

COMPARISON OF ELECTROSURGICAL AND FORMOCRESOL
PULPOTOMY PROCEDURES

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Submitted to the Graduate Faculty of the School of Dentistry
in partial fulfillment of the requirements for the degree of
Master of Science in Dentistry, Indiana University School
of Dentistry, 1997.

Thesis accepted by the faculty of the Department of Oral Facial Development, Section of Pediatric Dentistry, Indiana University School of Dentistry, in partial fulfillment of the requirements for the degree of Master of Science in Dentistry.

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ACKNOWLEDGMENTS

I dedicate this to my family. Their encouragement and guidance through life have made my many dreams become realities. Thank you for always being there and believing in me. I love you all.

I wish to thank the faculty and staff of Riley Dental Clinic and the Department of Oral Facial Development at Indiana University School of Dentistry for allowing me to further my dental education.

I would like to especially thank Dr. Jeffrey Dean, Dr. David Avery, Dr. Brian Sanders, Dr. Susan Zunt, and Dr. Joseph Legan for their participation on my graduate committee.

I extend my appreciation to Dr. Dean for his guidance, patience, and the time he dedicated to helping me through this project. It has been a valuable experience.

A special note of thanks goes to Birtcher Medical Systems for supporting this research project and donating the funds and equipment to make this possible.

I would like to thank George Eckert for analyzing the data and Dr. Ronald Mack for his contributions to this project.

To my wife, Kelly, thank you for your patience and understanding through this project. To my daughter, Emily, the sky is the limit. Your goals are reachable with confidence, hard work, and trusting in the Lord. I love you both very much.

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INTRODUCTION

There have been many pharmacotherapeutic agents employed to achieve successful pulpotomies in primary teeth. The use of formocresol, calcium hydroxide (CaOH), glutaraldehyde, ferric sulfate, and zinc oxide-eugenol (ZOE) have been used as pulpotomy agents, but with variable success. The use of formocresol as a pulpal medicament was first introduced by Sweet¹ in 1954 and has since been a popular agent of choice for use in the pulpotomy procedure, mainly because of ease in use and excellent clinical success. Surveys suggest that the formocresol pulpotomy in primary teeth is considered the treatment of choice in a majority of pediatric dentistry departments in North America.² Even though this pharmacologic agent is commonly used and produces very successful results, there are several animal studies that show that formocresol, or one of its metabolites, is apparent outside the tooth locally or systemically.³⁻⁸ The concern over the systemic distribution of formocresol and its potential for toxicity, allergenicity, carcinogenicity, and mutagenicity have led investigators to search for a safe and effective agent to be used in the pulpotomy procedure. The current trend is in reducing the toxicity of the standard drugs or finding new biocompatible agents.⁹ Any pulpotomy medicament or treatment used today to supplant the formocresol technique must be supported by well-documented evidence that the technique is effective, nonmutagenic, nonimmunogenic, and nondiffusible from the pulp canals.¹⁰

The development of a safe and effective nonpharmacologic technique, such as electrosurgery, would eliminate the need for the use of chemotherapeutic agents to achieve hemostasis during pulpotomy procedures. This research is

designed to compare the clinical and radiographic results of the electrosurgical and formocresol pulpotomy technique used on human primary molar teeth requiring pulp therapy after carious involvement. The hypothesis of this study is that clinical and radiographic success rates for the electrosurgical pulpotomy technique will be comparable to the clinical and radiographic success rates for the formocresol pulpotomy technique in human primary molars. With the use of a nonpharmacologic technique, concerns regarding the toxicity of chemotherapeutic agents used in the pulpotomy procedure can be eliminated.

REVIEW OF LITERATURE

The primary indication for a pulpotomy in primary teeth is infected coronal pulp tissue with healthy, vital radicular tissue, or affected but still vital tissue with no irreversible infection, by clinical and radiographic criteria. The 1995-1996 American Academy of Pediatric Dentistry Guidelines for Pulp Therapy for Primary and Young Permanent Teeth describe the pulpotomy procedure in primary teeth as amputation of the coronal portion of the affected or infected dental pulp, to preserve the vitality and function of all or part of the remaining radicular portion of the pulp.¹¹ Successful therapy requires that:

1. the vitality of the majority of the radicular pulp is maintained;
2. there are no prolonged adverse clinical signs or symptoms such as prolonged sensitivity, pain, or swelling;
3. no radiographic evidence is present of internal resorption or abnormal canal calcification;
4. no breakdown of periradicular supporting tissues has occurred and;
5. no harm has been done to succedaneous teeth.

Many pharmacotherapeutic agents have been employed to meet the above criteria when performing pulpotomies on primary teeth. Ranly,¹² in 1982, stated that the cells of the primary pulp are designed to provide resorption and are very easily stimulated toward that end. He said an ideal agent would fix the coronal pulp sufficiently to sterilize, detoxify, suppress metabolic activity, and inhibit autolysis without a continual devitalization of the radicular tissue. As mentioned earlier, formocresol has been a popular agent of choice for use in the pulpotomy procedure. Other medicaments, such as CaOH, glutaraldehyde,

ferric sulfate, and freeze-dried bone have been suggested as possible replacements for formocresol. Success rates have been variable depending on the agent used and the particular study; however, it is clear that additional research is required into the use of these and other pharmacotherapeutic agents.

The formocresol pulpotomy was first introduced in 1954 by Sweet¹ and since has been revised.^{13,14} Formocresol is thought to reduce post-endodontic pain, mummify residual pulpal tissue, and reduce the inflammatory reaction. Formocresol has been advocated in endodontic therapy to achieve canal sterilization, but studies have shown formocresol's action to be bacteriostatic.¹⁵ Buckley's formula is the most accepted and widely used formocresol in dentistry today. The formula contains 19-percent formaldehyde, 35-percent cresol and 15-percent glycerine, and water.¹⁶

Formaldehyde, the simplest form of the aldehydes, is a gas produced by the incomplete combustion of methanol. In aqueous solution, formaldehyde is known as formalin. When formalin is diluted, the paraformaldehyde is redissolved into aqueous formaldehyde. The action of formaldehyde on the pulp is to prevent autolysis of tissue. This is accomplished by the chemical bonding of formaldehyde with proteins of the microorganisms found in the pulp. Glycerin is added to lessen the polymerization of the paraformaldehyde, which causes a "clouding" and results in less formaldehyde being present.¹⁶ Cresol is a caustic and pungent organic compound that destroys cellular integrity and homogenizes the pulp. Cresol is not a fixative, but a strong disinfectant.¹⁷

Despite its long-term use and tremendous success rate, there has been much scrutiny over the use of formocresol in dentistry. Concerns regarding the systemic distribution of this agent and its potential for toxicity, allergenicity, carcinogenicity, and mutagenicity have led to additional research investigations into possible options. Formocresol has been shown to produce irreversible

damage to connective tissue and delays recovery of normal biological activities of affected connective tissue cells in rats. Formaldehyde alone alters the blood flow in the pulp and induces thrombus formation causing ischemia. The ischemia causes autolytic changes and coagulation necrosis resulting in deprivation of normal nutrients and respiration to the tissues.¹⁶ Local effects have been implied when treating primary molars with formocresol, including defects in the enamel on the succedaneous tooth.^{1,18}

The systemic distribution of formocresol in animals has been demonstrated in the vascular system after formocresol's use as a pulpotomy medicament. Also, formocresol has been found in the dentin, the pulp, and the urine.⁷ According to a literature review by Judd and Kenny, the breakdown of formocresol occurs mainly in the liver, but breakdown products have been noted in erythrocytes, the kidneys, the lungs, and the brain.¹⁹ In another review by Sipes and Binkley, findings show that formocresol cannot be confined to the dental pulp. The degree and extent of changes are dependent on the dose of formocresol used, because it is transported via the blood vessels. Therefore, it has been recommended that the dose of formocresol be reduced to one-fifth because the incidence of deleterious effects will be decreased, without diminishing the effectiveness in tissue fixation.¹⁵

Formaldehyde is a toxic molecule that elicits a cellular and humoral immune response.¹⁵ Toxic levels of formocresol have been shown to produce cardiovascular alterations and histologic changes in the heart, kidney, liver, and lung tissues of dogs.⁶ It is an intermediate metabolite in the mammalian biosynthesis of purine, thymine, histidine, and serine and is metabolized to formic acid, carbon dioxide, and other metabolites involved in amino acid formation.¹⁹ Therefore, the most susceptible organ for potential injury is the kidney.¹⁹ The cells and tissues of the young are generally more prone to

chemical effects than those of adults due to developmental stage. Concerns regarding allergenicity with formocresol have been noted. Patients being treated for or diagnosed with eczema are routinely screened for formocresol sensitization.¹⁹ In 1946, formaldehyde, a component of formocresol, was found to possess mutagenic properties.¹⁵ The Federal Panel on Formaldehyde¹⁵ stated that this compound should be regarded as possessing a carcinogenic risk to humans. The interaction of formocresol with genetic material of cells has shown the potential for carcinogenic and mutagenic changes.¹⁹

Formaldehyde is thought to be an initiator and a promoter, in that it has the capacity to damage DNA. This can lead to neoplastic transformation and cause cellular toxicity and regenerative proliferation with a promotional effect on carcinogenesis.¹⁹ Formaldehyde has produced mutations in human lymphoblastoid cells²⁰ and causes an increased rate of cell turnover in respiratory mucosa.²¹ Swenberg, et al.²² demonstrated that the vapor from formaldehyde will induce nasal squamous cell tumors in rats, and that long-term contact with formocresol is capable of transforming the epithelium into precancerous and cancerous states. The evidence that formocresol has the potential for human carcinogenic risk has been proven with animal bioassay models.¹⁹ Therefore, mutagenicity and carcinogenicity must be considered when using formocresol, even though the risk is incalculable. The relative toxicity is probably minor, if one considers the small quantity used in the pulpotomy technique.

Several studies have evaluated the clinical, radiographic, and histologic success of the formocresol pulpotomy technique. In 1965, Berger, et al.¹⁶ evaluated the reaction of formocresol and ZOE histologically, radiographically, and clinically when used for treatment of cariously exposed pulp tissue of primary teeth. Pulpotomies were performed on 52 primary molars of 40 children. The teeth were treated with a five-minute formocresol application and

then with either ZOE or a ZOE paste with formocresol was placed over the pulpal orifice. Then the teeth were restored with an alloy. Selection criteria consisted of primary teeth with a carious pulp exposure without clinical evidence of degeneration, no more than one-fourth of root resorption present, and vitality as defined by hemorrhaging.¹⁶ Histologically, three weeks after the formocresol treatment, the tissue appeared compressed and well-defined in the coronal aspect. Complete absence of cellular detail was noted in the apical third. By the seventh week there was an ingrowth of granulation tissue through the foramen that was replacing the necrotic tissue in the pulp canals. At 38 weeks the granulation tissue appeared to progress coronally up to the amputation site. Osteodentin was found lining the canal walls. The teeth treated with ZOE presented with active inflammation and internal resorption. The success rate histologically for formocresol was 82 percent. The radiographic success rates for formocresol and ZOE were 97 percent and 58 percent, respectively. This study shows that formocresol can be used as a pulpotomy agent with anticipation of good results. It is apparent in this study and others that ZOE produces persistent inflammation when in contact with pulp tissue and should not be used as an agent for pulpotomies.^{16,23}

Rolling, et al.²⁴ evaluated the state of the pulp of 19 primary molars that had been treated with formocresol and been determined to be successful clinically and radiographically for a period of three to 24 months. The aim was to establish a relation between the pulpal condition on a short-term and a long-term basis. The criteria used to identify a tooth needing a pulpotomy was the exposure of a vital pulp after excavation of caries, no periradicular pathology, and the ability to restore. The results indicated that pulpal changes occurred in all teeth ranging from acute to chronic inflammation, osteodentin formation along canal walls, and necrosis. Rolling considers the formocresol

method only a means to keep primary teeth functioning for a limited period of time.

Fenton and Rapp²⁵ evaluated the effects formocresol had on the vasculature of primary pulp tissue in the *Macaca rhesus* monkey. The researchers performed the conventional five-minute formocresol pulpotomy on 12 teeth and extracted them 84 days postoperatively. The results indicated perfused arterioles and venules in the pulp canal with poor differentiation at the apical portion due to close proximity of the vessels. The venules were located centrally and appeared larger than the arterioles with good drainage. The arterioles were located along the lateral walls of the pulp near the periphery, and a joining of the arterioles and venules by capillary plexuses was noted. It was concluded that the vascularity of the pulp tissue was not altered by the use of formocresol.

Another chemotherapeutic agent that has been investigated is CaOH. It is considered a safe drug in comparison with formocresol. The rationale for using CaOH for a pulp dressing in the primary dentition is that it is more biologically sound and promotes reparative dentin formation and physiologically sound roots.¹⁷ It was the first agent to demonstrate the capacity to induce regeneration of bone.⁹ A concern about CaOH is that the high pH wounds the pulp and permits the reparative process to begin, but the stimulus evoked is balanced between one of healing and one of resorption.⁹ Magnusson, et al.²⁶ investigated the clinical and histologic effects of CaOH paste as a wound dressing. The results showed that the agent caused a destructive process, which was usually internal root resorption. Doyle¹³ reported that the histologic success rate when comparing calcium hydroxide to formocresol was 50 percent and 92 percent, respectively. The hard setting preparations of calcium hydroxide have been recommended, because it releases fewer hydroxyl ions and is gentler to the pulp. Heileg,²⁷ in 1984, used Life, a hard setting CaOH, as a pulpotomy agent. The

results were encouraging, but the study lacked sufficient numbers and was too short-term to be considered legitimate in comparing the efficacy of the hard-setting preparation to the conventional CaOH.

In 1978, Schroder²⁸ performed pulpotomies on primary teeth using CaOH. The success rate was between 38 and 59 percent after two years. The most frequent complication seen in this study was internal resorption below the amputation site. This commonly occurred within the first six months. Schroder attributes the low success rate to leaving a blood clot on the wound surface and recommends taking steps to improve the technique, so that CaOH can be applied to a wound surface free of blood clots. Despite the desirable properties of CaOH, it often results in internal root resorption, and use cannot be recommended pulpotomies in the primary dentition. However, CaOH continues to be the medicament of choice in the permanent dentition.¹⁷

Another pharmacological agent used for pulpotomies is glutaraldehyde. It is a fixative used for electron microscopy, cytochemistry, and sterilization of surgical equipment and instruments.²⁹ Glutaraldehyde has also been used in human aortic valve implants due to a perceived ability to reduce antigenicity. Gravenmade³⁰ suggested the use of glutaraldehyde as a pulpotomy agent because of its bactericidal effects and because its fixative properties are less destructive than those of formocresol. Glutaraldehyde has the ability to establish intramolecular/intermolecular protein bonds of a macromolecular size, and this cross-linking of protein chains should prevent a recurrence of inflammation.

Kopel, et al.³¹ examined the reaction of the radicular pulp to glutaraldehyde in 30 children with carious primary molars indicated for a pulpotomy. The teeth were treated with 2-percent glutaraldehyde mimicking the five-minute formocresol technique and then evaluated at five minutes, one week, and at one, three, six, and 12 months. The histologic results showed the

replacement of the fixed tissue at the amputation site with connective tissue and the formation of osteodentin along the canal walls. The remaining pulp tissue was judged to be vital. The results would suggest that glutaraldehyde is an acceptable medicament for maintaining vitality in pulpally treated teeth.

van Velzen and van den Hooff³² concluded in their 1977 study that the aging process of the pulp tissue occurring from the use of glutaraldehyde is probable, because the fixed tissue is undergoing phagocytosis. This results in collagenous fibers being formed at the amputation site, and the narrowing of the canals is due to the formation of reparative dentin. Dankert, et al.³³ found only minimal diffusion of glutaraldehyde through the apices, and these findings are related to the strong ability of glutaraldehyde to establish intramolecular protein bonds, which reduce its solubility. Even though glutaraldehyde has proved to be successful clinically, the concern for systemic distribution, toxicity, allergenicity, carcinogenicity, and mutagenicity must be investigated before the routine use of glutaraldehyde as a pharmacologic agent can be recommended.

Ferric sulfate, another chemotherapeutic agent, has also been reported in the literature as a possible medicament for treating pulpally involved teeth in the primary dentition. It is used in gingival retraction cord and endodontic surgery because of its hemostatic properties. When ferric sulfate contacts blood, an ion-protein complex forms and seals the cut blood vessels mechanically.³⁴ Landau and Johnson³⁵ reported the use of ferric sulfate in pulpotomized monkey teeth to help control hemorrhage before the application of the pulpotomy agent. It was shown to provide adequate hemostasis with no fixation of tissue.

Fei, et al.³⁴ compared the clinical and radiographic success of ferric sulfate and formocresol as a pulpotomy medicament. Pulpotomies were performed on 83 primary molars. The teeth were divided into two groups, one using 15.5 percent ferric sulfate and the other using the conventional formocresol solution.

The specimens were evaluated at three, six, and 12-month intervals. The results showed that ferric sulfate was 96-percent successful, compared with the 77-percent success rate of formocresol. The initial use of ferric sulfate has proved to be successful clinically, but there is a need for further studies that include histological evaluation before ferric sulfate can be considered an acceptable pulpotomy agent.

Finally, another pharmacologic agent that has been investigated is freeze-dried bone. It is used as a grafting material for osseous defects in periodontal surgery and has been implemented in the fields of orthopedics and oral maxillofacial surgery.³⁶ McClean and Urist³⁷ observed that the proteins in the matrix of bone and dentin contain precursors for inducing bone formation. This has also been proved through clinical and histological studies. The induction of bone formation is from the interaction of freeze-dried bone with the mesodermal cells during the resorptive phase. Because freeze-dried bone acts as a stimulator for osteogenesis and cementogenesis, it would be reasonable to assume that freeze-dried bone would react favorably as a pulpotomy agent (because the pulp and dentin are comprised of mesodermal tissues).^{36,38,39}

Fadavi, et al.³⁶ studied the effect of freeze-dried bone on amputated pulps on 15 primary teeth of monkeys. The histologic results showed a formation of reparative dentin along the canal walls, which suggests an effort by the pulp to heal the area of insult. This also would suggest that freeze-dried bone could be a viable pulp amputation dressing without the dissemination and toxic ramifications of formocresol. The results appear favorable; however, further studies are needed to determine the long-term effects that freeze-dried bone has on the pulp; this study terminated after 12 weeks.

Besides chemotherapeutic agents, the use of nonpharmacologic techniques have been researched, i.e., electrosurgery and laser therapy. The use of lasers is

being implemented into many areas in the field of dentistry. Adrian, et al.⁴⁰ reported the effects of a ruby laser on the dental pulp, and Shoji⁴¹ reported the use of a CO₂ laser on the pulp tissue. The CO₂ laser has several advantages over other lasers. It makes a bloodless tissue incision; it has no mechanical contact with the tissue, provides hemostasis, and reduces bacterial contamination. Pulpotomies were performed on 10 mongrel dogs by using a focused and a unfocused laser beam at different output levels and intervals. The teeth were evaluated immediately after the procedure. Using the unfocused beam with a high output and low-interval period produced adequate charring of the dentin and pulp tissue. The preliminary results of laser therapy are promising, but further studies are needed to determine the effect that lasers have on the pulp and the clinical efficacy of this agent.

The use of electrosurgery as a nonpharmacologic pulpotomy technique has been well-documented and proven to have merit. It is much quicker than the formocresol technique; it is self-limiting; the pulpal penetration is only a few cell layers deep; ES provides good hemostasis and visualization without chemical coagulation, and there is no systemic involvement.⁴² In 1982, Ranly, et al.¹² stated the vital pulpotomy is accomplished by selection of a agent which preserves pulp vitality or promotes repair in contrast to mortal pulpotomy medicaments that deliberately necrotize tissue. The rationale for the electrosurgical pulpotomy is that the affected tissue of the coronal pulp is removed during pulpal amputation, and a layer of coagulation necrosis is caused by the electrosurgical application. This provides a barrier between healthy radicular tissue and any base material placed in the pulp chamber.¹²

Sheller and Morton,¹⁰ in 1987, performed pulpotomies on 11 caries-free human primary teeth using the electrosurgical pulpotomy technique. The teeth selected for treatment were indicated for extraction due to anterior crowding.

The criteria used to define success was histological evidence of viable pulp tissue in the apical third of the root with no inflammation and no clinical symptoms, radiographic changes, periapical involvement, or internal resorption. The clinical and radiographic successes 100 days postoperatively were obtained with 10 teeth, while only seven teeth showed histological success. The histologic results showed acute and chronic inflammation limited to the coronal third of the pulp with reparative dentin being located along the canal walls, and vital pulp tissue found in the apical third. The results from this study show that the electrosurgical technique produces favorable short-term results and can be used for the vital pulpotomy in the primary dentition.

Ruemping, Morton, and Anderson⁴² evaluated the histologic pulp response from the electrosurgical pulpotomy in three *Macaca nemestrina* monkeys and compared the results to the historic formocresol pulpotomy. Specimens were evaluated at one hour, one week, and two months postoperatively. Two months postoperatively the electrosurgical pulpotomy revealed a minimal acute and chronic inflammatory response with a reorganization of fibroblasts apical to the inflammation and the formation of secondary dentin along the canal walls with vital tissue found in the apical third. The evidence of reparative dentin formation suggests an effort by a healthy pulp to heal the area of insult. This is comparable to the histologic results seen with the formocresol pulpotomy and suggests that electrosurgery is a viable pulpotomy procedure without the dissemination and toxic ramifications of formocresol.

In contrast, Shulman, et al.,⁴³ histologically compared the effect on the pulp tissue of electrosurgery and formocresol. Eighty teeth in four *Macaca fascicularis* monkeys with complete caries-free primary dentition were used and were observed at three, 14, 41, and 65 days postoperatively. It was found that

the electrosurgical technique produced pathologic root resorption and periapical/furcal pathology. Shulman, et al. used electrosurgery to remove the coronal pulp tissue and to treat the pulpal stumps. Ruemping, et al.⁴² used mechanical pulp amputation, and then the remaining pulpal stumps were treated with electrosurgery. Problems with excessive production of heat and electricity may have been responsible for Shulman's poor results.

Shaw, et al.⁴⁴ performed electrosurgical pulpotomies in *Macaca nemestrina* monkeys and evaluated the histologic effects up to six months. This study differs from Ruemping, et al.⁴² in that only primary caries-free teeth were used and were evaluated over a longer period of time. These results were compared with the histologic tissue response produced by the conventional formocresol pulpotomy. The specimens were evaluated at postoperative intervals of one hour, three months, four months, five months, and six months. Each specimen was evaluated for the presence of inflammation, fibrosis, dentin formation, necrosis, periapical or furcation involvement, and internal/external root resorption. The histologic success rate for the electrosurgical and formocresol pulpotomy was 84 percent and 80 percent, respectively. The histologic picture, for both treatments, is described as an acute and chronic inflammation limited to the coronal third of the pulp with the formation of reparative dentin and vitality of tissue in the apical third.⁴⁴

Mack and Dean,⁴⁵ in 1993, conducted a clinical and radiographic retrospective study of the electrosurgical pulpotomy technique used on human primary molars in a private practice setting. The study reviewed a total of 164 pulpotomies that were treated with the Hyfrecator 705A set at 12 watts. The clinical and radiographic success rate was 99.5 percent. These findings were compared statistically with a retrospective formocresol study performed by Hicks, et al.⁴⁶ who showed the success rate of formocresol to be 93.9 percent.

This is a statistically significant difference, and the authors concluded that the electrosurgical pulpotomy is a viable technique.

In 1996, Fishman, et al.⁴⁷ evaluated the clinical and radiographic success of ZOE and CaOH, as pulp dressings, after the electrofulguration pulpotomy technique. The teeth were evaluated after one, three, and six months. After six months, the clinical success ranged from 77 to 81 percent, and the radiographic success was 55 to 57 percent for both groups. The results did not compare favorably with other studies. However, the authors did note upon review of pretreatment radiographs that signs of pulpal changes were evident. Perhaps the selection criteria were not properly defined. It was concluded that it was premature to recommend electrosurgical pulpotomies until further studies could be conducted.

Although several studies have investigated the electrosurgical pulpotomy technique, no well-controlled, long-term, human, prospective studies have been performed. Therefore, the purpose of this study is to prospectively compare the clinical and radiographic results of the electrosurgical and formocresol pulpotomy technique used on human primary molar teeth requiring pulp therapy secondary to carious involvement. The hypothesis of this study is that clinical and radiographic success rates for the electrosurgical pulpotomy technique in human primary molars are comparable to the clinical and radiographic success rates for the formocresol pulpotomy technique. By the use of a nonpharmacologic technique, such as electrosurgery, concerns regarding the toxicity of chemotherapeutic agents used in the pulpotomy procedure can be eliminated.

METHODS AND MATERIALS

This research is specifically designed to compare the clinical and radiographic results of the electrosurgical (ES) and formocresol (FC) pulpotomy techniques used on human primary molar teeth requiring pulp therapy secondary to carious involvement. Patients were recruited from the pediatric patient population served by the dental clinic at James Whitcomb Riley Hospital for Children and the Indiana University School of Dentistry. Both clinics are on the medical center campus of Indiana University located in Indianapolis and are part of the section of Pediatric Dentistry. Teeth were selected based upon the following criteria:

- Symptomless, carious or near-carious exposure of the vital pulp.
- No clinical or radiographical evidence of pulpal degeneration.
- Possibility of proper restoration of primary molars.

In addition to the patients meeting the criteria for need of a pulpotomy in a primary molar, additional acceptance criteria were that the study participants or their legal guardians:

- be willing to read and sign an informational letter of consent (Appendix 1);
- provide data regarding their medical history;
- have nothing in their medical history which contraindicates a pulpotomy;
- be willing to submit to periodic clinical and radiographic examination of the pulpotomized tooth (Appendix 2).

All appointments and procedures were performed at the two dental clinic sites at Indiana University. All pulpotomy procedures were performed by the principal investigators and co-investigator, or a clinician who was under supervision by the investigator of this project, to ensure consistency in the two techniques. Human primary molar teeth requiring a pulpotomy procedure secondary to exposure of the coronal tissue were randomly assigned by the flip of a coin to one of the two groups: formocresol (FC group) or electrosurgical (ES group). A subject with more than one tooth requiring a pulpotomy had only one tooth used in the study. Any other teeth from that participant requiring a pulpotomy were not included in the study. Following profound local anesthesia, quadrant rubber dam isolation, and occlusal reduction with a high-speed bur, the caries were removed with a large slow-speed round bur. When pulpal exposure occurred, the roof of the coronal pulp chamber was removed with a high-speed bur. Following this, the coronal pulp was amputated with hand instruments or with the previously mentioned large slow-speed round bur.

In the ES group, a series of large, sterile cotton pellets were placed into the chamber with pressure to obtain temporary hemostasis. The cotton pellets were then removed and the Hyfrecator 705A electrofulguration dental electrode (Birtcher Medical Systems, Irvine, Calif. 92718) was immediately placed slightly above the tissue (i.e., 1 to 2 mm). The Hyfrecator was set at 40-percent power (e.g., 12 watts) using the "high" port only. The electrical arc was allowed to bridge the gap to the first pulpal stump for 1 second followed by a cool-down period of 5 seconds. Heat and electrical transfer was minimized by keeping the electrode as far away from the pulpal stumps and tooth structure as would still allow electrical arcing to occur. This procedure was repeated up to a maximum of three times at each pulpal orifice. Single current applications of 1 second each were performed to each orifice in a rotational sequence to avoid heat build-up in

any one area of the tooth. After each current application, a new large sterile pellet was placed with pressure on the next pulpal orifice to be electrosurgically treated to absorb any blood or tissue fluids before the next current application (e.g., pellet-electrode-pellet-electrode, etc.) When properly completed, the pulpal stumps appeared dry and completely blackened.

For the FC group, gross hemorrhage control was obtained using dry sterile cotton pellets. Then, a sterile cotton pellet moistened with Buckley's formocresol (Sultan Chemists, Inc., Englewood, N.J.) was placed against the pulpal stumps for 5 minutes. If hemorrhage was not controlled, the pulpal stumps were checked and the pulp chamber cleansed and rinsed, then there was a second application of formocresol. If hemorrhage persisted, a pulpectomy was completed and the tooth eliminated from the study. When properly completed, the pulpal stumps were moist but free of hemorrhaging.

For both groups, a reinforced ZOE dressing was placed directly on the radicular pulpal stumps and in the coronal pulp space. The interproximal surfaces were then prepared, and the line angles were beveled and rounded with a high-speed bur. All teeth were then restored with stainless steel crowns. Either a recent preoperative or an immediate postoperative periapical radiographic film was obtained for each of the pulpotomized teeth. These patients were then placed on a six-month recall program. Each tooth was evaluated for clinical success by the investigators at the recall appointment. Clinical success was defined by the absence of pain, abscess, fistula, or excessive mobility.

The radiographs of the teeth in this study were evaluated by three different examiners with no knowledge as to which group the particular tooth was assigned. The examiners selected were full-time pediatric dentistry faculty members at Indiana University. Each pulpotomy was judged a radiographic

success or failure by using criteria such as the presence of a normal periodontal ligament space, absence of pathologic root resorption or canal calcification, and no periradicular radiolucency. The examiners had the option of rating the pulpotomy a success even though a radiographic change was associated with the tooth, if it were deemed by the examiners that the change was not associated with the pulpotomy itself (i.e., resorption secondary to an ectopic eruption) or that the change did not adversely affect the tooth's prognosis for normal retention.

In this study failure rates were determined over the minimum six-month follow-up period for each technique based on the clinical and radiographic exam. The rates (clinical and radiographic) were compared between the two techniques using a Fisher's Exact test.

RESULTS

A total of 50 pulpotomies were performed. There were 25 pulpotomies in each group (i.e., 25 in the ES group and 25 in the FC group.) In the electrosurgical group, the youngest patient at the time of treatment was two years, two months and the oldest was eight years, one month, with a mean treatment age of five years, three months. The postoperative observation time ranged from six months to 31 months, with a mean postoperative observation time of 10 months (Table I). Of the 25 teeth evaluated in the ES group, 17 were normal at the last observation visit; one had undergone normal exfoliation; three had a radiographic change associated with the pulpotomized tooth (either pre- or post-treatment), but they were not considered failures; and four were considered failures. Four failures out of 25 pulpotomized teeth represent a radiographic success rate of 84 percent (Table II). Pre- and postoperative radiographs of a "normal" case at the last visit are shown in Figures 1a, 1b, and 1c. The cases classified as having changes are shown in Figures 2a, 2b, and 2c. Radiographs of the failed cases are shown in Figures 3a, 3b, and 3c.

In the FC group, the youngest patient at the time of treatment was two years, eight months and the oldest was 10 years, six months, with a mean treatment age of 5 years, eight months. The postoperative observation time ranged from five to 25 months with a mean postoperative observation time of 11 months (Table III). The minimum postoperative observation period was six months, but a failure occurred at five months. Of the 25 teeth studied in the FC group, 20 were normal at the last observation visit; two had undergone normal exfoliation, and one had a radiographic change associated with the

pulpotomized tooth (either pre- or post-treatment); however, they were not considered failures. Two were considered failures. Two radiographic failures out of 25 teeth represent a radiographic success rate of 92 percent (Table IV). Pre- and postoperative radiographs of a "normal" case at the last visit are shown in Figures 4a and 4b. The case classified as having a radiographic change is shown in Figure 5. Radiographs of a failed case are shown in Figures 6a and 6b.

In this study, the agreement between examiners was measured using Kappa statistics. Kappa statistics were computed for each pair of examiners and the overall kappa was computed at 0.603, which is interpreted as a substantial agreement between the examiners (Table VII). The ES and FC groups were compared for differences in the percentage of successes using the Fisher's Exact test. The electrosurgical pulpotomy success rate was 84 percent, and the formocresol pulpotomy success rate was 92 percent. There was not a statistically significant difference at the $p < 0.05$ level. Approximate 95 percent confidence intervals were computed for the percentage of successes in the two groups and for the difference in percentage of successes between the groups (Table VIII).

FIGURES AND TABLES

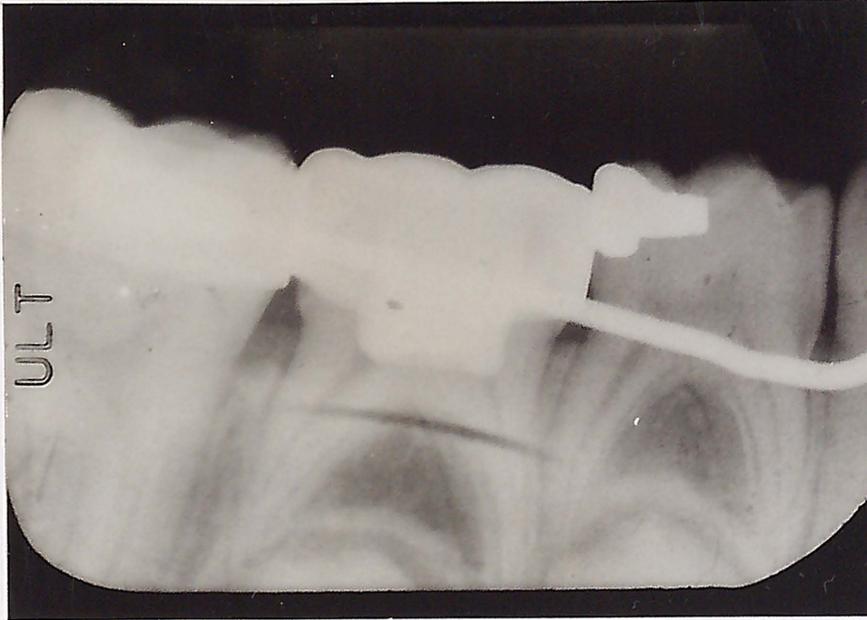


FIGURE 1a. Pre- and postoperative radiographs of an electrosurgically pulpotomized tooth (#T) that was normal at last observation. The pulpotomy was performed at age 8 years, 4 months and the postoperative radiograph was taken at age 10 years, 3 months.





FIGURE 1b. Pre- and postoperative radiographs of an electrosurgically pulpotomized tooth (#K) that was normal at last observation. The pulpotomy was performed at age 4 years, 6 months and the postoperative radiograph was taken at age 6 years.





FIGURE 1c. Pre- and postoperative radiographs of an electrosurgically pulpotomized tooth (#L) that was normal at last observation. The pulpotomy was performed at age 3 years, 1 month and the postoperative radiograph was taken at age 3 years, 11 months.



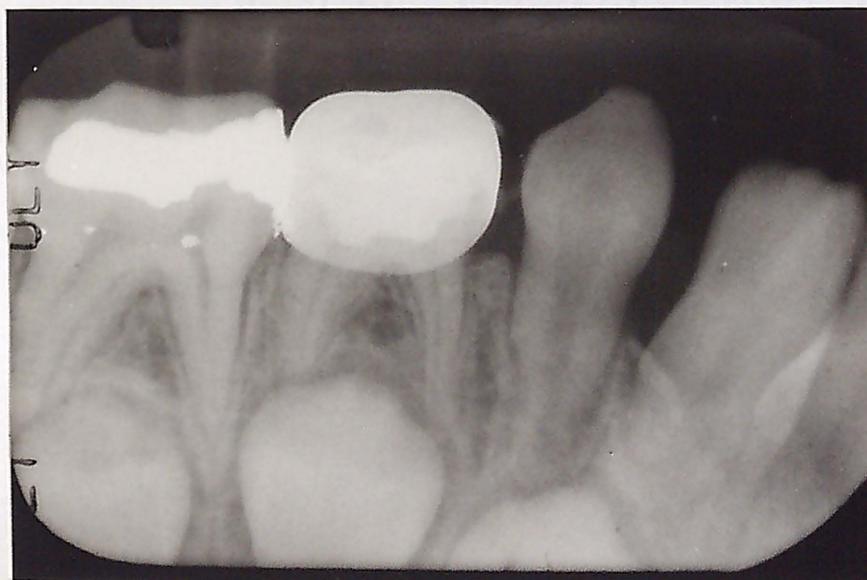


FIGURE 2a. Tooth (#J) has distal root resorption due to ectopic eruption of the maxillary first permanent molar.





FIGURE 2b. Tooth (#5) had exudate present around the gingival margin of the stainless steel crown.



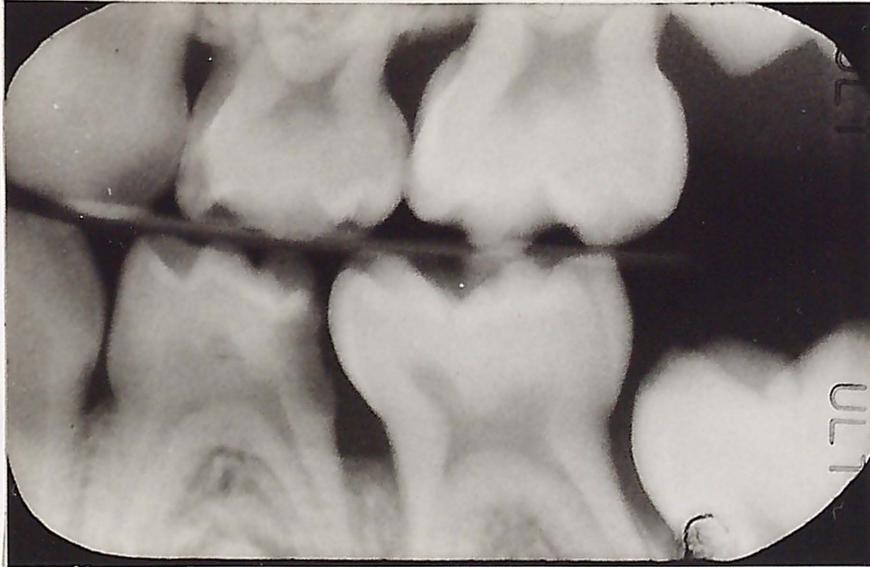
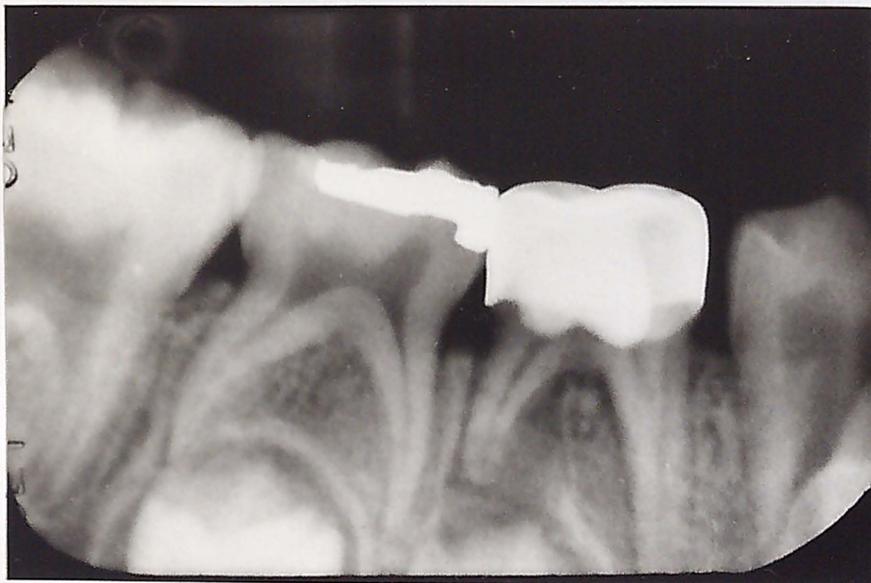


FIGURE 2c. Tooth (#L) had a poorly adapted crown.





FIGURE 3a. Tooth (#S) has distal root pathology.



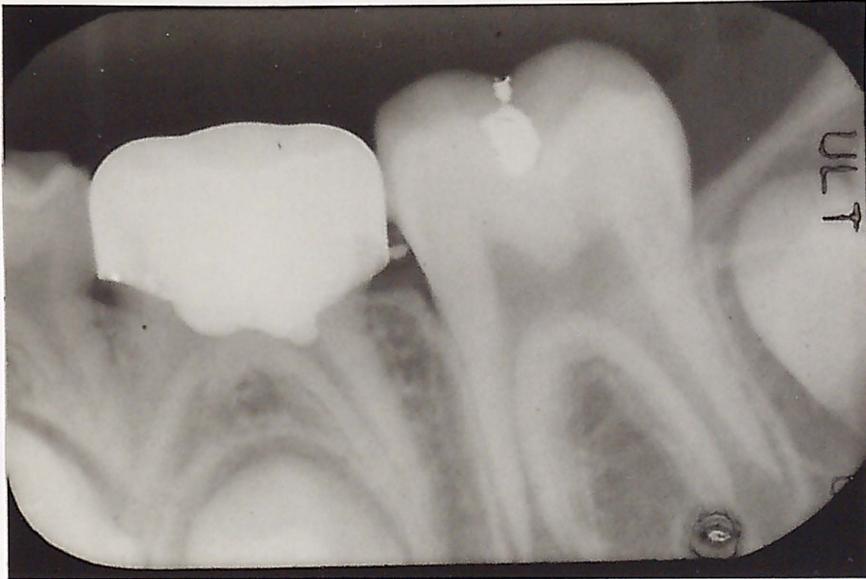


FIGURE 3b. Tooth (#K) has undergone internal resorption.

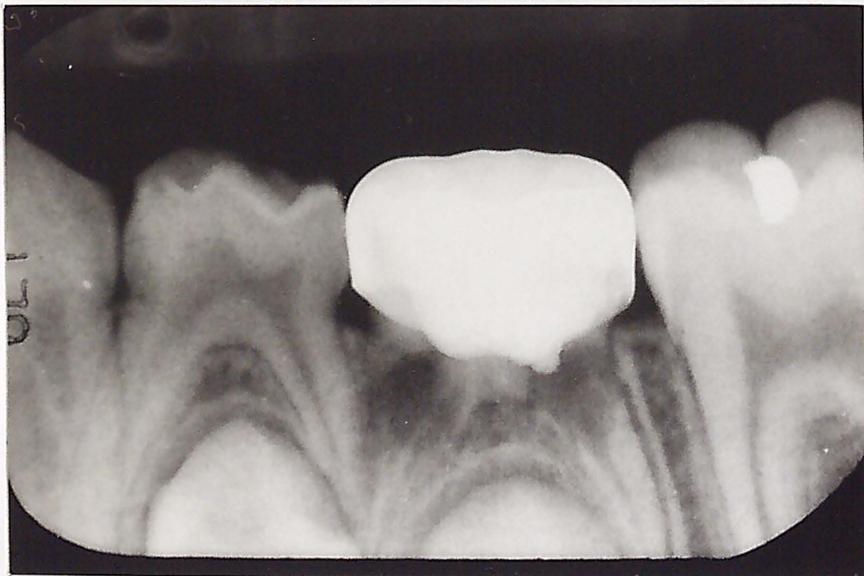




FIGURE 3c. Tooth (#K) has undergone internal resorption.





FIGURE 4a. Pre- and postoperative radiographs of a formocresol pulpotomized tooth (#S) that was considered normal at last observation. The pulpotomy was performed at age 4 years, 5 months and postoperative radiographs were taken at age 4 years, 11 months.





FIGURE 4b. Pre- and postoperative radiographs of a formocresol-pulpotomized tooth (#B) that was considered normal at last observation. The pulpotomy was performed at age 8 years, 3 months and postoperative radiographs were taken at age 9 years, 4 months.



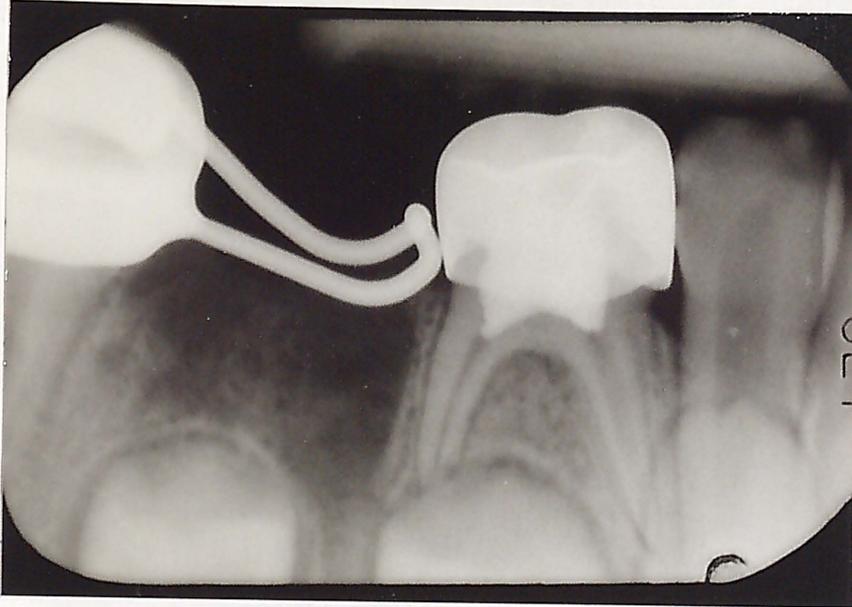


FIGURE 5. Tooth (#5) had exudate present around the stainless steel crown.

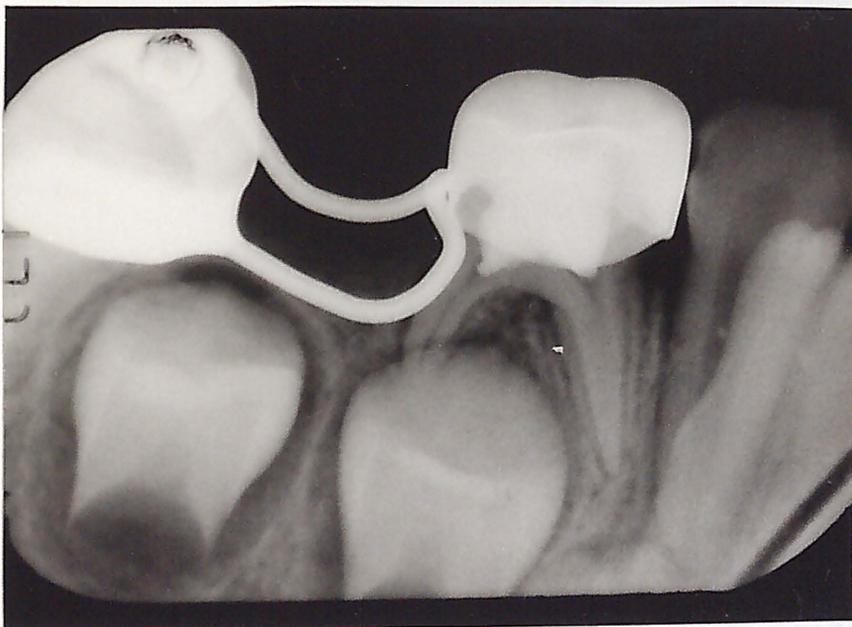




FIGURE 6a. Tooth (#T) is undergoing mesial root resorption.

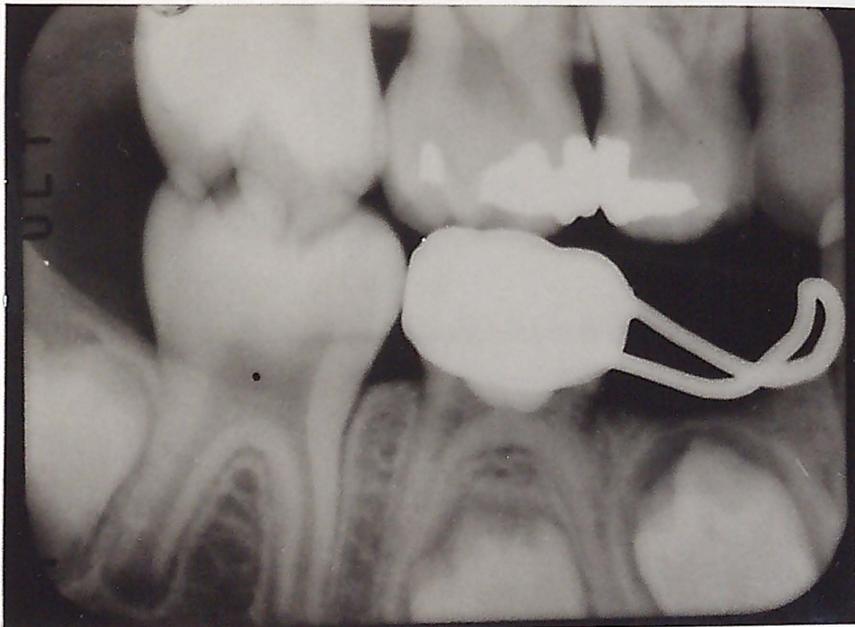




FIGURE 6b. Tooth (#5) has furcal pathology.



TABLE I

Electrosurgical group

| Age at time of treatment and post-op observation time | |
|---|--------------|
| Youngest at time of treatment | 26 months |
| Oldest at time of treatment | 97 months |
| Mean age at time of treatment | 63.6 months |
| Age range at time of treatment | 29-97 months |
| Mean post-op observation time | 10.9 months |
| Range of post-op observation time | 6-31 months |

TABLE II

Electrosurgical group

Clinical and radiographic result categories

| | | |
|----------------------------|----------|--------------------|
| Normal up to exfoliation | 1 | |
| Normal at last observation | 17 | Success rate = 84% |
| Radiographic changed noted | 3 | |
| Failure | <u>4</u> | Failure rate = 16% |
| Total teeth evaluated | 25 | |

TABLE III

Formocresol group

| Age at time of treatment and post-op observation time | |
|---|---------------|
| Youngest at time of treatment | 32 months |
| Oldest at time of treatment | 126 months |
| Mean age at time of treatment | 68.2 months |
| Age range at time of treatment | 32-126 months |
| Mean post-op observation time | 11.5 months |
| Range of post-op observation time | 5-25 months |

TABLE IV
Formocresol group

| Clinical and radiographic result categories | | |
|---|----------|----------------------|
| Normal up to exfoliation | 2 | |
| Normal at last observation | 20 | Success rate = 92.0% |
| Radiographic change noted | 1 | |
| Failure | <u>2</u> | Failure rate = 8.0% |
| Total teeth evaluated | 25 | |

TABLE V
Electrosurgical data

| <u>Subject</u> | <u>Age @ treatment</u> | <u>Post-op time</u> | <u>Result</u> |
|----------------|------------------------|---------------------|---------------|
| 1. | 100 months | 23 months | success |
| 2. | 50 months | 20 months | success |
| 3. | 60 months | 31 months | success* |
| 4. | 87 month | 10 months | fail** |
| 5. | 66 months | 6 months | fail |
| 6. | 88 months | 6 months | fail |
| 7. | 82 months | 11 months | fail |
| 8. | 93 months | 6 months | success* |
| 9. | 80 months | 6 months | success |
| 10. | 100 months | 7 months | success |
| 11. | 31 months | 6 months | success |
| 12. | 37 months | 10 months | success |
| 13. | 42 months | 6 months | success |
| 14. | 54 months | 18 months | success |
| 15. | 24 months | 6 months | success |
| 16. | 54 months | 6 months | success |
| 17. | 80 months | 6 months | success |
| 18. | 78 months | 6 months | success |
| 19. | 57 months | 6 months | success |
| 20. | 84 months | 6 months | success |
| 21. | 52 months | 7 months | success |

*Classified as having a radiographic change

**Classified as a clinical failure

(continued)

TABLE V (continued)

Electrosurgical data

| <u>Subject</u> | <u>Age @ treatment</u> | <u>Post-op time</u> | <u>Result</u> |
|----------------|------------------------|---------------------|---------------|
| 22. | 90 months | 30 months | success |
| 23. | 66 months | 6 months | success |
| 24. | 81 months | 24 months | success* |
| 25. | 69 months | 6 months | success |

*Classified as having a radiographic change

**Classified as a clinical failure

TABLE VI

Formocresol data

| <u>Subject</u> | <u>Age @ treatment</u> | <u>Post-op time</u> | <u>Result</u> |
|----------------|------------------------|---------------------|---------------|
| 1. | 64 months | 25 months | success |
| 2. | 68 months | 24 months | failure |
| 3. | 99 months | 13 months | success |
| 4. | 66 months | 12 months | success* |
| 5. | 81 months | 5 months | failure |
| 6. | 66 months | 24 months | success |
| 7. | 126 months | 12 months | success |
| 8. | 52 months | 6 months | success |
| 9. | 36 months | 6 months | success |
| 10. | 50 months | 6 months | success |
| 11. | 32 months | 6 months | success |
| 12. | 64 months | 9 months | success |
| 13. | 88 months | 6 months | success |
| 14. | 52 months | 6 months | success |
| 15. | 51 months | 10 months | success |
| 16. | 53 months | 6 months | success |
| 17. | 44 months | 12 months | success |
| 18. | 67 months | 6 months | success |
| 19. | 47 months | 6 months | success |
| 20. | 67 months | 6 months | success |
| 21. | 67 months | 19 months | success |
| 22. | 51 months | 6 months | success |

*Classified as having a radiographic change

(continued)

TABLE VI (continued)

Formocresol data

| <u>Subject</u> | <u>Age @ treatment</u> | <u>Post-op time</u> | <u>Result</u> |
|----------------|------------------------|---------------------|---------------|
| 23. | 58 months | 8 months | success |
| 24. | 41 months | 24 months | success |
| 25. | 75 months | 24 months | success |

*Classified as having a radiographic change

TABLE VII

Kappa interpretation

| | |
|--------------------------|-----------|
| Poor agreement | below 0.0 |
| Slight agreement | 0.00-0.20 |
| Fair agreement | 0.21-0.40 |
| Moderate agreement | 0.41-0.60 |
| Substantial agreement | 0.61-0.80 |
| Almost perfect agreement | 0.81-1.00 |

TABLE VIII

Interrater reliability scores

| | |
|--------------------------|--------------|
| Dr. 1 & Dr. 2 | 0.548 |
| Dr. 1 & Dr. 3 | 0.565 |
| <u>Dr. 2 & Dr. 3</u> | <u>0.737</u> |
| Overall | 0.603 |

TABLE IX
Statistical analysis

| <u>Group</u> | <u># Successes</u> | <u>Total #</u> | <u>% Success</u> | <u>Confidence Interval</u> |
|---------------------|--------------------|----------------|------------------|----------------------------|
| Formocresol | 23 | 25 | 92% | (74%, 99%) |
| <u>Electrosurg.</u> | <u>21</u> | <u>25</u> | <u>84%</u> | <u>(64%, 95%)</u> |
| Difference | | | 8% | (0%, 30%) |

DISCUSSION

The use of formocresol in the primary dentition as a pulpotomy agent has been well-documented in the literature since its introduction into dentistry in 1904. Over the years studies have shown formocresol to yield reasonable success rates when used as a pulpotomy medicament.^{13,46} Formocresol is the most accepted and widely used agent today, and any study investigating a new pulpotomy technique or agent should use formocresol as the control. Despite its favorable outcomes, formocresol has been shown to be a carcinogenic, mutagenic, allergenic, and potentially toxic agent that is systemically distributed in animal studies. Concerns over these findings have led investigators to search for a nonpharmacologic agent, and electrosurgery has been investigated as a result.

The original protocol of this study was revised after a two-year delay in completing the study. The modifications included performing 50 pulpotomies for evaluation instead of 100, having three examiners instead of two due to time constraints (eliminating the need for a conference between the examiners resolving their differences), and the use of kappa statistics. Kappa is a popular measure of association and is usually used to examine interobserver agreement on diagnostic tests, such as radiographs. In this study, with multiple examiners being used, kappa was used to do an intraclass correlation. The examiners were paired and a score was determined on their combined reliability. The scores fell in the range of moderate to substantial agreement, and this level is considered good. The average of the overall score shows that the examiners were in substantial agreement. And finally, the co-investigator, who was a postgraduate

pediatric dental resident using this project to fulfill his requirements for the Master of Science in Dentistry degree, was added to the study after being taught the electrosurgical technique by the principal investigator.

In this study, the examiners had the choice of rating each tooth a success, a success with a radiographic change, or a failure based on the selected criteria. Of the three successes having radiographic changes in the electrosurgical group, one tooth had a poor-fitting stainless steel crown; the other tooth had exudate expressed from the sulcus believed to be due to gingival irritation, probably caused by the stainless steel crown, and the third exhibited radiographic evidence of distal root resorption secondary to ectopic eruption of the maxillary first permanent molar as shown in Figures 2a, 2b, and 2c. All three abnormalities were asymptomatic at the last evaluation appointment. Appointments for replacement of the ill-fitting crowns were scheduled. These cases were difficult to categorize by the three examiners. The examiners said that the radiographic changes were not directly related to the pulpotomies themselves, so that they were judged successful, even though they could not be included as "normal." Radiographs of the failed cases are shown in Figures 3a, 3b, 3c, and 3d. One case (Figure 3a) exhibited clinical signs and symptoms of morbidity and radiographic pathology and was extracted 10 months after performing electrosurgical pulp therapy; a space maintainer was placed to prevent space loss. The other cases exhibited radiographic evidence of distal root resorption (Figure 3b) and internal root resorption (Figures 3c, 3d) without clinical signs or symptoms of morbidity.

In the FC group, the tooth classified as a success having a radiographic change had exudate present around the gingival margin of the stainless steel crown. The examiners felt that the radiographic change was not directly related to the pulpotomy itself, so that it was judged a success, even though it could not be included as "normal." The tooth was asymptomatic with no signs of

radiographic pathology. Radiographs of the two failed cases are shown in Figure 5. The first case exhibited radiographic evidence of internal root resorption without clinical signs or symptoms of morbidity and the second case exhibited radiographic evidence of furcal pathology without clinical signs or symptoms of morbidity.

The electrosurgical pulpotomy has gained popularity due to its nonpharmacologic nature, ease in use, and reported favorable results. The results of our study are comparable to those reported in the literature concerning electrosurgical and formocresol pulpotomies.^{10,13,16,45,46} Ruemping⁴² and Shaw⁴⁴ have reported histological success when using electrosurgery on caries-free primate teeth. Shulman⁴³ evaluated the pulp response of caries-free primate teeth histologically after being treated by electrosurgery. The study reported a histologic success of 56 percent. The poor results were possibly caused by the complete removal of the coronal pulp tissue with the electrosurgical unit, instead of the standard electrosurgical technique, which is to remove the coronal tissue mechanically and then treat the pulpal stumps with electrosurgery. Shulman's technique possibly caused excessive heat accumulation within the pulp and caused more necrosis. In comparison, Rolling and Hansen²⁴ evaluated the histological response of the pulp when treated with formocresol. The teeth were treated three to 24 months prior and were determined to be clinically and radiographically successful. The purpose of their study was to establish a relationship between the pulpal condition in short and long-term pulpotomized teeth. The findings led the authors to presume that complete repair of the pulp tissue could occur, but it is not a characteristic reaction after formocresol treatment. Therefore, they concluded that the formocresol pulpotomy is only a means to keep primary teeth with pulp exposures functioning for a limited period of time.

Sheller and Morton,¹⁰ Mack and Dean,⁴⁵ and Fishman⁴⁷ conducted human studies using electrosurgical pulpotomies. Sheller and Morton¹⁰ reported a clinical and radiographic success of 91 percent when using caries-free canines in humans, but a histologic success of only 64 percent. The poor histologic results may be directly related to the use of gutta percha as the base material instead of the standard base of ZOE, which was used by Ruemping⁴² and Shaw.⁴⁴ In a retrospective study by Mack and Dean,⁴⁵ they reviewed 164 electrosurgically pulpotomized teeth that had been treated within the last 10 years and reported a clinical and radiographic success rate of 99.5 percent. Even though this was a retrospective study and variations in the pulpotomy technique over the years probably occurred, the results are noteworthy and comparable to the retrospective study done by Hicks.⁴⁶ The study by Mack and Dean included 164 formocresol pulpotomies that were evaluated and reported to have a clinical and radiographic success rate of 93.9 percent.

In a recent prospective human study on the electrosurgical pulpotomy, Fishman et al.⁴⁷ compared the clinical and radiographic success rates between two different pulpotomy covering medicaments, ZOE and CaOH. They demonstrated clinical success rates of 77 and 81 percent, and radiographic success rates of 55 and 57 percent for the ZOE and CaOH, respectively. Compared with the Mack and Dean⁴⁵ retrospective study and our current study, their success rate is low. Several comments may help to explain the discrepancy. First, the authors were attempting to compare the success rates of ZOE or CaOH as pulpotomy medicaments, not the overall success of the electrosurgical technique as compared with a gold standard such as formocresol. Second, the authors noted that upon review of their pretreatment radiographs, pathology was present on some teeth, which indicated these teeth possibly required more extensive pulp therapy besides a pulpotomy. Third, the authors did not include

a rating category "success with a radiographic change" in their study. This is important, because factors other than the pulpotomy technique can cause pathology, i.e., poor fitting crowns or ectopic erupting molars. Finally, it is possible, although unlikely, that their technique was flawed. While the authors note direct communication with Dr. Ronald Mack, a noted authority in the electrosurgical technique, they did not receive any clinical training from him. The authors conclude their paper by stating that given the results of their study, it would be premature to recommend the use of the electrosurgical pulpotomy technique. This conclusion may be inappropriate, because their study was specifically designed to compare two different pulpotomy-covering medicaments after electrosurgical pulpotomies, not the success rate of the electrosurgical pulpotomy versus the formocresol pulpotomy. The results of our study indicate that the electrosurgical pulpotomy seems to be comparable to the formocresol pulpotomy for human primary molars for a postoperative period of a least six months.

As with most studies, this study has its limitations. For instance, some of the patients recruited for this study were treated in the operating room due to poor behavior in the clinical setting. This provided difficulty in obtaining ideal postoperative radiographs for evaluation. In addition, minor variations in performing the pulpotomy technique could have occurred between the two investigators, even though strict adherence to detail was given. However, despite the differences in experience levels between the two investigators, the failures were divided equally between the investigators.

Although the electrosurgical pulpotomy is a nonpharmacologic technique that produces favorable results, it is still a preservative technique. Future studies should investigate agents that leave the radicular pulp healthy and completely enclosed within an odontoblast-lined dentin chamber. One promising method

currently under investigation is the use of bone morphogenetic protein (BMP). Recent experiments have, in fact, demonstrated that BMP from both bone and dentin will promote dentinogenesis.^{48,49}

SUMMARY AND CONCLUSIONS

This study compared electrosurgical pulpotomies and formocresol pulpotomies in human primary molars requiring pulp therapy after carious involvement. The purpose was to determine how the electrosurgical pulpotomy compares to the formocresol pulpotomy for retaining the teeth described above.

A total of 50 pulpotomies were performed on 50 pediatric patients requiring pulp therapy secondary to carious involvement. The teeth were assigned to one of two groups: 1) electrosurgery (ES) or 2) formocresol (FC). Before treatment the patients' medical histories were reviewed and the consent forms signed by the parents or guardians and patients. A preoperative clinical exam and radiograph were made on each tooth. After at least five months, the teeth were evaluated by the investigators for clinical success and by three additional examiners for radiographic success. The examiners classified each tooth as a success, a success having a radiographic change, or a failure. The radiographic change was defined as a noteworthy radiographic finding that was not believed to be directly related to the pulpotomy, and that did not affect the success of the pulpotomy. In the ES group, 25 pulpotomies were performed in pediatric patients between the ages of 26 to 97 months. The postoperative observation time range was between six to 31 months. In the FC group, 25 pulpotomies were performed on children between the ages 32 to 126 months. The postoperative observation time range was between five to 25 months. The clinical success rate for electrosurgery and formocresol was 96 percent and 100 percent and the radiographic success rate was 84 percent and 92 percent, respectively. The ES and FC groups were compared for differences in the

percentage of successes using a Fisher's Exact test. There were no statistical differences between the two groups at the $p < 0.05$ level. Kappa statistics was used to measure the agreement among the examiners.

In conclusion, the hypothesis that the success rate of the electrosurgical pulpotomy is comparable to the formocresol pulpotomy is supported by this research.

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APPENDIXES

APPENDIX 1
INFORMED CONSENT STATEMENT
for

Comparison of Formocresol vs. Electrosurgical Pulpotomy Procedures

The Department of Pediatric Dentistry at the Indiana University School of Dentistry is inviting you and your child to participate in a research study. The purpose of this study is to determine if there is a safe and effective alternative technique for performing pulpotomy procedures in primary molars. Fifty children between the ages of 18 months and 10 years of age will be asked to participate. If you decide to participate, you must first read this letter and sign your name in the space provided.

Your child's dentist or dental student has determined that your child needs a pulpotomy procedure performed on a primary molar tooth. A pulpotomy involves removing the diseased or infected pulp tissue within a tooth and leaving the healthy, unaffected pulp tissue in place. This healthy tissue must be treated to stop any bleeding prior to placement of a restoration. In this study, your child will be treated with one of two pulpotomy procedures, a formocresol technique or an electrosurgical technique. Selection of the technique will be on a random basis by the principal investigator of this study, who will perform the procedure.

As part of this study you and your child will be asked to return to the clinic at 6 month intervals following the pulpotomy. Clinical and radiographic

observations of the treated teeth will be made. You will be compensated \$20.00 at the completion of the 6 month follow-up visit for your participation in the study.

The risks associated with both pulpotomy techniques include failure of the pulpotomy procedure with the need for either a pulpectomy or extraction of the tooth and space maintenance. The risks involved will be minimized by adhering to all accepted infection control and safety guidelines associated with performing pulpotomy procedures. When needed, the principle investigator will ensure the availability of follow-up care for the study participant. You and your child will be notified immediately if any adverse clinical and radiographic sequela of the study's treatment are observed:

I have been given an opportunity to ask questions about this study; answers to such questions (if any) have been satisfactory. The information in the study will be kept confidential and will be made available only to persons conducting the study unless I specifically give my permission in writing to do otherwise. If the results of this study are published, I will not be identified. I understand that the results of the study may be submitted to Birtcher Medical Systems and to the Food and Drug Administration. In the unlikely event of physical injury resulting from my participation in this research, emergency medical treatment will be provided by the James Whitcomb Riley Hospital for Children.

If I have questions regarding the study I can reach Dr. Brad Fulkerson at 274-3865. If I am unable to reach Dr. Fulkerson at this number in an emergency, I may call 274-5000 and ask for the pediatric dentistry resident on call. A patient representative who is not associated with this research to whom I may address complaints about this study, as well as questions about my rights as a research participant, may be reached at 274-6637. In consideration of all of the above, I

give my consent to participate in this voluntary research study. I understand that I may drop out of or be withdrawn from the study without fear of changing the investigator's interest or the quality of medical care which I may seek or receive in the future from the doctors participating in the study. I acknowledge receipt of a copy of this informed consent statement.

Subject's name _____ Date: _____

Signature of Parent/Legal Guardian _____

Signature of Child (Age 7 and above) _____

Signature of Witness _____

APPENDIX 2.

Examination Sheet

Panelist Data Sheet

ES vs. FC Prospective Pulpotomy Study

Chart # _____ Tooth# _____ Tx: ES/FC Tx. Date _____

Consent signed and attached _____ Med Hx: Neg/Pos

| <u>Date</u> | <u>Elapsed Time</u> | <u>X-ray</u> | <u>Success</u> | <u>Failure (describe)</u> |
|-------------|---------------------|--------------|----------------|---------------------------|
| | 0 | | | |
| | 6 months | | | |
| | 12 months | | | |
| | 18 months | | | |
| | 24 months | | | |
| | 36 months | | | |
| | 48 months | | | |
| | 60 months | | | |
| | Exfoliation | | | |

ABSTRACT

COMPARISON OF ELECTROSURGICAL AND FORMOCRESOL
PULPOTOMY PROCEDURES

by

Bradley T. Fulkerson

Indiana University School of Dentistry
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Formocresol is the most commonly used pharmacologic pulpotomy agent. Concerns over its safety have led investigators to search for new pulpotomy medicaments. This study compared the electrosurgical pulpotomy with the formocresol pulpotomy in teeth requiring pulp therapy after carious involvement. There were 25 pulpotomies performed in each group. The teeth were evaluated for clinical and radiographic success after at least six months. In the electrosurgical group, the clinical and radiographic success rates were 96 percent and 84 percent, respectively. The age range at the time of treatment was 26 to 97 months, with a mean treatment age of 63.6 months. The postoperative observation time range was six to 31 months, with the mean being 10.9 months. In the formocresol group, the clinical and radiographic success rates were 100 percent and 92 percent, respectively. The age range at the time of treatment was 32 to 126 months, with a mean treatment age of 68.2 months. The postoperative observation time ranged from five to 25 months, with the mean being 11.5 months. The electrosurgical and formocresol groups were compared for

differences in the percentage of successes by using a Fisher's Exact test. There were no statistical differences between the two groups at the $p < 0.05$ level. Therefore, this study failed to demonstrate a statistically significant difference in the success rate between the electrosurgical and formocresol pulpotomy techniques and supports the use of the electrosurgical pulpotomy as a viable and safe alternative to formocresol.

CURRICULUM VITAE

Bradley Todd Fulkerson

| | |
|----------------------------|---|
| August 21, 1970 | Born to Harold and Linda Fulkerson, Henderson, Kentucky |
| August 1988 to May 1991 | University of Kentucky, Lexington, Kentucky |
| August 1991 to May 1995 | Doctor of Dental Medicine (DMD) University of Kentucky College of Dentistry, Lexington, Kentucky |
| June 1995 to June 1997 | Master of Science in Dentistry (MSD) Major: Pediatric Dentistry Minor: Oral Pathology Indiana University School of Dentistry, Indianapolis, Indiana |
| June 1995 to June 1997 | Resident in Pediatric Dentistry James Whitcomb Riley Hospital for Children, Indiana University Medical Center, Indianapolis, Indiana |
| September 14, 1996 | Married Susan Kelly Wright Indianapolis, Indiana |

Professional Organizations

American Academy of Pediatric Dentistry
American Dental Association
American Academy of General Dentistry
American Society of Dentistry for Children
Indiana Society of Pediatric Dentistry