (Slegs ✓ in ☐ waar van toepassing)

2.1 ☐ Groepspraktyk

2.2 ☐ Pedodonsie

2.3 ☐ Verwys Dept.....

2.4 ☐ Nood (a) ☐ Noodvorm (b) ☐ Pan. Opname

(c) ☐ Binnesmondse opname..... Verwys. brief aangeheg JA ☐ NEE ☐

3. SLEGS VIR GROEPSPRAKTYK PASIËNTE:

3.1 ☐ Herstellend

Geskik vir:
☐ Jun. Stud.
☐ Sen. Stud.

Dui werk benodig aan

(a) ☐ Basiese herstellings

(b) ☐ Gekompliseerde herstellings

(c) ☐ Inlegsels met. ☐ pors.

(d) ☐ Krone

(e) ☐ Brûe

(f) ☐ Endodonsie ☐ ant. ☐ post.

3.2 ☐ Periodonsie (a) ☐ Eenvoudig (b) ☐ Gekompliseerd

3.3 ☐ Mondgeneeskunde

3.4 ☐ Prosteties (a) ☐ Gedeeltelik (b) ☐ Vol

3.5 ☐ K.G.M.....

3.6 ☐ Ortodonsie

4. Toestemmingsbrief nodig Ja ☐ Nee ☐

5. Lid van 'n mediese fonds Ja ☐ Nee ☐

6. Finansiële kategorie 1 ☐ 2 ☐ 3 ☐

Ontvang Ja ☐

Sitingsbeampte.....

Datum.....

NHD

Administrasie: Volksraad
Departement van
Gesondheidsdienste en
Welsyn

Administration: House of Assembly
Department of
Health Services and
Welfare

ORAL AND DENTAL TEACHING HOSPITAL
UNIVERSITY OF STELLENBOSCH
TYGERBERG CAMPUS

Hierdie vorm is ook in Afrikaans beskikbaar.

A	PATIENT'S DETAILS

1. SURNAME: 2. INITIALS: 3. TITLE:

4. DATE OF BIRTH: 5. OCCUPATION:

6. HOME ADDRESS:

7. WORK ADDRESS:

8. POSTAL ADDRESS: 9. POSTALCODE:

10. TEL NO. HOME: CODE: WORK: CODE:

11. MEDICAL AID SOCIETY: 12. MEMBER'S NAME: 13. NO:

B	PARENT OR GUARDIAN'S DETAILS (WHERE APPLICABLE)

1. SURNAME: 2. INITIALS: 3. TITLE:

4. HOME ADDRESS:

5. OCCUPATION:

6. TEL NO. HOME: CODE: WORK: CODE:

APPLICATION FOR TREATMENT

For Office Use		
1	2	3

1. Please read carefully before completing this form.
2. Should you have any queries, please consult the receptionist.

I, ...

(Surname and full names – please print)

the undersigned, do hereby apply for dental treatment for myself / my wife / my child / my dependant at the Oral and Dental Teaching Hospital of the University of Stellenbosch, hereinafter called the "Teaching Hospital".

Full name of patient: .....

Date of birth of patient: .....

I understand and accept the conditions, as set out below, whereby treatment is provided by the Oral and Dental Teaching Hospital of the University of Stellenbosch, namely:

1. That the treatment may be performed by students under the supervision and control of the professionally qualified staff of the Teaching Hospital and with their assistance.
2. That all the treatment deemed necessary by the Head of the Department concerned, should be carried out.
3. That I am responsible for the payment of all fees in respect of the services rendered and materials supplied for each treatment procedure.
4. That the Teaching Hospital reserves the right to verify any information supplied in this form and that should any such information be incorrect, the Teaching Hospital may withhold forthwith any further treatment for myself and / or my dependants.
5. That the Teaching Hospital at its discretion, may at any stage withhold further treatment for myself and / or any of my dependants.
6. (a) That the success of any treatment by a student, or member of the staff of the Teaching Hospital cannot be guaranteed and that such student or member of staff or the University or the State is indemnified against any legal action arising from any treatment performed at the Teaching Hospital.

   (b) That I am aware of the fact that treatment procedures may be carried out by students who are not yet fully qualified and that although every precaution will be taken to ensure the success of any procedure, I accept that such treatment will be undertaken entirely at my risk.

   Should any damage be incurred in consequence of the inexperience or fault of either a student or a member of the staff, I shall not institute any claims against such student or member of staff or the University or the State.

SIGNATURE: .....

Signature of Parent / Guardian if patient is less than 18 years of age.
(Delete the word not applicable).

PARENT / GUARDIAN: ....

DATE: .....

QUESTIONNAIRE ON GENERAL HEALTH
(must be filled in by or on behalf of the patient)

Please answer each question

1. Have you ever been a patient in a hospital or nursing home?.....
2. If so, how long ago?.....
3. For what reason?.....
4. Are you now, or have you been under the care of a doctor in the pas 5 years?.....
5. If so, for what?.....
6. Are you now, or have you been taking medicine for the past year?.....
7. If so please specify:.....

   .....
8. Have you ever taken any of the following medicines? If so, tick the square opposite the medicine and indicate next to for what period:

   Cortisone ☐ _____ Medicine for blood presure ☐ _____

   Anticoagulants ☐ _____ Heart medicine ☐ _____

   Other ☐ _____ Specify_____
9. Are you allergic to any medicine?.....
10. If so, which medicine(s)?.....
11. Have you ever had excessive bleeding requiring special treatment?.....
12. Have you ever had any of the following diseases? If so, encircle the appropriate condition:
    Asthma, chronic cough, diabetes, tuberculosis, jaundice, arthritis, scarlet fever, stroke, angina, porphyria, rheumatic fever.

    Other (specify).....
13. Did you suffer from one or more of the following conditions? If so, please tick the square opposite the condition:

    Fever and nightsweats ☐ Stomach pain and diarrhoea ☐

    Loss of weight ☐ Swelling of glands ☐
14. If relevant: Are you pregnant?.....
15. Have you had hepatitis?.....
16. If so, when?.....
17. Are you aware of any diseas of which you may be a carrier?.....

    .....
18. Have you had any other serious illnesses, excluding the usual children's diseases?.....
19. If so, which?.....

Signature of patient / guardian:.....

Date:.....

APPENDIX B

INFORMED CONSENT

Title of research project: A comparison of two liner materials for use in the ferric sulfate pulpotomy

STATEMENT BY PARENT (On behalf of child patient)

I, the undersigned, _____, of (address) _____

_____

confirm that:

1. I was requested to allow my child to participate in the above-mentioned research project, undertaken by the Paediatric Dentistry division of the School of Oral Health Sciences.

2. It was explained to me that:

   - The aim of the study is to compare two different lining materials used in a procedure where the nerve of the tooth is affected (Ferric sulfate pulpotomy).
   - Both materials are routinely used in everyday dental practice.
   - The purpose of the study is to ascertain which of the two materials is superior.
   - My child will be assigned randomly to one of the two groups.
   - My child will be recalled at six-monthly intervals where radiographs will be taken and that this is standard procedure for all patients treated at the School of Dentistry.
   - No additional costs will be incurred, as both the techniques are standard procedures, which are routinely used at the School of Dentistry.
   - The information obtained from the study is strictly confidential but that the results could be used in articles and presentations at a later stage.

3. I have been informed of the pros and cons of the procedure, namely that:

   - The ferric sulfate pulpotomy has been shown to have a success rate of between 96 and 100%.

- This procedure is a way of trying to maintain the tooth for a longer period of time, thereby preventing problems such as loss of space.
- If a pulpotomy is not performed, the treatment of choice is an extraction of the tooth with resulting space loss.
- There is a chance that the pulpotomy procedure might fail and that the treatment options would then include root canal therapy or extraction of the tooth.

4. I was informed that there will always be a doctor on hand if an emergency should arise. (**Dr. N. Mohamed** – tel: 9373056/7 or 9373073 [W]; 6374424 [H]; 083 2705 105 [cell]).

5. The above information was explained to me in English/ Afrikaans by _____. I was given the opportunity to ask questions and my questions were answered satisfactorily.

6. It was explained to me that there was no compulsion on my part to allow my child to be a part of this study, and that should I refuse, such refusal would have no influence on future treatment or rights that I / the patient would normally enjoy.

I voluntarily agree to allow my child, _____ to participate in the above-mentioned study.

Signed at _____ on _____ 20

_____ _____

Parent Witness

INGELIGTE TOESTEMMING

Titel van navorsingsprojek: 'n Vergelyking van twee basis materiale vir gebruik in die ferrisulfaat pulpotomie

VERKLARING DEUR OUER (Namens kinderpasiënt)

Ek, die ondergetekende, _____, van (adres)

_____

bevestig dat:

1. Ek gevra is om my kind toe te laat om aan die bogenoemde studie deel te neem, wat deur die afdeling Pediatriese Tandheelkunde van die Skool vir Mondheelkunde onderneem word.

2. Dit is aan my verduidelik dat:

   - Die doel van die studie is om twee verskillende basis materiale te vergelyk in 'n prosedure waar die senuwee van die tand aangetas is (ferrisulfaat pulpotomie).
   - Albei materiale gewoonweg in alledaagse tandheelkundige praktyk gebruik word.
   - Die doel van die studie is om vas te stel watter een van die twee materiale beter is.
   - My kind lukraak aan een van die twee groepe toegeken sal word.
   - My kind elke ses maande teruggeroep sal word vir 'n opvolgafspraak waartydens radiografiese opnames geneem sal word en dat dit standaard prosedure is vir alle pasiënte wat by die Skool vir Mondheelkunde behandel word.
   - Omdat albei prosedures standaard prosedures is wat gewoonweg by die Skool vir Mondheelkunde gebruik word, daar geen addisionele kostes daaraan verbonde sal wees nie.
   - Die inligting verkry vanuit hierdie studie streng vertroulik is en dat die resultate wel op 'n latere stadium in artikels en voordragte gebruik kan word.

3. Die voor- en nadele van die prosedure is aan my verduidelik, naamlik:

   - Die kanse van sukses van die ferrisulfaat pulpotomie tussen 96 en 100% is.
   - Hierdie prosedure is 'n manier om die tand vir 'n langer periode in the mond te behou en op so 'n wyse, probleme soos spasieverlies, uit te skakel.
   - Indien 'n pulpotomie nie uitgevoer word nie, is die behandeling van keuse ekstraksie van die tand met gevolglike spasieverlies.
   - Daar is 'n kans dat die pulpotomie prosedure onsuksesvol kan wees en dat die behandelingsopsies dan wortelkanaalterapie of ekstraksie van die tand sal insluit.

4. Ek was ingelig dat daar altyd 'n dokter beskikbaar sal wees in 'n noodgeval. (**Dr. N. Mohamed** – tel: 9373056/7 or 9373073 [W]; 6374424 [H]; 083 2705 105 [sel]).

5. Die bostaande inligting is in Engels/ Afrikaans aan my verduidelik deur _____. Ek is die geleentheid gegee om vrae te vra en al my vrae is bevredigend beantwoord.

6. Dit is aan my verduidelik dat ek nie verplig is om my kind toe te laat om deel te wees van hierdie studie nie en dat, indien ek weier, dit geen invloed sal hê op toekomstige behandeling of regte wat ek/ die pasiënt normaalweg sou geniet nie.

Ek stem vrywilliglik in om my kind, _____ toe te laat om deel te neem aan die bogenoemde studie.

Geteken te _____ op _____ 20

_____ _____

Ouer Getuie

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