

A CLINICAL AND HISTOLOGICAL EVALUATION
R R R
OF LIFE , DYCAL AND CAVITEC
IN CONSERVATIVE PULPAL THERAPY

by

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DEDICATION

To my wife, Maureen, for her unselfish love,
understanding and patience.

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TABLE OF CONTENTS

DEDICATION.....	ii
ACKNOWLEDGMENTS.....	iii
LIST OF FIGURES.....	vi
LIST OF TABLES.....	vii
LIST OF APPENDIXES.....	ix
INTRODUCTION.....	1
LITERATURE REVIEW.....	4
I. Historical Review.....	4
II. Clinical Evaluation and Diagnosis.....	18
III. Current Clinical Treatments.....	22
IV. Histological Evaluation of Pulpal Tissues.....	24
V. Summary.....	27
METHODS AND MATERIALS.....	30
I. Case Selection and Distribution.....	30
II. Clinical Procedures.....	32
III. Histological Procedures.....	37
IV. Statistical.....	38
RESULTS.....	40
I. Demographic Data.....	40
II. Clinical Evaluation.....	42
III. Histological Evaluation.....	59
IV. Histological-Clinical Comparison.....	70
DISCUSSION.....	72
I. Methods of Clinical Evaluation.....	72
II. Comparison of Materials.....	77
III. Comparison of Treatment Types.....	79
IV. Histological Evaluations.....	81
V. Clinical Applications.....	83
VI. Suggested Further Study.....	83

SUMMARY.....	85
CONCLUSIONS.....	88
APPENDIXES.....	90
BIBLIOGRAPHY.....	117

LIST OF FIGURES

Figure	Page
1. Typical Untreated Control Tooth Showing No Inflammation and Well Defined Odontoblastic, Cell-Free and Cell-Rich Zones in the Coronal Pulp.....	60
2. Cavitec ^R Treated Complete Caries Removal Tooth 6 Months Following Treatment Showing No Inflammation and Well Defined Odontoblastic, Cell-Free and Cell-Rich Zones Adjacent to the Cut Tubules.....	61
3. Life ^R Treated Direct Pulp Capped Tooth 6 Months Following Treatment Showing Bridging Against the Life ^R , Amorphous Dentin, Tubular Dentin and Cellular Inclusions in the Dentin Bridge.....	64
4. Life ^R Treated Direct Pulp Capped Tooth 6 Months Following Treatment Showing Bridging Against the Life ^R , Dentin Chips, Tubular Dentin and Cellular Inclusions in the Dentin Bridge.....	65
5. Dycal ^R Treated Direct Pulp Capped Tooth 6 Months Following Treatment Showing Bridging Against the Dycal ^R , Amorphous Debris, Dentin Chips, Amorphous Dentin and Cellular Inclusions in the Dentin Bridge.....	67
6. Dycal ^R Treated Direct Pulp Capped Tooth 6 Months Following Treatment Showing Bridging at a Distance From the Dycal ^R , Amorphous Debris Between the Capping Agent and Bridge, Cellular Inclusions and Amorphous Debris in the Dentin Bridge.....	68
7. Dycal ^R Treated Direct Pulp Capped Tooth 1 Week Following Treatment Showing a Moderate Inflammatory Reaction and Incomplete Pulpal Organization at the Exposure Site	69

LIST OF TABLES

Table	Page
1. Materials Used.....	36
2. Criteria for Grading Tooth Pulp Histology.....	39
3. Distribution of Teeth by Treatment Type.....	41
4. Student "t" Tests on the AVGDIFF in Electric Pulp Test Measurements for Life ^R and Dycal ^R by Treatment Type.....	43
5. Student "t" Tests on the AVGDIFF in Electric Pulp Test Measurements for Different Medicament Types in Complete CR Nonexposures....	44
6. Significant Differences Between Medicament Type and Clinical Signs and Symptoms by Treatment Type.....	46
7. Student "t" Tests on the AVGDIFF in Electric Pulp Test Measurements for Different Treatment Types by Medicament Type.....	48
8. Student "t" Tests on the AVGDIFF in Electric Pulp Test Measurements for Different Treatment Types - Life ^R and Dycal ^R Combined.....	49
9. Significant Differences Between IPC, Complete CR and DPC Treatments and Clinical Signs and Symptoms in Teeth Treated with Life ^R	50
10. Significant Differences Between Complete CR and DPC Treatments and Clinical Signs and Symptoms in Teeth Treated with Life ^R	52
11. Significant Differences Between IPC and DPC Treatments and Clinical Signs and Symptoms in Teeth Treated with Dycal ^R	53
12. Significant Differences Between Complete CR and DPC Treatments and Clinical Signs and Symptoms in Teeth Treated with Dycal ^R	55

13.	Significant Differences Between IPC and Complete CR Treatments and Clinical Signs and Symptoms in Life ^R and Dycal ^R Treated Teeth.....	56
14.	Significant Differences Between IPC and DPC Treatments and Clinical Signs and Symptoms in Life ^R and Dycal ^R treated teeth.....	57
15.	Significant Differences Between Complete CR and DPC Treatments and Clinical Signs and Symptoms in Life ^R and Dycal ^R treated teeth.....	58
16.	Comparison Between Medicament Type and Histological Evaluation on DPC Treated Teeth at 6 Months Post Treatment.....	63
17.	Comparison Between Clinical Signs and Symptoms and Histological Evaluation on DPC Treated Teeth at 6 Months Post Treatment.....	71

LIST OF APPENDIXES

Appendix	Page
I. Copy of Patient Consent Form.....	90
II. Copy of Human Subjects Committee Approval.....	91
III. Tooth Surface Temperatures.....	94
IV. Clinical Data.....	95
V. Histological Data.....	116

INTRODUCTION

The treatment of the exposed dental pulp and the extensively carious tooth has been a challenge to the clinician for many years. Since the 1800's, various preparations and techniques have been developed for pulpal protection and treatment of deep carious lesions and exposed pulps. Among these, direct and indirect pulp capping procedures have become popular treatment modalities.

In cases where it is suspected that complete caries removal may result in exposure of the pulp tissue, an indirect pulp capping procedure may be performed. In this procedure, the caries is removed until a thin layer of carious dentin is left in the deepest part of the carious lesion, avoiding exposure of the underlying pulp tissue. This remaining carious dentin is then covered by a thin layer of a calcium hydroxide (Ca(OH)₂) containing material and the tooth restored. It is believed by some that further treatment of that tooth will not be necessary because once the remaining carious dentin is adequately sealed off by the restoration it will become inactive and the integrity of the pulp will be maintained and protected by the formation of reparative dentin. If vital pulpal

tissue is exposed during treatment, a direct pulp cap procedure can be performed. This consists of placing a Ca(OH)₂ containing material over the exposure site and then restoring the tooth with either a temporary or permanent restoration.

Both of these procedures involve the use of calcium hydroxide containing materials for augmenting pulpal healing. Various Ca(OH)₂ containing intermediary bases are commercially available, for example, Life^R and Dycal^R. These materials have been extensively tested in animal model systems. However, their clinical efficacy relative to each other is not well documented. Because of their increasing clinical usage, knowledge of this relative efficacy is becoming more important. Furthermore, there remains a controversy as to whether Ca(OH)₂ or zinc oxide-eugenol (ZOE) is the material of choice in moderately deep carious lesions following complete caries removal. It is believed by some that ZOE intermediary bases have a sedative effect on irritated pulp tissue. Others believe that these ZOE materials may interfere with pulpal healing and that Ca(OH)₂ is needed to promote pulpal healing.

The purpose of this study was to:

- (1) evaluate the effect of a new calcium hydroxide (Ca(OH)₂) intermediary base material, Life^R, on the human pulp when used for direct and indirect pulp capping;
- (2) compare the relative effectiveness of Life^R and Dycal^R in these clinical treatments; and

(3) compare the pulpal responses of Ca(OH)^R (Life^R and Dycal^R) and zinc oxide-eugenol (Cavitec^R) intermediary bases when used in moderately deep carious lesions following caries removal.

Knowledge regarding these factors is important in order to establish scientifically based treatment protocols for restoring carious teeth. Such protocols need to be formulated with a knowledge of both clinical and histological effects of various treatment modalities currently being used.

Both clinical and histological evaluation of these restorative materials in direct pulp capped, indirect pulp capped and deeply excavated, non-exposed human teeth was made. Clinical evaluations of these teeth were performed at the time of treatment, seven days later and then six months following treatment. Histological evaluation was performed, when possible, six months after treatment. This protocol was established to permit comparisons between clinical and histological results as well as comparison of clinical success between the Ca(OH)² and ZOE² containing intermediary bases.

This combination of the clinical and histological results of this study will, it is believed, permit the selection of sound, scientifically based clinical restorative modalities that will optimize the healing potential of caries compromised teeth.

LITERATURE REVIEW

I. HISTORICAL REVIEW

In 1860, Taft¹ reported that 50 percent of carious exposures that were dried and then filled with a temporary filling material consisting of 15 parts quartz, 10 parts potash and 1 part charcoal would form a bony deposition that would restore the continuity of the dentin. In the same publication, Westcott² questioned whether any hard tissue deposition could occur once the pulpal tissue was exposed. At that time the majority opinion agreed with Westcott.

Pulpal therapy was a major point of interest at the 1862 American Dental Convention. There Westcott³ again questioned the success of conservative pulpal therapy. However, this pessimism did not seem to deter the dental practitioner from testing various methods and materials based on not much more than empirical thought plus trial and error. Some of these procedures varied from using a solution of tannic acid and creosote to capping the exposed pulp with celluloid and ether after depressing the heart rate by administering a bromide and a circulatory depressant⁴.

⁵
Cravens , in 1876, suggested that exposed pulp tissue should be treated with bone material instead of caustic agents. This was followed by Stellwagen's⁶ use of non-carious dentin scrapings and G. V. Black's⁷ recommendation to use a zinc oxyphosphate cement that was "non-harmful" to the exposed pulp.

⁸
Indirect pulp capping, described by Baume and Holz in 1981 as a "dressing which aims to conserve pulpal vitality at the site of penetrating caries, the removal of which would induce pulp exposure", was advocated in 1928 by Grove⁹. In his technique, Grove recommended that a stiff paste of cement and liquid hydrated chloral be placed over the remaining layer of carious dentin in order to "prevent decomposition" of the remaining dentin. Grove believed that pulp capping should never be regarded as a treatment assuring permanent results. Thus, he recommended his technique to be used only on carious teeth with incomplete root end closure until root development occurred that would permit conventional endodontic therapy.

The late 1930's marked the beginning of the use of calcium hydroxide to treat exposed pulps. Zander¹⁰, in 1939, treated 150 pulp exposures in human teeth by performing pulpotomies using either calcium hydroxide and water paste or Calxyl, a calcium hydroxide containing base, followed by a layer of paraffin, a cement base and a metal restoration. Radiographic examinations two years

following treatment revealed no apical changes in 71 per cent of the cases. Pulpal reactions of the successful treatments were also described by Zander. These consisted of dentin bridges that started as a dark, amorphous, structureless layer that formed the matrix for regular dentin with functioning odontoblasts. Zander also believed that dentin formation could occur, not only in a healthy pulp, but also in the presence of inflammatory reactions. However, Zander was careful to recommend this treatment as an emergency treatment only in "teeth in which either the root end is not completely formed or, as in deciduous teeth, resorption is taking place".

The clinical success reported in Zander's 1939 paper spurred numerous other studies using pulp capping materials containing calcium hydroxide as their principal ingredient. In 1949 Wheeler¹¹ published an article that reported a 90 percent clinical success of direct pulp capping on 250 carious human teeth for up to 5 years. For this study, a quick setting pulp capping material called "pulpcapper" was made by mixing a powder containing calcium phosphate and calcium hydroxide with a liquid of eugenol and linseed oil. Following exposure of the pulp, the cavity preparation was washed with an antiseptic of bichloride of mercury in dioxygen 1/1000, the exposure covered with the "pulpcapper" and the tooth restored with a permanent filling. Pre- and post-treatment clinical

signs and symptoms as well as details of the clinical nature of the exposure itself were recorded, however, no histologic evaluations were made. Wheeler concluded that salivary contamination, age of patient and history of slight preoperative pain had no influence on clinical success of his pulp capping technique. Also in 1949, Glass and Zander¹² reported on the histologic results of using zinc oxide-eugenol and calcium hydroxide water pastes sealed with zinc oxide-eugenol on 40 exposed, non-carious, human pulps for 24 hours, 2, 4, 6, 8, and 12 weeks. Histologically, no hard tissue formation or dentin bridging was observed in the exposed pulps capped with zinc oxide-eugenol. Those pulps, although they remained vital, had chronic inflammatory reactions persisting at the exposure site. The pulps capped with calcium hydroxide demonstrated a rapid healing process that was relatively free of inflammation resulting in a complete dentin bridge within four weeks. A study using six dog's teeth mechanically exposed and capped with Pulpdent^R, a calcium hydroxide-methyl cellulose paste, was reported by Berk¹³ in 1950. Histologic examination of those teeth 2 1/2 months following treatment showed that pulpal healing occurred in all of the teeth.

Nyborg^{14,15} published two papers on pulp capping during the 1950's that were among the first attempts to relate experimental and clinical pulp capping data using both clinical and histological evaluation. The first

14
publication , in 1955, described pulpal reactions to direct pulp capping in 73 dog pulps and in 77 human teeth for two days to 32 months using calcium hydroxide with water and an inert material for capping agents. Also included were descriptions of 31 dog and 54 human untreated control teeth. Clinical evaluations consisting of case histories of pain or discomfort, percussion and pressure tests, sensitivity to hot and cold and electric pulp testing responses were recorded on each treated human tooth and untreated control tooth just prior to extraction. The dog pulps treated with the inert capping material displayed marked inflammation and signs of abscess formation or necrosis. Those treated with calcium hydroxide demonstrated healing in 34 of the 43 treated teeth (79 percent). The histologic observations of the human pulps closely followed those of the treated dog pulps. Although no healing was observed in teeth capped with the inert capping material, 70 percent of the teeth treated with calcium hydroxide showed signs of pulpal healing. The healing resulted in a new layer of calcified tissue across the exposure site. This barrier of calcified tissue contained a superficial layer of necrotic tissue at the calcium hydroxide material interface and reorganized odontoblastic layer on its pulpal side. Comparison between clinical and histologic results revealed no correlation between clinical signs and symptoms and histological

pulpal status.

In 1958, Nyborg¹⁵ published a second article on pulp capping. In that study, 225 carious human teeth that were either exposed during caries removal or already carious exposures at the time of treatment were pulp capped with a calcium hydroxide containing base, Calxyl^R, a layer of silver foil over the Calxyl^R and restored with a phosphate cement and an amalgam filling. Prior to treatment, case histories and reactions to percussion and pressure were recorded. Some teeth were also tested for sensitivity to hot and cold. Clinical and histological examinations were conducted on 81 of the teeth 4 hours to 9 years following treatment. Healing was observed in 62 percent of those teeth that did not have an exudate at the time of capping. This healing was similar to that observed by Nyborg¹⁴ in his 1955 study except that most of the barriers contained irregular spaces that were either empty or contained debris. Once again, clinical findings did not relate to the corresponding histologic findings. The remaining 144 teeth were observed only clinically for up to 13 years. Of these, 86 percent of the 124 teeth that did not have visible signs of pulpitis at the time of treatment were judged clinically sound.

As a result of Zander's, Berk's and Nyborg's studies, pulp capping began to gain acceptance as a viable treatment in select cases. Castagnola¹⁶, in 1950, stated^R that direct capping and vital amputation using Calxyl^R

should have an important place in modern preventive dentistry. Berk¹⁷, in 1957, presented indications and contraindications for both calcium hydroxide direct pulp capping and vital amputations. Clinical and histological success following the use of calcium hydroxide was reported in direct pulp capping by Armstrong and Hoffman¹⁸ and in pulpotomies by Schröder^{19,20}. Other investigators expressed their support of pulp capping by attempting to develop different pulp capping materials that would be superior to the calcium hydroxide pastes being used at that time. Berk's¹³ use of methyl cellulose as a vehicle to carry the calcium hydroxide powder was an attempt to improve some of the handling characteristics of calcium hydroxide pastes. Sodium penicillin alone and with zinc oxide-eugenol was used as a capping agent in 154 cariously exposed human teeth by Kutscher²¹ in 1950 in an attempt to utilize the bacteriostatic, bacteriocidal and sedative properties of these materials. Of those 154 teeth, only 3 were classified as clinical failures after 2 1/2 years of treatment. In 1951, Tananbaum²² compared calcium hydroxide and zinc oxide-eugenol as capping agents in 128 permanent and primary human teeth treated from 5 to 39 months. Those teeth treated with calcium hydroxide had a 92 percent clinical success rate while the zinc oxide-eugenol treated teeth were clinically successful 89 percent of the time. However, only 4 percent of the zinc

oxide-eugenol group showed radiographic evidence of dentin bridge formation in contrast to 89 percent of the calcium hydroxide group. These studies were some of the first attempts to incorporate antibacterial or anti-inflammatory properties into pulp capping agents.

Through the years, zinc oxide-eugenol has been tested as a pulp capping agent in an attempt to utilize its bacteriostatic/bacteriocidal and purported obtundent effects. Kapur and Shglar²³, in 1964, described clinical and histological pulpal responses of exposed, caries free human teeth that were capped with either calcium hydroxide or zinc oxide-eugenol. Those teeth treated with calcium hydroxide had a connective tissue barrier around the exposure, whereas, the zinc oxide-eugenol treated teeth displayed a mild chronic pulpal inflammation with no tissue barrier. Once again, there was no relationship between clinical signs and symptoms and histologic pulpal condition. These results were substantiated in a rat model system by Sela and Ulmansk²⁴ and in monkeys by Weiss and Bjorvatan²⁵. Langer et al.²⁶, in 1970, compared pulpal healing between Calxyl^R alone and Calxyl^R covered by zinc oxide-eugenol in partial pulpotomies performed on human premolars. His findings suggested that the subjective quality of the bridge formed was better in those teeth treated with the Calxyl^R covered by zinc oxide-eugenol. All of these studies, however, utilized caries free, uninflamed teeth. Tronstad²⁷, in 1972,

tested calcium hydroxide and water and zinc oxide-eugenol as capping agents in 55 experimentally inflamed monkey teeth. By placing warmed gutta percha or soft carious dentin in deep Class 5 buccal cavity preparations for 8 days, slight to moderate or severe pulpal inflammatory reactions were selectively created. Following this 8 day period, the cavity preparations were cleaned, the pulp exposed, capped with either calcium hydroxide and water or zinc oxide-eugenol and sealed with amalgam for 8 or 83 days. A severe reaction was observed in all of the pulp capped teeth 8 days following treatment. However, in contrast to the findings of Kapur and Shglar²³, Sela and Ulmansky²⁴, Weiss and Bjorvatan²⁵ and Langer et al.²⁶, Tronstad found that, at 83 days, many of the teeth capped with calcium hydroxide were either necrotic or severely inflamed, whereas, those treated with zinc oxide-eugenol demonstrated more favorable reactions consisting of secondary dentin formation and little or no inflammation.

Others²⁸⁻³⁰ have tried using corticosteroids in pulp capping procedures in an attempt to reduce the degree of pulp inflammation. Kakehashi et al.³¹, in 1969, demonstrated that a topical corticosteroid alone was not capable of promoting pulpal healing when used as a pulp capping agent in conventional rats. At the same time, Bhaskar et al.³² studied the effect of a prednisolone and calcium hydroxide containing pulp capping agent on

exposed, noninflamed, rat tooth pulps at varying time periods. When compared to control teeth that were treated with a non-steroid calcium hydroxide preparation, the corticosteroid treated teeth had less intense and shorter duration edema, reduced inflammation, reduced tissue necrosis and reduced dystrophic calcification. Baume and Fiore-Donno³, in 1970, published a review article that suggested the use of corticosteroids in pulpal therapy be limited to painful primary teeth, as a temporary dressing in unexposed painful permanent teeth, for palliative treatment of pulps of permanent teeth which are subsequently to be endodontically treated and to prevent exacerbations of necrotic pulps. Mjör and Lervik³⁴ indirectly supported these recommendations when they studied the effect of a corticosteroid containing cement, Ledermix^R, on non-exposed, inflamed monkey teeth. They concluded that healing of localized inflammation occurred more slowly subjacent to amalgam covered dentin than adjacent to corticosteroid covered dentin. However, the corticosteroid cement did not exhibit an additional healing effect as compared to that seen subjacent to calcium hydroxide covered and zinc oxide-eugenol covered dentin seen in a previous study³⁵. Ulmanky et al.³⁶, using human premolars, found that the application of Ledermix^R to a pulpotomy wound for more than 48 hours followed by a complete rinsing and capping with Calxyl^R for 4 weeks produced much more inflammation and pulp

necrosis than if the Ledermix^R was applied for less than 24 hours. Paterson³⁷ found similar unfavorable results using germ free rats and Ledermix^R alone.

Using a different approach, other investigators have added antibiotics in their pulp capping procedures in an attempt to control infection and thus indirectly inflammation. Gardner et al.³⁸, in 1971, bacterially infected and inflamed 71 exposed monkey pulps and then capped them with Vancomycin^R and calcium hydroxide-methyl cellulose, Vancomycin^R-methyl cellulose and calcium hydroxide-methyl cellulose. They found that although the Vancomycin^R-methyl cellulose preparation did not promote pulpal healing, the calcium hydroxide preparations, with and without Vancomycin^R, were about equally effective in promoting pulpal healing. Similar results using either Keflin^R or Dycal^R alone as the capping agent in monkey teeth were reported by McWalter et al.^{39,40} in 1973 and 1976. An antibiotic, corticosteroid and calcium hydroxide were used alone or in combinations in coronal pulpotomies performed on dog teeth by de Souza and Holland⁴¹ in 1974. This study also supported the findings of Gardner et al.³⁸ and McWalter et al.^{39,40}.

Other materials have also been tried as pulp capping agents. Bhaskar et al.⁴² obtained promising results using a isobutyl cyanoacrylate spray as a pulp capping agent in pig teeth. In that study, it was reported that the spray

was easy to apply, produced immediate hemostasis, was well tolerated by the pulp tissue, evoked less inflammation and did not show the usual zone of necrosis seen under some calcium hydroxide preparations. Denatured albumin was found to be unacceptable as a capping agent by Molven in 1970⁴³. Heller et al.⁴⁴, using non-inflamed monkey teeth, demonstrated that a resorptive tricalcium phosphate ceramic in saline produced more favorable healing than calcium hydroxide in saline when used as capping agents in pulpotomies. Brännström et al.⁴⁵, using dogs and humans, found that neither a microbicidal cleanser nor a fluoride treatment had any influence on the healing process of exposed pulps capped with calcium hydroxide.

Current trends in pulp capping have focused on the use of commercially produced calcium hydroxide containing capping agents that are supplied as a base and catalyst and set to a hard consistency when mixed and applied to the tooth. These materials appear to have as good or better clinical and experimental results as the calcium hydroxide and water or methyl cellulose mixes and have the added advantage of ease of preparation, consistency of mix and relative surface hardness. Phaneuf et al.⁴⁶, in 1968, tested two commercially available hard setting calcium hydroxide materials, Dycal^R and Hydrex^R, against a commercially available calcium hydroxide methyl cellulose preparation, Pulpdent^R, in human primary teeth. Clinically and radiographically all three were successful

in pulpotomies on sound teeth. However, histologically, Dycal^R and Hydrex^R did not seem to promote pulpal healing and bridge formation as well as the Pulpdent^R. Sayegh and Reed⁴⁷ performed direct and indirect pulp caps on non-carious human teeth using either Hydrex^R or zinc oxide-eugenol. This study also found that clinical success, measured by lack of symptomatology, was better than histological success as measured by normal pulpal tissue. In addition, it was observed that Hydrex^R had a better histological success than the zinc oxide-eugenol. Stanley⁴⁸, in 1972, tested Dycal^R as a capping agent in 35 human teeth for up to 330 days. Of these teeth, only one was extracted prematurely because of pain. Histologically, the pulp demonstrated normal healing in 27 teeth, fair healing in five and poor healing to abscess formation, in three. It was also noted that the dentin bridge formed directly against the Dycal^R after the "mummified tissue" had been replaced by granulation tissue which differentiated into new odontoblasts. Two years later, Tronstad⁴⁹ tested Dycal^R against calcium hydroxide and water in pulp exposed monkey teeth for time periods of 48 hours, 8, 14, 38 and 82 days. His findings supported what Stanley⁴⁸ reported for Dycal^R. Additionally, Tronstad^R noted that bridging with Dycal^R occurred at the Dycal^R-pulp interface and not at some distance from the exposure site as seen when calcium hydroxide was used.

37 Patterson obtained favorable results using Dycal^R on exposed teeth in germ free rats as did Negm et al.^{50,51} in rats and humans. Negm's results, however, suggested the possibility that human teeth responded better to Dycal^R therapy than rat teeth. Pitt Ford⁵² and Hørsted et al.⁵³ reported similar results with Dycal^R in exposed monkey teeth.

54 Fitzgerald, in 1979, described successful early pulpal healing in monkeys following pulp exposure and immediate direct pulp capping using an experimental calcium hydroxide containing material that was later commercially marketed as Life^R. This report was followed by Heys et al.⁵⁵ who found that Dycal^R and the same experimental Life^R material were equally effective as direct pulp capping agents in exposed, noninflamed monkey teeth. In an attempt to simulate clinically infected or inflamed teeth, Isermann and Kaminski⁵⁶, in 1979, left exposed pulps in dog teeth open for two days before capping with Dycal^R. Of the nine viable pulps that were bacterially contaminated and capped with Dycal^R, all but one had vital pulpal tissue and no periapical abnormalities 90 days after treatment. Cox et al.⁵⁷, in 1982, used Life^R and Dycal^R to cap mechanically exposed monkey tooth pulps that had been left open to the oral environment for 0, 1, 24 hours and 7 days prior to capping. Five weeks following treatment, pulpal healing and dentin bridge formation was observed in up to 90

percent of the contaminated teeth.

These commercially available calcium hydroxide containing agents have also been tested as cavity liners in deep cavity preparations. Tronstad and Mjör⁵⁸ found that Dycal^R, Hydrex^R and Pulpdent^R were acceptable as base materials in deep, non exposure cavity preparations in monkey teeth. Heys et al.⁵⁹ compared Dycal^R and Pulpdent^R with Cavitec^R (a zinc oxide-eugenol containing base) in non exposed primary and permanent monkey teeth at 3 days, 5 and 8 weeks. They found that the pulpal responses associated with Cavitec^R were milder than those for Dycal^R and Pulpdent^R, with the Pulpdent^R response at 3 days being the most severe.

II. CLINICAL EVALUATION AND DIAGNOSIS

The increase in the use of conservative pulpal treatments such as direct and indirect pulp capping has placed a greater emphasis on accurate diagnosis of pulpal conditions. In 1963, Seltzer et al.⁶⁰ said "success of conservative procedures aimed at preserving the vitality of the pulp or healing pulp inflammation can be effective only if the status of the pulp is correctly assessed". However, they also noted that "a sense of inadequacy, often bordering on frustration, frequently accompanies any attempt to predict the pathologic state of the dental

pulp". Unfortunately, little has since happened to lessen that frustration. Information that can be utilized to help diagnose pulpal conditions include: intensity, duration and previous history of odontalgia; presence and extent of dental caries, restorations, swelling and/or periodontal disease; radiographic findings; and results of thermal, percussion, palpation and electric pulp tests⁶¹.

The tests listed are basically electrical, thermal and mechanical and may be collectively called vitality tests⁶². Important limitations of these testing methods include: 1.) they can only indicate whether a viable nerve supply exists, not whether vital pulpal tissue is present⁶³; 2.) there is a lack of objectivity of the tests because they all rely on the subjective nature of pain^{60,64}; 3.) they tend to lack reproducibility⁶⁵; and 4.) there is no relationship with the histological condition of the pulp^{60,61,66-68}. This apparent lack of a relationship between clinical assesment of signs and symptoms and actual pulpal inflamation is what makes reliable clinical evaluation in conservative pulpal treatment, both in pre- and post-treatment phases, difficult. However, one relationship does exist. There is a statistically significant relationship between absence of a response to these pulp tests and the presence of pulpal necrosis^{60,61}. In spite of this lack of relationship between clinical signs and symptoms and pulpal histology, mechanical, thermal and electrical pulp

tests still have their place in clinical pulpal diagnosis.

Mechanical stimulation tests include probing or blowing air onto exposed dentine, test cavity preparations, percussion tests and palpation for intraoral swellings^{62,66}. Of these, the percussion and palpation tests are the least invasive. However, they do not necessarily test pulpal vitality. Rather, percussion tests only whether there is significant periodontal inflammation in the apical region, while palpation only tests for swellings and tenderness beneath the alveolar mucosa. A positive response to percussion in a very carious tooth may indicate that there is apical periodontal inflammation because of pulp necrosis⁶². Dummer⁶⁶ found that intraoral swellings and incidence of tenderness above the apex as well as tenderness to percussion was greater in teeth with inflamed pulps.

Thermal pulp testing involves either heating or cooling the tooth. Their reliability in diagnosing pulpal conditions depends heavily on their intent. There is a high correlation between no response to increasing cold or heat stimulus and non vital pulps^{60,66}. So, if the intent is to determine pulpal vitality in a yes-no situation, then no response to extreme heat or cold can fairly reliably predict a non vital pulp. However, if the intent is to predict the pulpal histology in a vital tooth, then the reliability of thermal tests is greatly reduced

because the evaluation of response then must be interpreted in terms of intensity, onset, and duration of pain, all of which have proven to be unreliable in predicting pulpal histology^{60,61,66,67}.

Electric pulp testing relies on direct electrical stimulation of sensory nerves in the pulp⁶². Although they have been largely discounted in the past as being unreliable^{60,61}, recent improvements in their design, use and interpretation have increased their clinical value.⁶⁶ Dummer found that the pulp in question, when compared to a control tooth, was more likely not to be inflamed if it had a similar reading and more likely to be inflamed if it had a higher or lower reading. The electric pulp testers also provide an additional piece of diagnostic evidence to aid in clinical diagnosis. These clinical tests can be combined with radiographic findings, clinical evaluation and history of pain.

Although there appears to be no correlation between the nature or character of pain or exacerbating and relieving factors and pulpal histology⁶¹, there is evidence to suggest that a history of previous episodes of pain occurs more often in teeth with inflamed pulps⁶⁶. Massler and Pawlak⁶⁹, in 1977, found that clinically acute and very painful odontalgia was often associated with inflamed but not bacterially infected pulps, whereas, the infected and partially necrotic pulp had a history of lesser pain that was more chronic. They also described

dentinal and pulpal pain in an attempt to define the quality of pain. Dentinal pain was characterized as a sharp lancinating pain that is easily localized and responds immediately to specific stimuli such as heat and cold. They suggest that this pain is most often associated with a noninfected pulp. Conversely, pulpal pain is a dull throbbing ache, poorly localized, often not associated with a specific stimulus that slowly responds to heat or increased venous pressure during sleep. This pain is most often associated with an infected pulp that most likely is in some stage of irreversible pulpitis. Radiographic evaluation can be used to look for the presence or absence of deep caries, extensive or deep restorations, root fractures, internal or external resorption, width of canal and pulp chamber and periapical abnormalities⁶¹. Even though there does not appear to be any clear correlation of signs or symptoms with pulpal histology⁶⁰⁻⁶⁸, from a clinical standpoint, it is still possible to look at these signs and symptoms and obtain an evaluation of the probable state of pulpal health^{66,67}.

III. CURRENT CLINICAL TREATMENTS

If it has been determined that conservative pulpal therapy is to be performed, then the clinician must decide on the type of treatment and restorative materials. Of

the treatments available, the direct and indirect pulp capping techniques are more frequently being used. A common criticism of performing a direct pulp cap on a vital pulp that has been exposed in the presence of carious dentin is that the bacteria present in the carious dentin may cause a nonreversible bacterial infection which can ultimately lead to pulpal necrosis⁷⁰. In an attempt to avoid exposing the pulp tissue while treating deep carious lesions,^{8,70-73} many investigators and clinicians have suggested that an indirect pulp capping procedure may protect the integrity of the pulpal-dentin interface. In this procedure, carious dentin is removed until a thin layer of affected dentin remains in the deepest part of the pulp. A base material is then applied over this affected dentin and the tooth is restored either with a temporary or permanent restoration. The base material used in indirect pulp capping, according to Fisher⁷⁰, should have two special characteristics. First, the material should not damage the pulp whether it is directly on the pulp tissue or at a distance from it. And second, the material should sterilize the carious lesion or at least inactivate the carious process. Both zinc oxide-eugenol^{72,73} and calcium hydroxide⁷¹⁻⁷⁶ preparations have been used for this procedure. However, calcium hydroxide containing materials probably have the most general application as the initial base. Fisher^{70,77} and Knight

and Marchelya⁷⁴ have demonstrated that some commercial calcium hydroxide products are effective in sterilizing carious lesions. Fisher⁷⁰ and Stanley⁷⁸ recommended calcium hydroxide products as opposed to zinc oxide-eugenol products for indirect pulp capping because calcium hydroxide is better suited to treat microscopic exposures that may be created during caries removal prior to capping. These calcium hydroxide products have also been demonstrated to be effective in direct pulp capping of human teeth^{10-12,14,15,18-20,22,23,46-48,79-84}. However, there are no studies that have compared the clinical effectiveness of Life^R and Dycal^R.

IV. HISTOLOGICAL EVALUATION OF PULPAL TISSUES

As early as 1939, when Zander¹⁰ described the histology of successful pulpal reactions, attempts have been made to categorize histologic pulpal reactions^{14,15,18,19,20,23}. In 1963, Seltzer et al.⁶⁰ attempted to establish classification of pulp conditions and then correlate these to clinical findings. They developed lengthy definitions for six classifications: 1.) Intact-inflamed pulp; 2.) Atrophic pulp; 3.) Intact pulp with scattered chronic inflammatory cells; 4.) Chronic partial pulpitis; 5.) Chronic total pulpitis; and 6.) Total necrosis. These categories attempted to combine all phases of soft tissue pulpal response into distinct,

separate categories but did not address the hard tissue dynamics. Sayegh⁸¹, in 1969, chose to emphasize dentin bridge formation in his histologic assesment of pulp capping. He described bridge formation as being either present or absent and then categorized the types of bridges as being fibrillar, globular or tubular. Sekine et al.⁸², established the following criteria for evaluating histologic results of pulp capping:

- "a.) "Good" Cases that, manifesting evidence of tissue repair in the site of exposure, showed no inflammatory or destructive changes in the pulp.
- b.) "Fair" Cases that showed evidence of marked pulp resistance, even though inflammatory or destructive superficial changes were observed, or cases in which tissue repair might be encouraged within a certain future period, even though inflammatory changes were presently observed in the site of exposure.
- c.) "Bad" Cases with extensive destruction of the coronal or radicular portion of the pulp but with little expectation of pulp repair."

These criteria, although they attempted to integrate both soft and hard tissue responses, required the evaluator to make a supposition concerning future pulpal response. Garfunkel et al.⁶⁷, in 1973, attempted to correlate clinical and histological findings by establishing four clinical categories and four analogous histologic categories. These categories resembled those of Seltzer et al.⁶⁰ in 1963. All of these evaluation techniques were developed in an attempt to explain

clinical findings in histologic terms rather than to independently assess the histologic pulpal reactions and then evaluate those responses in terms of clinical findings.

83

Bergenholtz , in 1977, in studying inflammatory reactions in the pulp that were caused by bacterial products, used the following criteria to evaluate inflammatory cell responses:

"Degree 1 - Slight infiltration of neutrophils in the odontoblast layer.

Degree 2 - Moderate infiltration of neutrophils in the odontoblast layer and cell infiltration also detectable in both cell-free and cell-rich zones.

Degree 3 - Severe infiltration of neutrophils frequently observed as abscesses".

These criteria were established independently of any preconceived clinical condition and thus were valid to use in any evaluation of pulpal response. Negm et al. ⁵⁰ , in 1980, evaluated histological pulpal response in terms of degree of inflammation (mild, moderate, moderate to severe and severe), reduction in number of odontoblasts (none, slight and moderate to severe) and incidence and quantity of dentin formed (none, just beginning and a considerable amount). These categories attempted to evaluate the inflammatory cell response, soft tissue response and hard tissue responses of the pulpal tissue. In 1982, Cox et al. ⁵⁷ also evaluated the inflammatory cell, soft tissue and hard tissue response using pre-

defined criteria. These criteria, as listed in Table 2, were used by each of the investigators and then, teeth with evaluation differences between investigators were reevaluated and discussed jointly until a consensus was reached. This system accomplished three goals: 1.) it established a set of criteria that permitted a more uniform evaluation of the histologic material; 2.) reduced the chance of missing important histological findings by permitting evaluation by more than one investigator and defining the important areas to be evaluated; and 3.) helped to reduce evaluator bias by demanding a consensus agreement among the evaluators.

V. SUMMARY

Direct and indirect pulp capping techniques are more frequently being used as conservative pulpal therapies in teeth with deep carious lesions. For the past several decades, calcium hydroxide containing materials have been used in direct pulp capping and complete caries removal procedures. Calcium hydroxide powder mixed in either water or methylcellulose has been shown to be effective in promoting pulpal healing in direct pulp capping procedures both in animals^{13,14,27} and humans^{10,12,14-16,19,20,22,23,26}.

. Commercial products containing calcium hydroxide have also been demonstrated to be effective in

direct pulp capping procedures both in
 37,39,40,49,50,52-57 and humans 46-48,51,75
 animals .

However, other agents, such as zinc oxide-
 12,22-25,27,47 28-32,34-37,41
 eugenol , corticosteroids and
 38-41
 antibiotics have been demonstrated to be less
 effective than these commercial products.

Indirect pulp capping procedures have been
 recommended as procedures of choice for treating deep
 carious lesions in order to protect the integrity of the
 8,70-73
 pulpal-dentin interface . The base material used
 should not damage the pulp and should sterilize the
 70
 carious lesion or inactivate the carious process .
 72,73
 Although both zinc oxide-eugenol and calcium
 71-76
 hydroxide preparations have been used for this
 procedure, the calcium hydroxide materials probably have
 70-78
 the most general application as the initial base .
 Both zinc oxide-eugenol materials and calcium hydroxide
 materials have been shown to be effective in non exposed
 58,59
 complete caries removal teeth . However there are no
 studies that have compared the clinical effectiveness of
 Life^R and Dycal^R in pulp capping, indirect pulp capping
 or exposed complete caries removal procedures.

These conservative treatments have placed a greater
 emphasis on accurate diagnosis of pulpal conditions.
 Clinical diagnosis relies on evaluating radiographs and
 the results of electrical, thermal and manipulative tests.
 However, the reliability of these procedures as they

relate to clinical diagnosis is not high because of four important limitations: 1.) they can only indicate whether a viable nerve supply exists, not whether vital pulpal tissue is present⁶³; 2.) there is a lack of objectivity of the tests because they all rely on the subjective nature of pain^{60,64}; 3.) they tend to lack reproducibility⁶⁵; and 4.) there is a lack of correlation^{60,61,66-68} with the pulpal histology .

METHODS AND MATERIALS

I. CASE SELECTION AND DISTRIBUTION

Patients were selected from registered clinic patients, or those presenting for urgency treatment at The University of Michigan School of Dentistry. These patients were informed of the intent of the study and given a written informed consent form (Appendix 1) to read and sign if they agreed to participate. It was made clear that in no way would their refusal or acceptance to participate alter their eligibility or opportunity for further treatment at the dental school. At that time a current set of radiographs were taken and appropriate teeth were chosen for restoration. During restoration, the teeth were assigned to one of the following groups:

Group 1 - Radiographic evidence of a deep carious lesion in which pulp exposure was suspected if complete caries removal was performed. These were restored as Indirect Pulp Capped (IPC) teeth.

Group 2 - Radiographic evidence of a deep carious lesion in which pulp exposure was NOT suspected if complete caries removal was performed. These were restored as Complete Caries Removal (Complete CR) teeth.

Group 3 - All teeth which, in the course of treatment, the pulp was exposed. These were restored as Direct Pulp Capped (DPC) teeth.

Teeth that were periodontally compromised or had a previous history of spontaneous pain were not included in this study. Medicaments were selected at random at the time of treatment. The resultant distribution of treatment types and medicaments was as follows:

Group 1	
Indirect Pulp Cap (IPC) (Incomplete CR)	Life ^R = 24 teeth Dycal ^R = 26 teeth
Group 2	
Complete Caries Removal (Complete CR)	Life ^R = 20 teeth Dycal ^R = 23 teeth Cavitec ^R = 20 teeth
Group 3	
Direct Pulp Cap (DPC)	Life ^R = 19 teeth Dycal ^R = 19 teeth

These numbers represent a combined total of teeth that were to be: 1.) restored and maintained or 2.) extracted because of prosthetic or other reasons. This selection provided a histological as well as clinical assessment of teeth. The teeth extracted for histological evaluation were distributed as follows:

7 Untreated Controls

3 Complete Caries Removal
 2 treated with Dycal^R
 1 treated with Cavitec^R

16 Direct Pulp Capped
 8 treated with Life^R
 8 treated with Dycal^R

One of the Dycal^R treated DPC teeth was extracted 1 week following treatment due to painful symptomatology (prolonged sensitivity to heat and cold). The remaining 15 DPC and 3 Complete CR teeth were extracted following the 6 month clinical evaluation. The 7 control teeth were carious and noncarious, previously nonrestored teeth.

II. CLINICAL PROCEDURES

Signs and symptoms were recorded for each tooth both immediately prior to restoration and at subsequent 1 week and 6 month recall visits by performing the following clinical tests commonly used to diagnose pulpal condition^{60,63,66}:

(1) Electrical pulp testing: An Analytic Technology Digital Pulp Tester model 2001R (Table 1) was used to measure pulp vitality response. The tests were made by placing the tip of the pulp tester probe on the cervical 1/3 of the buccal aspect of the tooth. A nonfluoridated toothpaste, Sensodyne^R (Table 1), was used for the conductive paste. Care was taken to prevent the probe or

the conductive paste from contacting adjacent hard or soft tissues. The patient was instructed to indicate the point at which any change in sensation in the tooth was noted. Teeth that did not respond to electrical pulp testing during the pretreatment evaluation were excluded from this study. At each visit, five readings for each treated tooth and the nontreated control tooth were taken. The numerical middle three readings were then averaged and the difference between the average reading of the test and average reading of the control tooth computed (average reading test tooth - average reading control tooth). This value was then labeled AVGDIFF.

(2) Heat response of the test tooth: Moyco Modeling Compound #55071 (Table 1) was warmed over a gas flame and then applied to the buccal surface of the test tooth for 5 seconds. The average tooth surface temperatures generated by this procedure were determined using a YSI Model 42SC Tele-Thermometer (Table 1). The modeling compound was prepared as described and placed on the buccal surface of the tooth directly over the heat probe. Temperatures were recorded immediately after placement and 5 seconds later. These measurements were repeated 10 times, allowing the tooth to return to normal surface temperature for several minutes between each test. The tooth surface temperature produced by this procedure was $56^{\circ}\text{C} \pm 4^{\circ}$ initially that cooled to $49^{\circ}\text{C} \pm 4^{\circ}$ at the end of the 5 seconds of

application (Appendix 3). The intensity and duration of any patient sensitivity during or immediately following application was recorded.

(3) Cold response of the test tooth: Ice was applied directly to the buccal surface of the test tooth for 5 seconds. The intensity and duration of any patient sensitivity during or immediately following application was recorded.

(4) Pressure response of the test tooth: Firm axial and lateral pressure was applied to the test tooth. Any patient sensitivity to the pressure was recorded.

(5) Percussion response of the test tooth: A mouth mirror handle was used to percuss the test tooth and adjacent teeth. Any patient sensitivity was recorded.

(6) History of pain associated with the test tooth: Any history of pain to heat, cold, sweets, percussion or any other stimulus that could be recalled by the patient was recorded. Any teeth with a history of spontaneous pain without associated stimulus were excluded from the study.

Operating sites were isolated with a rubber dam when possible and the lesion uncovered to an intact dentino-enamel junction using a high speed air turbine handpiece with a carbide round and/or straight fissure bur under an air-water spray coolant.

Teeth in the Indirect Pulp Cap (IPC) group had caries removed with spoon excavators and low-speed rotary instrumentation (200-5000 RPM) using steel round burs to a

point at which, in the operator's clinical judgment, further excavation would result in a carious exposure. Life^R or Dycal^R, selected at random, was placed as an indirect pulp capping agent directly over and 1 to 2 millimeters beyond the remaining carious dentin. The tooth was then restored using cavity varnish (Copalite^R), zinc phosphate cement (Tenacin^R) and amalgam (Sybraloy^R) or an acid etched, bonded composite resin (Simulate^R) with no varnish or zinc phosphate cement base. All materials used are listed in Table 1.

Teeth in the Complete Caries Removal (Complete CR) group had caries completely removed and either Life^R, Dycal^R or Cavitec^R, selected at random, was placed as an intermediary base. These teeth were then restored in the same manner as the Group 1 teeth.

If the pulp was exposed during treatment, caries removal was completed, then Life^R or Dycal^R, selected at random, was used as a direct pulp capping agent directly over and 1 to 2 millimeters beyond the exposed pulp. These teeth were then restored as in the other two groups. These teeth constituted the Direct Pulp Capped (DPC) group.

Recalls were made 1 week and 6 months following treatment. During these recalls, all clinical tests performed preoperatively were repeated and radiographs of the treated teeth were taken. A telephone follow-up was

Table 1

MATERIALS USED

PRODUCT	MANUFACTURER	LOT #
R Life	Kerr/Sybron Romulus, MI 48174	Base-01227 Catalyst-01267
R Dycal	L.D. Caulk Co. Milford, DE 19963	Base-100980 Catalyst-100980
R Cavitec	Kerr/Sybron Romulus, MI 48174	Base-01210 Catalyst-01220
R Tenacin	L.D. Caulk Co. Milford, DE 19963	
R Sybraloy	Kerr/Sybron Romulus, MI 48174	100680 2259 061581 2062 120781 9293
R Simulate	Kerr/Sybron Romulus, MI 48174	Base-01302 Catalyst-02304 Etchant-91158
R Copalite	Cooley & Cooley LTD. Houston, TX 77006	
R Sensodyne	Dentco Inc. Jersey City, NJ 07304	C231 L101
Electric Pulp Tester	Analytic Technology Redmond, WA 98052	06732
Moyco Modeling Compound #55071	Moyco Industries, Inc. Phila., PA 19132	
YSI Model 42SC Tele-Thermometer	Yellow Springs Instrument Co., Inc. Yellow Springs, OH 45387	

made 24 and 72 hours postoperatively to solicit information regarding the patient's comfort.

Seven additional non-treated carious and non-carious teeth that were treatment planned for extraction were obtained in order to establish baseline histological data. These teeth were not treated and were used to provide needed information to better evaluate the experimental histologic material. Prior to extraction, the teeth were evaluated in the same manner as the treated teeth. They were then processed and evaluated in the same manner as the extracted treated teeth.

III. HISTOLOGICAL PROCEDURES

For patients whose total treatment plan indicated need for removal of the study teeth, the scheduling of the extraction was determined by the sequence of treatment which was most appropriate for the patient's dental health. All clinical pulp tests were performed just prior to extraction. Immediately following extraction, the apical one-third of the root was removed and the crown placed in a phosphate buffered paraformaldehyde-glutaraldehyde (PBF-GTA) fixative for 2 days. A 0.5M EDTA solution was used for demineralization and radiographs used to determine end point demineralization. Following demineralization, the teeth were dehydrated, embedded in Paraplast Plus^R paraffin and serially sectioned at 7-10

micrometers through the entire pulp. Alternate slides were stained with Hematoxylin and Eosin and a modified Preece Trichrome for histologic examination. Prior to identification of the test procedure, each tooth was independently evaluated by two examiners according to an established set of criteria listed in Table 2. Teeth with evaluation differences between investigators were reevaluated and discussed jointly until a consensus was reached.

IV. STATISTICAL

All preoperative and postoperative clinical evaluations were assembled and correlated with histological evaluations when possible. Student "t", Chi-squared and Fisher's Exact p-values were calculated using The University of Michigan Computing Center statistical program, MIDAS, for statistical analysis of the data at the 0.05 confidence level.

Table 2

CRITERIA FOR GRADING TOOTH PULP HISTOLOGY

INFLAMMATORY CELL RESPONSE

1. None to slight inflammatory response in the coronal pulp. A few scattered lymphocytes may be present.
2. Moderate cellular infiltrate of neutrophils and/or monocytes in the coronal pulp.
3. Severe inflammatory response with the presence of neutrophils and/or monocytes involving at least 1/3 of the coronal pulp.
4. Total necrosis of the coronal pulp.

SOFT TISSUE ORGANIZATION

1. Normal or close to normal cellular morphology at the exposure site or adjacent to the cut tubules and throughout the coronal pulp.
2. Incomplete cellular organization at the exposure site or adjacent to the cut tubules, however, the remaining coronal pulp is normal.
3. Definitive cellular degeneration in at least the coronal third of the pulp.

HARD TISSUE ORGANIZATION - EXPOSED PULPS

1. Organization of a calcified tissue directly against some portion of the medicament interface.
2. Organization of a calcified tissue at some distance from the medicament interface. Some necrotic or amorphous debris may be interposed between the medicament and calcified tissue.
3. No evidence of any calcified tissue formation at the exposure site.

HARD TISSUE ORGANIZATION - NON EXPOSED PULPS

1. No additional or abnormal increase in reparative dentin thickness adjacent to the cut tubules.
2. A thin rim of new reparative dentin directly adjacent to the cut tubules.
3. A large bulk of new reparative dentin directly adjacent to the cut tubules.

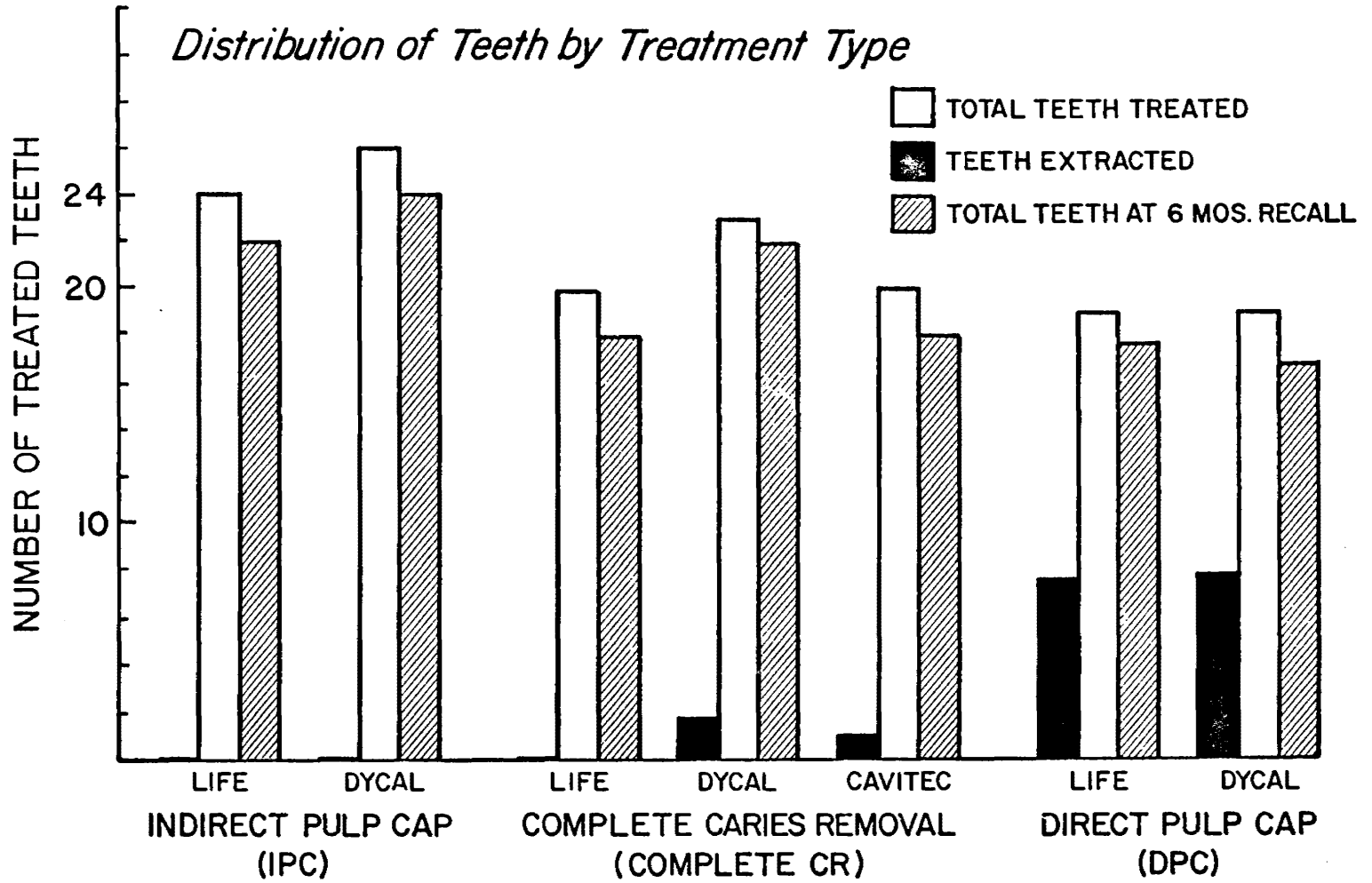
RESULTS

I. DEMOGRAPHIC DATA

The distribution of the 151 teeth treated in the present study may be seen in Table 3. These teeth were distributed between 55 patients, 29 male and 26 female, whose ages ranged from 20 to 60 years (mean 27 ± 5). Of these 151 teeth, 12 were lost from the study at the 6 month recall. One of the teeth that was planned for extraction at 6 months was extracted at 1 week due to painful symptomatology (prolonged sensitivity to heat and cold) and the other 11 were lost due to patient attrition. This represents an overall 7.9 percent attrition rate over the 6 month period. The 139 teeth evaluated at the 6 month recall were distributed as follows: 59 treated with Life^R, 63 treated with Dycal^R and 18 treated with Cavitec^R.

The data for the responses to percussion, heat and cold, were divided into two categories: 1.) negative and 2.) positive. This was to insure adequate numbers of cases per cell in the two way contingency tables thus permitting proper Chi-square analysis. This recategorization was achieved by assigning all positive

Table 3



responses to clinical tests or subjective symptoms to the positive category and all non-responses to the negative category. With the exception of the one tooth extracted at 1 week, there were no cases of prolonged sensitivity to heat, cold or percussion in any of the teeth either before or after treatment.

II. CLINICAL EVALUATION

COMPARING MEDICAMENTS - ELECTRICAL PULP TEST MEASUREMENTS:

Electric pulp test measurements for Life^R and Dycal^R treated teeth at the initial appointment, 1 week and 6 month recalls were compared using Student "t" tests, first by treatment type and then with all treatments combined (Table 4). In addition, Cavitec^R was compared to Life^R and Dycal^R in Complete CR treated teeth (Table 5). There were no statistical differences at the 0.05 confidence level in the average difference between Life^R and Dycal^R for any time period within any treatment type or with all treatment types combined (Table 4). Also, there were no statistical differences in the average differences between Life^R, Dycal^R and Cavitec^R in the complete caries removal group (Treatment 2) as seen in Table 5.

COMPARING MEDICAMENTS - CLINICAL SIGNS AND SYMPTOMS:

The clinical signs and symptoms for Life^R vs. Dycal^R treated teeth at the initial appointment, 1 and 3 day,

Table 4

*
 STUDENT "t" TESTS ON THE AVGDIFF IN ELECTRIC PULP TEST
 MEASUREMENTS FOR LIFE^R AND DYCAL^R
 BY TREATMENT TYPE

	R LIFE			R DYCAL			
	N	MEAN ± STD	N	MEAN ± STD		p	
IPC							
Initial	24	-0.58 ± 12.12	26	2.65 ± 12.45		.3573	
1 Week	24	0.65 ± 15.83	26	2.90 ± 14.56		.6023	
6 Months	22	-0.67 ± 12.48	24	1.90 ± 10.89		.4609	
COMPLETE CR							
Initial	20	2.45 ± 12.68	23	1.36 ± 11.05		.7641	
1 Week	19	5.08 ± 8.74	23	3.00 ± 13.19		.5579	
6 Months	18	2.90 ± 13.31	22	4.43 ± 11.71		.7017	
DPC							
Initial	19	5.37 ± 14.21	19	5.21 ± 14.54		.9723	
1 Week	19	0.65 ± 12.36	19	5.96 ± 18.62		.3072	
6 Months	18	3.85 ± 11.55	17	6.70 ± 16.60		.5576	
ALL TREATMENTS							
Initial	63	2.18 ± 12.98	68	2.93 ± 12.53		.7365	
1 Week	62	2.01 ± 12.90	68	3.79 ± 15.20		.4750	
6 Months	58	1.84 ± 12.41	63	4.08 ± 12.86		.3335	

* AVGDIFF = Average test response of treated tooth -
 Average test response of control tooth

Table 5

*

STUDENT "t" TESTS ON THE AVGDIFF IN ELECTRIC PULP TEST
MEASUREMENTS FOR DIFFERENT MEDICAMENT TYPES
IN COMPLETE CR NONEXPOSURES

	N	MEAN ± STD	N	MEAN ± STD	p
INITIAL					
L v.s. D	20	2.45 ± 12.68	23	1.36 ± 11.06	.7705
L v.s. C	20	2.45 ± 12.68	20	-3.57 ± 12.96	.1243
D v.s. C	23	1.36 ± 11.06	20	-3.57 ± 12.96	.1921
1 WEEK					
L v.s. D	19	5.08 ± 8.74	23	3.00 ± 13.19	.6015
L v.s. C	19	5.08 ± 8.74	20	-1.25 ± 15.41	.1286
D v.s. C	23	3.00 ± 13.19	20	-1.25 ± 15.41	.2835
6 MONTHS					
L v.s. D	18	2.90 ± 13.31	22	4.43 ± 11.71	.7296
L v.s. C	18	2.90 ± 13.31	18	0.01 ± 16.51	.5336
D v.s. C	22	4.43 ± 11.71	18	0.01 ± 16.51	.3196

* AVGDIFF = Average test response of treated tooth -
Average test response of control tooth

1 week and 6 month recalls were compared by Chi-square analysis first by treatment type and then with all treatments combined. In addition, Cavitec^R was compared to Life^R and Dycal^R in Complete Caries Removal (Complete CR) teeth. The two way contingency tables of the significant differences ($p < 0.05$) found in these tests are listed in Table 6. There were no significant differences between Life^R and Dycal^R in indirect pulp capped teeth (IPC) with two exceptions. At 24 hours following treatment, there were more positive responses to patient history of sensitivity to heat and at three days more positive responses to patient history of sensitivity to cold in teeth treated with Life^R. There were no significant differences between Life^R, Dycal^R and Cavitec^R in Complete CR for any clinical sign or symptom at any time period ($p > 0.05$). The Direct Pulp Capping Group (DPC) also had no significant differences between Life^R and Dycal^R ($p > 0.05$) except for the tested response to cold initially and at 6 months. In both of these situations, there were more Life^R treated teeth sensitive to cold. When all treatment types were combined, there were no significant differences in the clinical signs and symptoms between Life^R and Dycal^R at any time period ($p > 0.05$).

COMPARING TREATMENT TYPES - ELECTRIC PULP TEST MEASUREMENTS:

The electric pulp test measurements for different treatment types (IPC, Complete CR and DPC) at the initial

Table 6

*
SIGNIFICANT DIFFERENCES BETWEEN MEDICAMENT
TYPE AND CLINICAL SIGNS AND SYMPTOMS
BY TREATMENT TYPE

	LIFE ^R	DYCAL ^R	Chi ² p	Fisher's Exact p
<u>IPC</u>				
1 Day History of Heat Sensitivity				
Negative	19	26	.0142	.0201
Positive	5	0		
3 Day History of Cold Sensitivity				
Negative	16	25	.0067	.0082
Positive	8	1		

COMPLETE CR - No significant differences between Life^R, Dycal^R or Cavitec^R.

<u>DPC</u>				
Initial Tested Cold Sensitivity				
Negative	12	17	.0564	.0622
Positive	7	2		
6 Month Tested Cold Sensitivity				
Negative	12	16	.0424	.0517
Positive	6	1		

ALL GROUPS - No significant differences between Life^R and Dycal^R.

* $p \leq 0.05$

appointment, 1 week and 6 month recalls were compared using Student-"t" tests, first by medicament type and then with all Life^R and Dycal^R treated teeth combined (Tables 7 and 8). There were no statistical differences ($p>0.05$) in the AVGDIFF between any combination of treatment types for Life^R or Dycal^R either separately or combined. Two teeth tested devital at the 6 month recall. Both were DPC teeth, one treated with Life^R and one with Dycal^R. The tooth treated with Life^R was previously scheduled for extraction. Histologically, the pulp of this tooth was totally necrotic. The other tooth was asymptomatic with no periapical radiolucency. This tooth was not extracted for histological evaluation.

COMPARING TREATMENT TYPES - CLINICAL SIGNS AND SYMPTOMS:

The clinical signs and symptoms for the different treatment types at the initial appointment, 1 and 3 day, 1 week and 6 month recalls were compared by Chi-square analysis first with Life^R and Dycal^R separately and then with Life^R and Dycal^R treated teeth combined (Tables 9-15).

There were only two significant differences between Indirect Pulp Capped (IPC) and Complete Caries Removal (Complete CR) teeth treated with Life^R (Table 9). At the initial appointment the IPC teeth had more patient histories of sensitivity to cold than the Complete CR

Table 7

*

STUDENT "t" TESTS ON THE AVGDIFF IN ELECTRIC PULP TEST
MEASUREMENTS FOR DIFFERENT TREATMENT TYPES
BY MEDICAMENT TYPE

	N	MEAN ± STD	N	MEAN ± STD	p
R					
LIFE					
		IPC		COMPLETE CR	
Initial	24	-0.58 ± 12.12	20	2.45 ± 12.68	.4227
1 Week	24	0.65 ± 15.83	19	5.08 ± 8.74	.2797
6 Months	22	-0.67 ± 12.48	18	2.90 ± 13.31	.3881
		IPC		DPC	
Initial	24	-0.58 ± 12.12	19	5.37 ± 14.21	.1456
1 Week	24	0.65 ± 15.83	19	0.65 ± 12.36	.9997
6 Months	22	-0.67 ± 12.48	18	3.85 ± 11.35	.2463
		COMPLETE CR		DPC	
Initial	20	2.45 ± 12.68	19	5.37 ± 14.21	.5016
1 Week	19	5.08 ± 8.74	19	0.65 ± 12.36	.2096
6 Months	18	2.90 ± 13.31	18	3.85 ± 11.55	.8205
R					
DYCAL					
		IPC		COMPLETE CR	
Initial	26	2.65 ± 12.45	23	1.36 ± 10.05	.7039
1 Week	26	2.90 ± 14.56	23	3.00 ± 13.19	.9810
6 Months	24	1.89 ± 10.89	22	4.43 ± 11.71	.4514
		IPC		DPC	
Initial	26	2.65 ± 12.45	19	5.21 ± 14.54	.5289
1 Week	26	2.90 ± 14.56	19	5.96 ± 18.62	.5395
6 Months	24	1.90 ± 10.89	17	6.70 ± 16.60	.2694
		COMPLETE CR		DPC	
Initial	26	1.36 ± 10.05	19	5.21 ± 14.54	.3351
1 Week	23	3.00 ± 13.19	19	5.96 ± 18.62	.5503
6 Months	22	4.43 ± 11.71	17	6.70 ± 16.60	.6190

* AVGDIFF = Average test response of treated tooth -
Average test response of control tooth

Table 8

*

STUDENT "t" TESTS ON THE AVGDIFF IN ELECTRIC PULP TEST
MEASUREMENTS FOR DIFFERENT TREATMENT TYPES
LIFE^R AND DICAL^R COMBINED

	N	MEAN ± STD	N	MEAN ± STD	p
		IPC		COMPLETE CR	
Initial	50	1.10 ± 12.27	43	1.87 ± 11.71	.7596
1 Week	50	1.82 ± 15.07	42	3.94 ± 11.31	.4541
6 Months	46	0.67 ± 11.62	40	3.74 ± 12.31	.2379
		IPC		DPC	
Initial	50	1.10 ± 12.27	38	5.29 ± 14.18	.1413
1 Week	50	1.82 ± 15.07	38	3.30 ± 15.82	.6552
6 Months	46	0.67 ± 11.62	35	5.23 ± 14.09	.1142
		COMPLETE CR		DPC	
Initial	43	1.87 ± 11.71	38	5.29 ± 14.18	.2373
1 Week	42	3.94 ± 11.31	38	3.30 ± 15.82	.8350
6 Months	40	3.74 ± 12.31	35	5.23 ± 14.09	.6254

* AVGDIFF = Average test response of treated tooth -
Average test response of control tooth

Table 9

*
SIGNIFICANT DIFFERENCES BETWEEN IPC, COMPLETE CR
AND DPC TREATMENTS AND CLINICAL SIGNS AND SYMPTOMS
IN TEETH TREATED WITH LIFE^R

	IPC	COMPLETE CR	Chi ² p	Fisher's Exact p
Initial History of Cold Sensitivity				
Negative	12	19	.0011	.0011
Positive	12	1		
3 Day History of Heat Sensitivity				
Negative	19	19	.0343	.0442
Positive	5	0		
1 Week History of Heat Sensitivity				
Negative	24	15	.0183	.0314
Positive	0	4		

* $p \leq 0.05$

teeth. The other difference was seen at three days where there were more IPC teeth with a history of sensitivity to heat. Indirect Pulp Capping (IPC) v.s. Direct Pulp Capping (DPC) with Life^R resulted in only one significant difference in clinical signs and symptoms (Table 9). At one week the DPC group had more reports of patient sensitivity to heat.

There were five significant differences in signs and symptoms when Complete CR and DPC teeth treated with Life^R were compared (Table 10). One day, three days and 1 week following treatment more DPC patients had histories of sensitivity to cold than Complete CR patients. There were also more DPC patients sensitive to heat at 3 days. And at 6 months, more DPC treated teeth tested sensitive to cold.

Differences in clinical signs and symptoms between treatment types in teeth treated with Dycal^R can be seen in Tables 11 and 12. There were no differences in clinical signs and symptoms between Indirect Pulp Capped (IPC) and Complete Caries Removal (Complete CR) teeth when they were treated with Dycal^R. However, this was not true when IPC and DPC were compared (Table 11). There were six differences in clinical signs and symptoms between IPC and DPC. Initially, there were more IPC teeth that tested sensitive to cold. But, at 1 day, 3 days and 1 week this trend was reversed with more DPC patients reporting a history of sensitivity to cold. At 1 day there were more reports of sensitivity to heat in the DPC patients and at

Table 10

*
SIGNIFICANT DIFFERENCES BETWEEN COMPLETE CR
AND DPC TREATMENTS AND CLINICAL SIGNS
AND SYMPTOMS IN TEETH TREATED WITH LIFE^R

	COMPLETE CR	DPC	Chi ² p	Fisher's Exact p
1 Day History of Cold Sensitivity				
Negative	17	9	.0052	.0064
Positive	2	10		
3 Day History of Heat Sensitivity				
Negative	19	15	.0345	.0001
Positive	0	4		
3 Day History of Cold Sensitivity				
Negative	15	9	.0436	.0455
Positive	4	10		
1 Week History of Cold Sensitivity				
Negative	18	11	.0076	.0094
Positive	1	8		
6 Month Tested Cold Sensitivity				
Negative	17	12	.0352	.0438
Positive	1	6		

* $p \leq 0.05$

Table 11

*
SIGNIFICANT DIFFERENCES BETWEEN IPC AND DPC
TREATMENTS AND CLINICAL SIGNS AND SYMPTOMS
IN TEETH TREATED WITH DYCAL^R

	IPC	DPC	Chi ² p	Fisher's Exact p
Initial Tested				
Cold Sensitivity				
Negative	13	17	.0055	.0036
Positive	13	2		
1 Day History of Heat Sensitivity				
Negative	26	16	.0360	.0683
Positive	0	3		
1 Day History of Cold Sensitivity				
Negative	23	9	.0027	.0036
Positive	3	10		
3 Day History of Cold Sensitivity				
Negative	25	9	.0002	.0002
Positive	1	10		
1 Week History of Cold Sensitivity				
Negative	24	10	.0022	.0032
Positive	2	9		
1 Week Tested Percussion Sensitivity				
Negative	24	13	.0384	.0473
Positive	2	6		

* $p \leq 0.05$

1 week, more DPC teeth tested sensitive to percussion. There were four significant differences in clinical signs and symptoms between Complete CR and DPC teeth treated with Dycal^R (Table 12). In this comparison, there were more reported histories of sensitivity to cold for the DPC group at 1 day, 3 days and 1 week following treatment. Additionally, there were more histories of sensitivity to percussion at 1 week for the DPC group.

Combining the Life^R and Dycal^R treated teeth together by treatment produced slightly different results. Significant differences in clinical signs and symptoms between IPC and Complete CR teeth (Table 13) were seen in the number of initial histories of sensitivity to cold (IPC > Complete CR), initial tested sensitivity to cold (IPC > Complete CR) and 1 week tested sensitivity to heat (IPC > Complete CR). There were also significant differences in signs and symptoms between the IPC and DPC teeth (Table 14). At the initial appointment more IPC teeth tested sensitive to cold but at 1 day, 3 days and 1 week there were more histories of sensitivity to cold in the DPC treated teeth. Also at 1 week there were more histories of sensitivity to heat in the DPC treated teeth. Finally, significant differences in clinical signs and symptoms were seen between Complete CR and DPC teeth (Table 15). In this comparison, the DPC teeth had more histories of sensitivity to cold at 1 day, 3 days and 1 week, more histories of sensitivity to heat at 3 days,

Table 12

*
SIGNIFICANT DIFFERENCES BETWEEN COMPLETE CR
AND DPC TREATMENTS AND CLINICAL SIGNS AND SYMPTOMS
IN TEETH TREATED WITH DICAL^R

	COMPLETE CR	DPC	Chi ² p	Fisher's Exact p
1 Day History of Cold Sensitivity				
Negative	19	9	.0159	.0183
Positive	4	10		
3 Day History of Cold Sensitivity				
Negative	19	9	.0159	.0183
Positive	4	10		
1 Week History of Cold Sensitivity				
Negative	21	10	.0046	.0060
Positive	2	9		
1 Week History of Percussion Sensitivity				
Negative	22	13	.0184	.0250
Positive	1	6		

* $p \leq 0.05$

Table 13

*
SIGNIFICANT DIFFERENCES BETWEEN IPC AND COMPLETE CR
TREATMENTS AND CLINICAL SIGNS AND SYMPTOMS
IN LIFE^R AND DICAL^R TREATED TEETH

	IPC	COMPLETE CR	Chi ² p	Fisher's Exact p
Initial History of Cold Sensitivity				
Negative	31	39	.0014	.0378
Positive	19	4		
Initial Tested Cold Sensitivity				
Negative	26	31	.0473	.0436
Positive	24	12		
1 Week Tested Heat Sensitivity				
Negative	39	39	.0481	.0413
Positive	11	3		

* $p \leq 0.05$

Table 14

*
SIGNIFICANT DIFFERENCES BETWEEN IPC AND DPC
TREATMENTS AND CLINICAL SIGNS AND SYMPTOMS
IN LIFE^R AND DYCAL^R TREATED TEETH

	IPC	DPC	Chi ² p	Fisher's Exact p
Initial Tested				
Cold Sensitivity				
Negative	26	29	.0196	.0166
Positive	24	9		
1 Day History of Cold Sensitivity				
Negative	40	18	.0014	.0014
Positive	10	20		
3 Day History of Cold Sensitivity				
Negative	41	18	.0006	.0007
Positive	9	20		
1 Week History of Heat Sensitivity				
Negative	49	32	.0179	.0237
Positive	1	6		
1 Week History of Cold Sensitivity				
Negative	44	21	.0005	.0006
Positive	6	17		

* p ≤ 0.05

Table 15

*
SIGNIFICANT DIFFERENCES BETWEEN COMPLETE CR AND DPC
TREATMENTS AND CLINICAL SIGNS AND SYMPTOMS IN
LIFE^R AND DYCAL^R TREATED TEETH

	COMPLETE CR	DPC	Chi ² p	Fisher's Exact p
1 Day History of Cold Sensitivity				
Negative	36	18		
Positive	6	20	.0003	.0003
3 Day History of Heat Sensitivity				
Negative	41	30		
Positive	1	8	.0083	.0096
3 Day History of Cold Sensitivity				
Negative	34	18		
Positive	8	20	.0017	.0017
1 Week History of Cold Sensitivity				
Negative	39	21		
Positive	3	17	.0001	.0001
1 Week Tested Percussion Sensitivity				
Negative	41	30		
Positive	1	8	.0083	.0096
6 Month Tested Heat Sensitivity				
Negative	40	31		
Positive	0	4	.0280	.0431

* p ≤ 0.05

more tested sensitivity to percussion at 1 week and more tested sensitivity to heat at 6 months.

III. HISTOLOGICAL EVALUATION

CONTROL TEETH

All 7 control teeth, irrespective of presence or absence of clinical caries had no inflammation (Inflammatory cell response category 1, Table 2) and normal cellular morphology (Soft tissue response category 1, Table 2). Five of these teeth, three of which had clinical evidence of caries, had no evidence of increased thickness of reparative dentin (Reparative dentin deposition category 1, Table 2), one clinically carious tooth had a thin rim of reparative dentin (category 2) and one non-erupted, caries free third molar had a large bulk of reparative dentin (Category 3). A typical example of an untreated control tooth can be seen in Figure 1. In this figure, well defined odontoblastic, cell-free and cell-rich zones can be identified. Larger blood vessels and collagen bundles were frequently located centrally in the pulp.

COMPLETE CARIES REMOVAL:

The complete caries removal teeth (Figure 2) were very similar in histological appearance to the non-treated controls (Figure 1). All three had no inflammatory

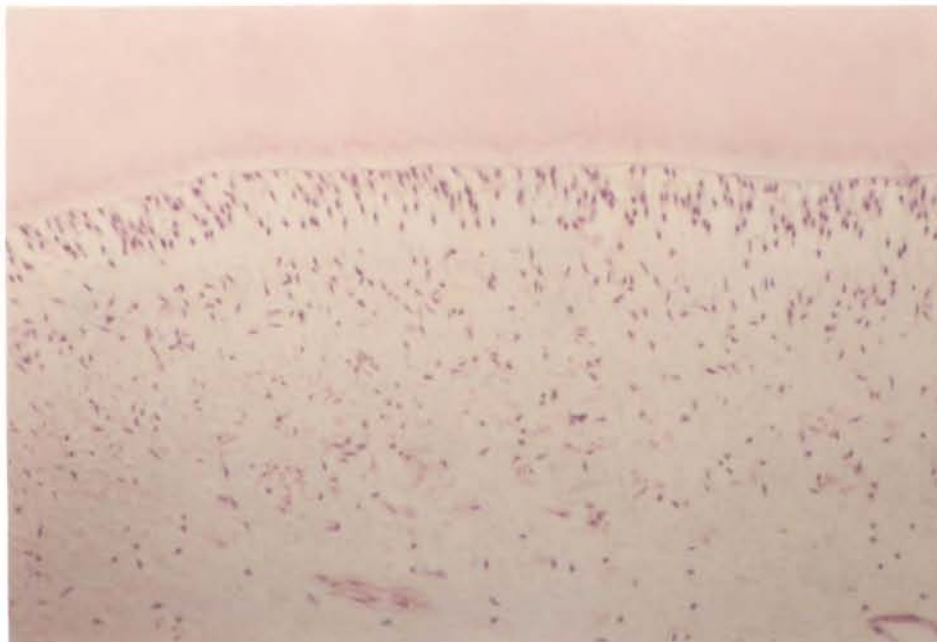
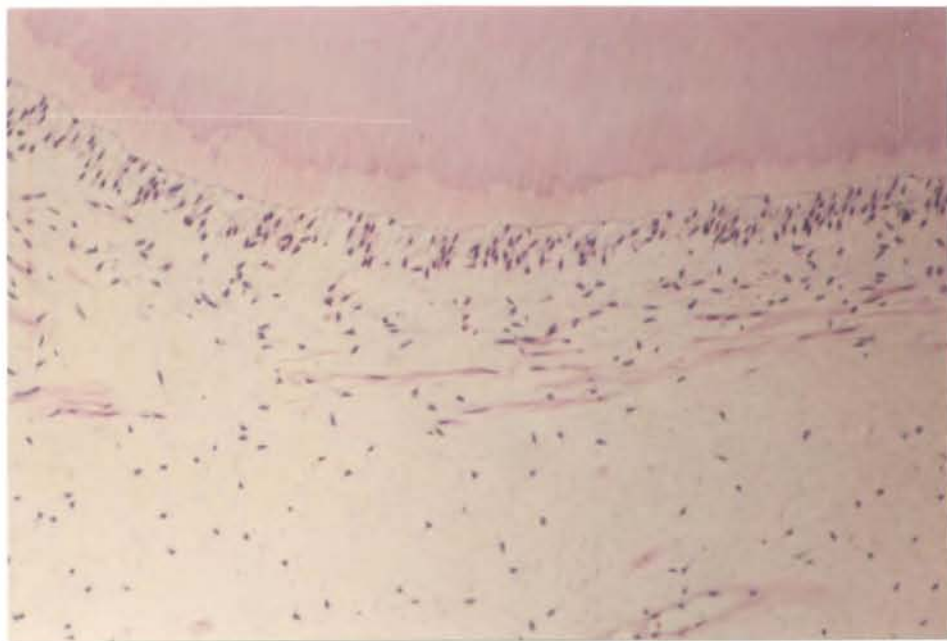


Figure 1

A typical untreated control tooth showing no inflammation and well defined odontoblastic, cell-free and cell-rich zones in the coronal pulp (Original Magnification X100).

Figure 2

A Cavitec^R treated complete caries removal tooth 6 months following treatment showing no inflammation and well defined odontoblastic, cell-free and cell-rich zones adjacent to the cut tubules (Original Magnification X100).



reaction and normal cellular morphology. Also, each of the three reparative dentin categories were represented by the three teeth.

DIRECT PULP CAP:

There was no difference in the histological response between Life^R and Dycal^R treated teeth after 6 months of treatment (Table 16). The exposures ranged in width from 350 um to 1200um. Eight of the 15 direct pulp capped teeth extracted at 6 months were treated with Life^R. Of these eight, one displayed pulpal necrosis, with total degeneration of the pulp and no dentin bridge formation. The other seven had no inflammation and normal or close to normal pulpal morphology. In one tooth, the hard tissue associated with the exposure site was lost due to sectioning difficulties. The other six teeth demonstrated bridging against the medicament (Figures 3 and 4).

The remaining seven direct pulp capped teeth extracted at 6 months were treated with Dycal^R (Table 16) and were histologically indistinguishable from the Life^R treated teeth. As in the Life^R treated teeth, one of the 6 month Dycal^R treated teeth displayed pulpal necrosis, total degeneration of the pulp and no dentin bridge formation. These two failures, one treated with Life^R and one with Dycal^R, were in the same individual and treated on the same day. The other six Dycal^R treated exposures

Table 16

COMPARISON BETWEEN MEDICAMENT TYPE AND HISTOLOGICAL
EVALUATION ON DPC TREATED TEETH 6 MONTHS FOLLOWING TREATMENT

	LIFE ^R	DYCAL ^R	Chi ² p*	Fisher's Exact p*
INFLAMMATORY RESPONSE**				
1	7	6		
2	0	0	.5094	.7333
3	0	0		
4	1	1		
SOFT TISSUE RESPONSE**				
1	7	6		
2	0	0	.5094	.7333
3	1	1		
HARD TISSUE RESPONSE**				
1	6	5		
2	0	1	1.0000	.5000
3	1	1		

* Computed by combining responses 2,3 and 4 into one category to form a 2x2 contingency table.

** See Table 2 for definitions of categories

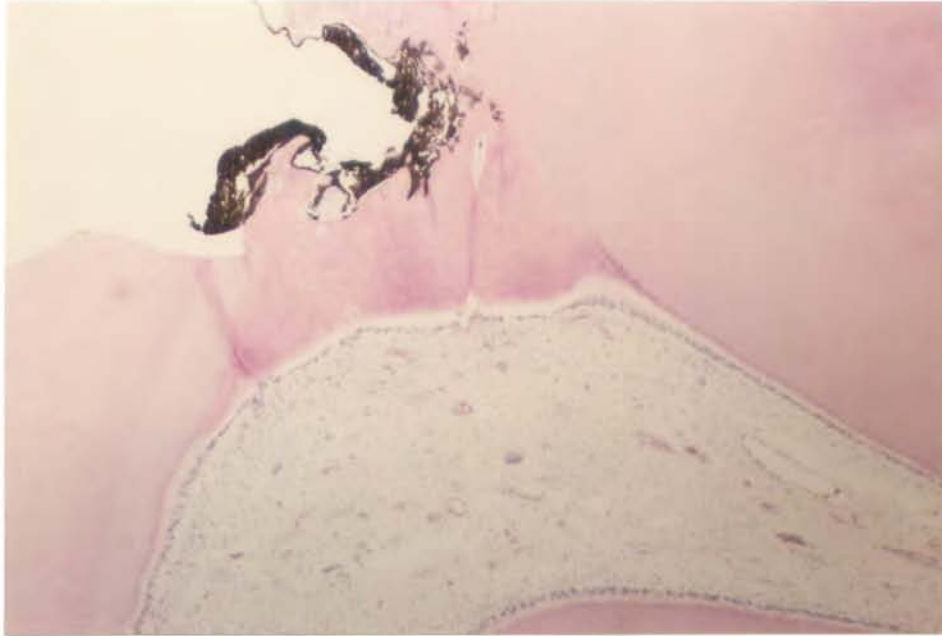
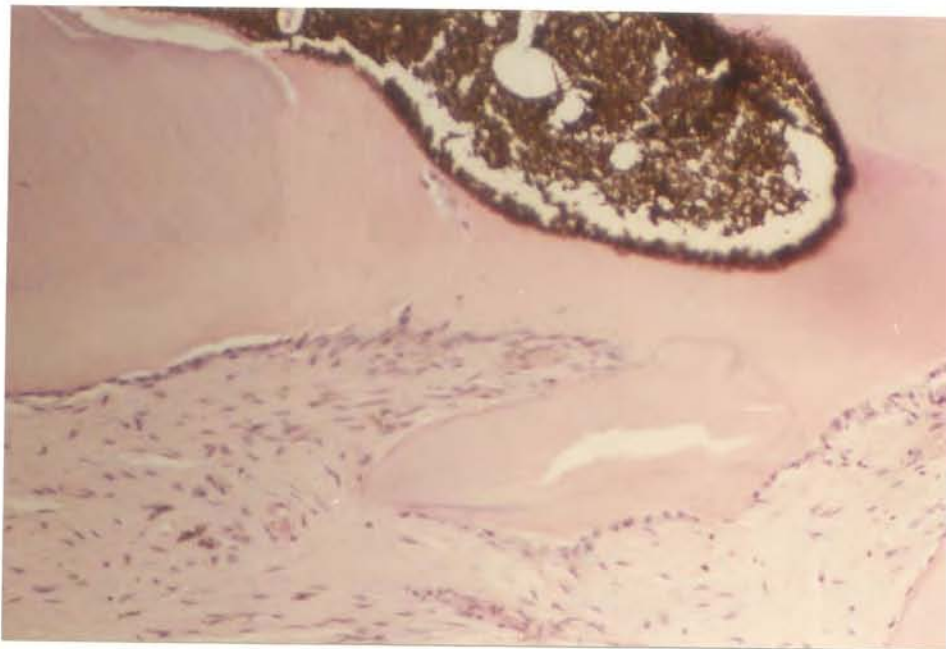


Figure 3

A Life^R treated direct pulp capped tooth 6 months^R following treatment showing bridging against the Life^R, amorphous dentin, tubular dentin and cellular inclusions in the dentin bridge (Original Magnification X25).

Figure 4

Life^R treated direct pulp capped tooth 6 months^R following treatment showing bridging against the Life^R, dentin chips, tubular dentin and cellular inclusions in the dentin bridge. Note the lack of inflammation in the pulp adjacent to the bridge, squamous to cuboidal odontoblasts and medicament filled cells in the adjacent pulp (Original Magnification X100).



had no inflammation, normal or close to normal pulpal morphology and dentin bridge formation. Five of the dentin bridges were against the medicament interface (Figure 5) and one had a layer of amorphous material interposed between the medicament and bridge (Figure 6).

Both the Life^R and Dycal^R treated teeth had dentin bridges that consisted of tubular dentin, amorphous dentin, amorphous debris, cellular inclusions and dentin chips in varying amounts and combinations (Figures 3-6). Characteristically, the new odontoblasts along the dentin bridge were few in number and squamous shaped. Many of these bridges had at least small gaps in their integrity, permitting cellular communication between the underlying pulpal tissue and medicament interface. Cells containing what appeared to be medicament, were often seen in the pulpal tissue directly adjacent to the bridge (Figure 4).

The one Dycal^R treated direct pulp capped tooth that was extracted 7 days following treatment because of acute prolonged sensitivity to heat and cold, displayed moderate inflammation and incomplete pulpal organization at the exposure site but normal deeper pulp tissue (Figure 7). Most of the inflammatory cell infiltrate was confined to the blood-fibrin clot immediately subjacent to the exposure. The medicament completely covered the exposure itself. Fibroblast-like profiles, seemingly polarized with their long axis directed toward the exposure, could also be observed at the periphery of the clot. There were

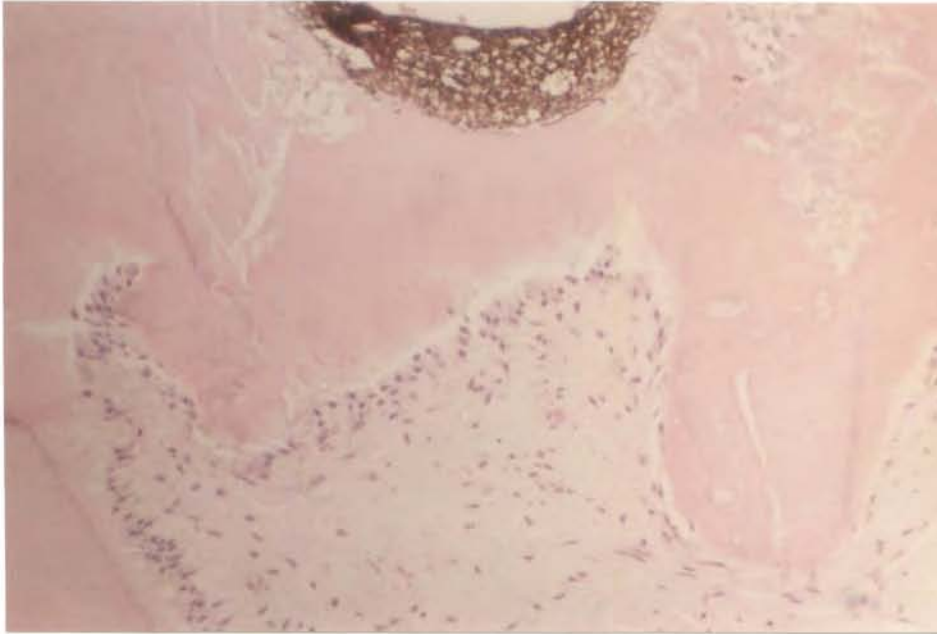
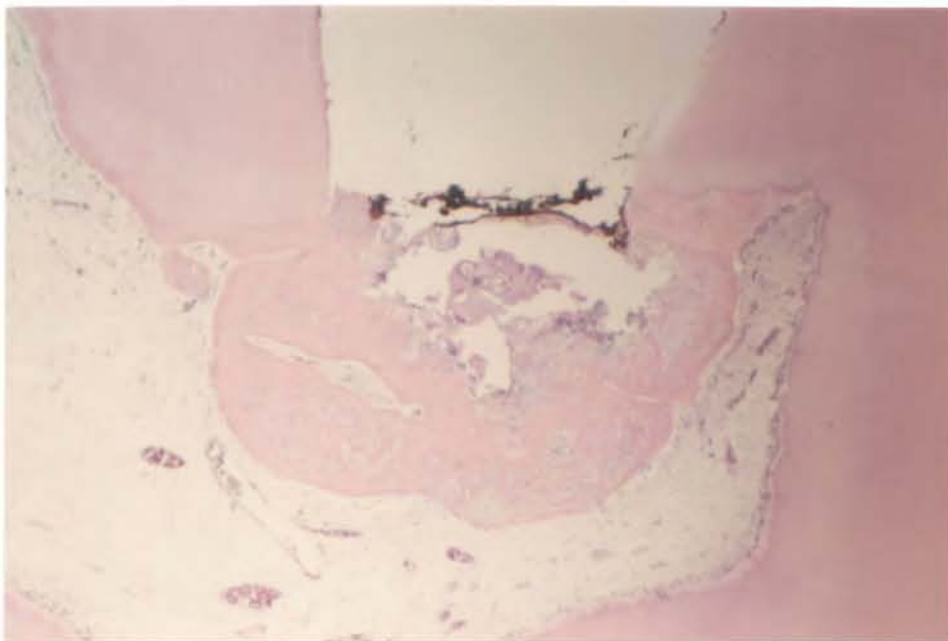


Figure 5

Dycal^R treated direct pulp capped tooth 6 months^R following treatment showing bridging against the Dycal^R, amorphous debris, dentin chips, amorphous dentin and cellular inclusions in the dentin bridge (Original Magnification X100).

Figure 6

Dycal^R treated direct pulp capped tooth 6 months following treatment showing bridging at a distance from the Dycal^R, amorphous debris between the capping agent and bridge, cellular inclusions and amorphous debris in the dentin bridge (Original Magnification X25).



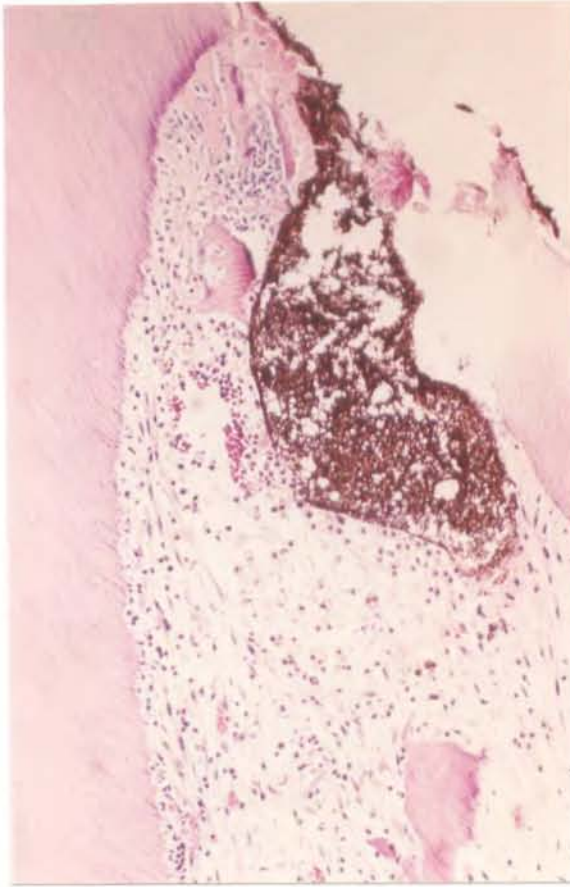


Figure 7

Dycal^R treated direct pulp capped tooth 1 week following treatment showing a moderate inflammatory reaction and incomplete pulpal organization at the exposure site (Original Magnification X100).

also many nuclear profiles seen in the cut tubules. Deeper in the coronal pulp, near one of the root canals, was a large non-attached pulp stone with a neural bundle in close proximity. Prior to treatment, this tooth had history of a similar episode of acute prolonged sensitivity to heat and cold.

IV. HISTOLOGICAL - CLINICAL COMPARISON

There was no relationship between the histological response and clinical signs and symptoms (Table 17). At the time of extraction, only 4 of the 19 treated teeth had any reported or tested clinical symptomatology. All four were DPC treated teeth, 3 treated with Dycal^R and 1 treated with Life^R. One of these four was the tooth extracted at 1 week post-treatment because of acute, prolonged sensitivity to heat and cold. This tooth had moderate inflammation and incomplete pulpal organization (Figure 7). The other three symptomatic teeth as well as 13 of the 15 remaining asymptomatic teeth, had no inflammation and normal or close to normal pulpal morphology. The other two asymptomatic teeth were the two DPC teeth with necrotic pulps. One of these two DPC teeth tested vital (50 on a scale of 80) with the electric pulp tester immediately prior to extraction. This reading was within the manufacturer's listed normal readings. The other DPC tooth that had a necrotic pulp tested devital.

Table 17

COMPARISON BETWEEN CLINICAL SIGNS AND SYMPTOMS AT TIME
OF EXTRACTION AND HISTOLOGICAL EVALUATION
ON DPC TREATED TEETH 6 MONTHS FOLLOWING TREATMENT

INFLAMMATORY RESPONSE**	CLINICAL SIGNS AND SYMPTOMS		Chi ² p	Fisher's Exact p
	Negative	Positive		
1	13	3	.8391	.5304
2	0	1		
3	0	0		
4	2	0		
SOFT TISSUE				
RESPONSE**				
1	13	3	.8391	.5304
2	0	1		
3	2	0		

* Computed by combining responses 2,3 and 4 into one category to form a 2x2 contingency table.

** Negative = no positive clinical signs or symptoms
Positive = at least one positive clinical sign or symptom present

DISCUSSION

I. METHODS OF CLINICAL EVALUATION

The Analytical Technology Pulp Tester was well accepted by the patients and easy to use. Clinically, it gave the impression of being able to provide reproducible readings. A common complaint of the older Burton style pulp tester was that it often generated a rather unpleasant shock sensation to the tooth^{62,64}. The scale of 0 to 80 and automatic incremental increase on the Analytical Technology Pulp Tester provided a gradual enough incremental stimulus increase to permit the patient to sense the stimulation before it became noxious. Consequently, it was well received by the patients. Also, the silent operation, automatic reset, variable incremental increase control and digital display of the Analytical Technology Pulp Tester made it very easy to perform repeated measurements without patient anticipation of onset of sensation. It had been hoped that these qualities would permit more sensitive pulp vitality measurements that might be used to detect variations in pulpal response to the test materials and procedures. This hope, however, may have been unfounded as

demonstrated by the lack of significant differences in treatment and medicament types in the electric pulp test measurements (Tables 4,5,7 and 8).

This lack of significant differences in the electric pulp test measurements may have been due to one or more reasons. First, there may have actually been no differences present. There were remarkably few differences seen in the other clinical measurements and essentially no histological differences seen at 6 months. It would not be surprising, then, to find that there were no differences in the electric pulp test measurements. A second possibility is that the electric pulp testing method used was not sensitive enough to measure any differences present. This could be due to:

1.) Inherent inadequacies of electric pulp testers that prevent them from having adequate discriminating power^{62,64}. For example, there is no way of knowing if pulpal, gingival or periodontal ligament nerve fibers are being stimulated.

2.) Lack of reproducibility due to variations in conductance tip placement and signal output⁶⁵.

3.) Patient responses to stimuli not always being reliable or reproducible^{60,64}. Thus, a stimulus adequate to elicit a response on one day may be inadequate on a second day, even though the pulpal condition remained unchanged.

4.) There was way to know if the untreated control was normal or had changed since the last recall⁶⁰. The

analysis used in the present study relied on an untreated control tooth as a stable reference. If that control tooth in fact was not normal or stable, then the reliability of the analysis of the measurements would be suspect. A third possibility for the lack of differences in the electric pulp test measurements is that the analysis of the measurements was inadequate. The use of the AVGDIFF value may not have been sensitive enough. One problem with the AVGDIFF value was that there was always a small AVGDIFF number with a large standard deviation. If the output of the Analytical Technology Pulp Tester was not linear, it could be that the large standard deviation was an artificial one created by applying linear analysis to a non linear model. Ranked Student "t" tests were applied to the data in order to reduce the effect of the large standard deviations, but the results were the same as the Student "t" tests. This suggests that there actually may have been no differences. Further study in this area is needed.

Advantages of the clinical evaluation methods used to measure and record clinical signs and symptoms include:

- 1.) They are easy and efficient to use. This should aid in inter- and intra-examiner reliability. However, further study is needed to verify and quantify this advantage. The present study used one examiner throughout the entire experiment and thus, this

reliability question was not addressed. Also, these evaluation methods helped to keep the recall appointment short, thus theoretically improving patient acceptance and cooperation.

2.) They test clinical signs and symptoms that are currently considered clinically appropriate ⁶⁰⁻⁶⁸.

However, there are also some currently unavoidable disadvantages such as:

1.) All of the evaluation methods used, including the electric pulp test measurements, relied on patient response to a stimulus. This response, as discussed by Chambers ⁶² and Schaffer ⁶⁵, can vary both between patients (i.e. the same stimulus applied to a "normal" tooth in two individuals can elicit different responses) and within patients at different times (i.e. the same stimulus applied to an "unchanged" tooth in the same individual at different times can elicit different responses).

2.) Lack of agreement between histories of signs and symptoms and tested signs and symptoms. The tested signs and symptoms often were negative when the history was positive. This may have been due to different stimuli being present (i.e. direct application of ice for 5 seconds vs. cold liquids held in the mouth during drinking), different location of stimulus application (i.e. buccal of tooth vs. whole tooth) or false positive histories from a different tooth in the arch.

3.) Histories of signs and symptoms relied on the patient remembering the stimulus that elicited a response and the intensity and duration of the response. At times it was difficult to tell if the response was to heat, cold, percussion or to other postoperative sequelae such as muscle discomfort from the patient holding their mouth open for long periods of time and injection site tenderness.

4.) There is reduced objectivity because of the subjective nature of pain^{60,64}. This subjectivity has an important impact on all of the previously mentioned aspects of clinical evaluation because, in the final analysis, they all involve some parameter of pain.

These clinical evaluation methods, although they have many disadvantages, are currently the only ones clinically feasible. Further study investigating the reliability of tests that utilize heat and cold probes capable of producing variable temperatures may enhance the diagnostic capabilities of clinical evaluation.

Even when statistically significant differences in signs and symptoms are seen, the clinical relevancy of these differences is not readily apparent. This clinical relevancy comes into question when one considers the above mentioned drawbacks of clinical evaluation methods. The questions of reliability, reproducibility and objectivity place strong constraints on accepting the statistically significant differences as being clinically relevant. It

should be the responsibility of those evaluating the results to decide if the statistical differences are, in fact, clinically relevant or not. The discussion that follows reflects the decisions of this author on the clinical relevance of the present study's data.

II. COMPARISON OF MATERIALS

There were no statistically significant clinical differences between Life^R and Dycal^R if all treatment types were combined. There were some statistically significant clinical differences between Life^R and Dycal^R if compared within different treatment types (Table 6).

When compared in the Indirect Pulp Cap (IPC) treatment group, there were two statistically significant clinical differences between Life^R and Dycal^R. These differences were in the histories of sensitivity to heat at 1 day and cold at 3 days. However, the clinical relevancy of these differences is not readily apparent. These differences actually represent 2 Dycal^R treated teeth changing from a history of initial heat sensitivity to no heat sensitivity over this 3 day time period. The relevancy comes into question when one considers the drawbacks of clinical evaluation mentioned previously. Reports of histories of sensitivity probably are the least reliable data in this study because of the great chance

of false positives, patient variability and patient error in remembering exact stimuli and reactions. Therefore, although there may have been statistically significant differences in clinical signs and symptoms between Life^R and Dycal^R in IPC treated teeth, these differences are most likely not clinically relevant. It is important to note that at 6 months there were no statistically significant differences in clinical signs and symptoms between the two materials. Thus, it appears that there are no clinically relevant differences in clinical signs and symptoms between these materials in IPC treated teeth.

There were no clinically relevant differences seen in the Complete Caries Removal (Complete CR) treated teeth. Life^R, Dycal^R and Cavitec^R were clinically indistinguishable in this category. Also, there were no histological differences observed between Dycal^R and Cavitec^R. This suggests that the obtundent effect ascribed to zinc oxide-eugenol containing materials may either be clinically irrelevant or nonfunctional in Complete CR treatments of this type.

Direct Pulp Capped (DPC) teeth treated with Life^R were histologically identical to DPC teeth treated with Dycal^R. There were two statistically significant differences in the clinical signs and symptoms between Life^R and Dycal^R in these DPC treated teeth. These differences were the initial and 6 month tested sensitivities to cold. Both of these differences were

marginally significant at the 0.05 level. In addition, the differences between the initial and 6 month data are due more to patient attrition than actual changes in clinical signs and symptoms. Because of the marginal statistical differences, minor changes between initial and 6 month data and the identical histological results, there probably is no clinically relevant difference between Life^R and Dycal^R in DPC treated teeth. It should be kept in mind that throughout the present study, there was only one case of severe sensitivity to heat and cold and only a few cases of moderate sensitivity.

III. COMPARISON OF TREATMENT TYPES

Since there were no clinically relevant differences in clinical signs and symptoms between materials used, this discussion will be confined to the results of the statistical analysis of the differences between treatment types with all materials combined.

Probably of most clinical importance is the comparison of Indirect Pulp Capped (IPC) to Direct Pulp Capped (DPC) teeth (Table 14). In this comparison, all statistically significant differences in clinical signs and symptoms were in the patient histories of sensitivity to heat and cold. Because of the low p-values and large numerical differences in these categories, these

differences may actually be clinically relevant. However, it is interesting to note that there were no post-treatment differences in the tested clinical signs and symptoms. This fact casts some suspicion on the reliability of the tested clinical signs and symptoms. In general, DPC treated teeth initially tended to be more sensitive to heat and cold than IPC treated teeth. This may have been due to the greater pulpal trauma associated with exposing the pulp causing more post operative discomfort for the patient. The IPC teeth showed a general decrease in initial sensitivity during the first week following treatment. The DPC treated teeth showed an increase in sensitivity initially that started to decrease after 3 days. After 1 week there were no differences in clinical signs and symptoms between IPC and DPC treated teeth. Clinical success, as measured by lack of moderate or severe symptomatology and vital tooth response to electric pulp testing was 100 percent for IPC treated teeth and 87 percent for DPC treated teeth. These percentages are comparable to those of other investigators who tested direct ^{46-48,51,75} and indirect ^{71-73,75} pulp capping treatments in humans. It is interesting to note that, in contrast to other investigators findings ^{14,15,23,47}, the clinical and histological successes of DPC treated teeth in the present study were identical. This may be due to the relatively short test period (6 months) of the present study.

The comparisons of IPC and DPC treatments to Complete CR are probably of more academic than clinical interest. The only statistically significant post-treatment difference in clinical signs and symptoms between IPC and Complete CR treated teeth was at 1 week when there were more IPC teeth that tested sensitive to heat (Table 13). Consequently, it may be said that there are few clinically relevant differences between these treatments. As might be expected, there were many statistically significant differences in clinical signs and symptoms between Complete CR and DPC treated teeth (Table 15). In general, the DPC treated teeth were more sensitive to heat and cold than Complete CR teeth. However, most of the significant differences were no longer present after 1 week. Perhaps the increased sensitivity in the DPC treated teeth during the first week following treatment is due to greater pulpal damage from the exposure and once this damage is repaired the teeth respond alike clinically. This is supported by the fact that histologically, at 1 week there is pulpal disorganization, residual inflammation and minor pulp damage and at 6 months following treatment, there was no difference between these two treatments in the inflammatory cell or soft tissue response.

IV. HISTOLOGICAL EVALUATIONS

With the exception of the two necrotic pulps, all

tissue evaluated after 6 months treatment, regardless of treatment type or material used, was generally characterized by little to no inflammation and normal or close to normal soft tissue morphology. Histologically, 87 percent of the DPC treated teeth were successful treatments as characterized by lack of inflammation, normal or close to normal soft tissue organization and dentin bridge formation at the exposure site (Table 16). It is interesting to note that one of the teeth that had a totally necrotic pulp tested vital with the electric pulp tester just prior to extraction. This once again points out the lack of correlation between clinical signs and symptoms and pulpal histology ^{11,14,15,23,47}

Although 12 of the 14 DPC treated teeth evaluated histologically 6 months after treatment had dentin bridges at the exposure site, there was noticeable variation in the quality of these bridges. Many bridges had cellular inclusions and/or amorphous debris incorporated into the bridge. Similar inclusions have been reported by other investigators in dogs ^{13,14}, monkeys ^{25,39,40,49,55,57} and humans ^{12,14,15,22,23,26,48}. The amorphous debris may be a slurry of cut dentin and water left behind when the pulp was exposed. If this is the case, it may be advisable to clean the exposure site more thoroughly prior to capping, although the presence of the debris does not seem to adversely affect the final healing. This debris may also

be necrotic debris created during the exposure and capping that was not resorbed.

V. CLINICAL APPLICATIONS

The clinical and histological results of the present study, combined with the findings of other clinical studies suggest that:

- 1.) When treating deep carious lesions, if an exposure is expected during complete caries removal, an indirect pulp capping procedure would be more desirable than a direct pulp capping procedure because it will result in a greater chance of success with less postoperative symptomatology⁷⁰⁻⁷⁸.
- 2.) If the pulp is exposed during the course of caries removal, then caries removal should be completed and the exposure rinsed well and capped with either Life^R or Dycal^R.
- 3.) In non exposed, complete caries removal teeth, Life^R, Dycal^R or Cavitec^R can be used with equal clinical and histological success^{58,59}.

VI. SUGGESTED FURTHER STUDY

These findings suggest that further studies utilizing the same protocol should be carried out that would:

1.) Study the long term (2 or more years) clinical success of Life^R, Dycal^R and Cavitec^R in conservative pulpal therapy. It is necessary to determine if the long term prognosis of direct pulp capping, indirect pulp capping and complete caries removal changes with time. Special attention should be given to determining the causes of any long term failures, evaluating direct and indirect pulp capping procedures at different time periods and determining if excessive reparative dentin production occurs as the result of direct pulp capping procedures with Life^R or Dycal^R.

2.) Study the long term (2 or more years) histological success of Life^R, Dycal^R and Cavitec^R in conservative pulpal therapy. Special emphasis should be placed on comparing direct and indirect pulp capping treatments and evaluating relative effectiveness of the different materials.

3.) Add bacterial culturing to the protocol to determine if long term (greater than 2 years) indirect pulp capping procedures are bacteriologically stable (i.e. Is it necessary to re-enter the cavity preparation at a later date to remove the remaining affected dentin?). This protocol could be used to see if there are any correlations between bacteria in general or specific bacterial species found in the last dentin removed prior to restoration and clinical/histological failures.

SUMMARY

This study evaluated the effect of a new calcium hydroxide intermediary base material, Life^R, on human pulp when used for direct and indirect pulp capping, compared the effectiveness of Life^R and Dycal^R in these clinical treatments, and compared the pulpal responses of Life^R, Dycal^R and Cavitec^R when used in moderately deep carious lesions following caries removal.

Signs and symptoms were recorded for each tooth immediately prior to restoration and at subsequent recall visits by recording histories of sensitivity to heat, cold and percussion, testing for sensitivity to heat, cold and percussion, and testing pulp vitality using an electric pulp tester. Life^R or Dycal^R, selected at random, was used in 50 indirect and 38 direct pulp cap procedures on carious human teeth. An additional 63 non exposed teeth were treated with Life^R, Dycal^R or Cavitec^R, selected at random, following complete caries removal. All teeth were then restored with either varnish, zinc phosphate cement and amalgam or an acid etched and bonded composite resin. Signs and symptoms were recorded for each tooth immediately prior to restoration and at subsequent 1 week and 6 month recall visits by testing for and recording

histories of sensitivity to heat, cold and percussion, and testing pulp vitality using an electric pulp tester. In addition, a telephone follow-up was made 24 and 72 hours postoperatively to solicit information regarding patient comfort.

Three of the complete caries removal teeth and 16 of the direct pulp capped teeth were extracted, processed for histological evaluation and evaluated according to a pre-established set of histological criteria. Seven additional non treated carious and noncarious teeth were also extracted and evaluated histologically to establish baseline histological data.

All preoperative and postoperative clinical evaluations were assembled and compared with histological evaluations when possible. Student "t", Chi-square and Fisher's exact probabilities were used for statistical analysis at the 0.05 confidence level.

The results showed that at 6 months there were no statistically significant differences in clinical signs and symptoms between Life^R and Dycal^R in direct or indirect pulp capping procedures. Also there were no statistically significant differences in clinical signs and symptoms between Life^R, Dycal^R or Cavitec^R in complete caries removal non exposed teeth. Histologically, there were no statistically significant differences between Life^R and Dycal^R in direct pulp capping and no differences between Cavitec^R and Dycal^R in complete caries removal non

exposed teeth 6 months following treatment.

Direct pulp capped teeth tended to be more symptomatic initially than indirect pulp capped teeth or complete caries removal teeth. However, by 6 months there were no statistically significant differences in clinical signs and symptoms between direct and indirect pulp capped teeth and only a slight increased sensitivity to heat for the direct pulp capped teeth when compared to complete caries removal teeth. At 6 months post treatment, there were statistically no differences between indirect pulp capped and complete caries removal teeth.

CONCLUSIONS

1.) There were no statistically significant differences in clinical signs and symptoms between Life and Dycal^R in direct pulp capped teeth 6 months following treatment.

2.) There were no statistically significant differences in clinical signs and symptoms between Life and Dycal^R in direct pulp capped teeth 6 months following treatment.

3.) There were no statistically significant differences in clinical signs and symptoms between Life^R, Dycal^R and Cavitec in complete caries removal non exposed teeth for up to 6 months following treatment.

4.) There were no histological differences between Cavitec^R and Dycal^R in complete caries removal teeth 6 months following treatment.

5.) There were no statistically significant histological differences between Life^R and Dycal^R in direct pulp capped teeth 6 months following treatment.

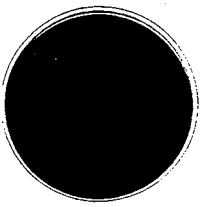
6.) Although direct pulp capped teeth initially tended to be more sensitive to heat and cold than indirect pulp capped and complete caries removal teeth, there were no statistically significant differences in clinical signs

and symptoms between direct and indirect pulp capped teeth and indirect pulp capped and complete caries removal teeth 6 months following treatment.

7.) There were no histological differences in inflammatory cell response and soft tissue response between complete caries removal and direct pulp capped teeth 6 months following treatment.

8.) There was no relationship between clinical signs and symptoms and pulpal histology either preoperatively, at 1 week or 6 months following treatment.

9.) Further clinical and histological study of direct and indirect pulp capping involving longer treatment times is needed to evaluate the long term effect of these procedures.



The University of Michigan

SCHOOL OF DENTISTRY

ANN ARBOR, MICHIGAN 48109

Appendix 1

PATIENT CONSENT FORM

I consent to participate in a controlled study to evaluate a commonly used dental material LIFE^R which is used in teeth to prevent irritation to the teeth and to aid in repair of the teeth.

I understand that the treatment will involve removing dental caries from teeth and the placement of the material, followed by an appropriate silver or white filling material. All procedures to be done are commonly used procedures in the field of operative dentistry.

I understand that the University will provide first-aid medical treatment in the unlikely event of physical injury resulting from research procedures. Additional medical treatment will be provided in accordance with the University's determination of its responsibility to do so. The University does not, however, provide compensation to a person who is injured while participating as a subject in research.

I also grant The University of Michigan permission to use the results obtained from this study for dental education or professional publication.

Signature of Patient

Date: _____

Signature of Witness

Appendix II

HUMAN SUBJECTS COMMITTEE APPROVAL

TO: INVESTIGATORS APPLYING TO THE USPHS FOR SUPPORT OF CLINICAL RESEARCH AND INVESTIGATION INVOLVING HUMAN BEINGS.

FROM: THE UNIVERSITY OF MICHIGAN, SCHOOL OF DENTISTRY COMMITTEE ON CLINICAL RESEARCH AND INVESTIGATION INVOLVING HUMAN BEINGS.

In fulfillment of Public Health Service and University policies, this Committee must, in respect to your research project and/or grant application, independently review: 1) The rights and welfare of the individual or individuals involved; 2) The appropriateness of the methods used to secure informed consent; and 3) The risks and potential medical benefits of the investigation. In order for the Committee to do this, please provide the following information:

1. Project Title and grant number:

Clinical Evaluation of LIFE[®] for Direct and Indirect Pulp Capping

2. Inclusive dates of project:

August 1980 to July 1983

3. In what ways will the human beings be involved in your investigation?

Please be specific. Human beings will participate as dental patients receiving treatment for diagnosed carious lesions. It is anticipated that most teeth will remain in situ. However, carious teeth that have been planned, in the regular course of treatment, for extraction will undergo caries removal and appropriate treatment for whatever the remaining dentin and previous history suggests. Extraction scheduling will be determined by the sequence of treatment which is most appropriate for the patient's dental health.

4. a) Are there risks of any kind to human participants beyond those usually involved in dental clinical practice. If yes, please explain in detail:

There are no risks to the patients beyond those usually involved in clinical dental practice. However, certain teeth may not normally require the caries removal prior to extraction. Compensation for the additional appointment will be monetary in the form of a reduced fee for some aspect of treatment.

b) Briefly state the potential benefits of this research:

The potential benefits of this research are:

- (1) a better correlation of clinical signs and symptoms with treatment of deeper carious lesions and subsequent patient comfort;
- (2) assessment of the effect of a calcium hydroxide preparation upon carious human teeth as judged clinically and histologically;
- (3) relative effect of calcium hydroxide and zinc oxide eugenol upon the tooth following removal of caries of moderate depth - as judged clinically and histologically.

- 5. a) Outline the procedure by which the subject is to be fully informed of the nature of the research, the potential hazards and the potential benefits prior to giving his consent to participate:

The patient will be fully informed of the nature of the research, its potential hazards and benefits by a printed form together with discussion and the answering of questions.

- b) How will consent be obtained?

Consent will be obtained in writing.

- c) If written, please include form.

See attached form.

- 6. a) What measures will be employed to protect human participants (subjects) from the risks stated?

The usual measures of diagnosis and treatment will be used to protect patients from the risks involved in dental treatment.

- b) What measures will be used to protect the rights and welfare of human subjects?

Subjects will be free to withdraw from participation in this project at any time without jeopardizing treatment for which they may otherwise be eligible at the School of Dentistry.

- c) Please include protocol explanation on separate sheet. Include:

1. Project Plan (SEE ENCLOSED).
2. Methodology
3. Significance

Gerald T. Charbeneau
 NAME OF DEPARTMENT HEAD
GERALD T. CHARBENEAU
 NAME OF INVESTIGATOR
Professorial Chairman, Dept. of Dent
 TITLE AND DEPARTMENT

Gerald T. Charbeneau
 SIGNATURE
Gerald T. Charbeneau
 SIGNATURE
July 18, 1950
 DATE

August 4, 1980

Date

MEMO TO: Gerald T. Charbeneau, Chairman, Operative Department
 FROM: James K. Avery, Chairman, School of Dentistry Review Committee
 SUBJECT: Clinical Research and Investigation Involving Human Subjects
 REFERENCE: CLINICAL EVALUATION OF LIFE FOR DIRECT AND INDIRECT
PULP CAPPING.

Principal Investigator: Gerald T. Charbeneau

Upon review of the research plan submitted on behalf of the principal investigator, the School of Dentistry Committee to Review Grants for Clinical Research and Investigation Involving Human Subjects has determined independently that the rights and welfare of the individuals involved in this research are carefully guarded. The methods used to obtain informed consent are appropriate. The risks to the individuals involved are felt to be minor, and the potential health benefits of this investigation are of importance.

A copy of this memorandum is being routed to the principal investigator. This memorandum, in addition to indicating favorable review, will emphasize the principal investigator's obligation to advise the Committee of any change in the protocol which might bring into question the involvement of human subjects in a manner at variance with the considerations on which the prior approval was based.


 Signature

Appendix III

TOOTH SURFACE TEMPERATURES

Trial #	Tooth Surface Temperature C		
	Immediately after Application	5 Seconds of Application	
1	64.0	56.5	
2	58.5	46.0	
3	52.0	47.0	
4	58.0	48.0	
5	57.0	52.5	
6	55.0	47.0	
7	51.0	45.0	
8	57.0	52.0	
9	54.5	51.0	
10	49.5	42.0	
	MEAN	55.7 ± 4.2	48.7 ± 4.3

* Measured by placing warmed Moyco Modeling Compound on the buccal surface of the tooth directly over the thermal probe tip of a YSI Model 42SC Tele-Thermometer.

Appendix IV

CLINICAL DATA

LEGEND

CODE	Patient code number
SEQ	Treatment sequence (i.e. 3=third tooth treated in that patient)
AGE	Patient age at time of treatment
TXTOOTH	Treated tooth
CTRL	Control tooth (not treated)
SEX	1=Male 2=Female
EXT	1=Txtooth extracted 2=Txtooth not extracted
SURF	Surfaces restored: 1=Mesial-occlusal 6=Mesial-occlusal-distal 2=Distal-occlusal 7=Mesial-occlusal-distal with cusp(s) protected 3=Buccal 8=Mesial-occlusal with cusp(s) protected 4=Lingual 9=Distal-occlusal with cusp(s) protected 5=Occlusal
RD	1=Rubber dam used 2=Rubber dam not used
SET	Anticipated chance of pulp exposure: 1=Exposure expected pre-operatively if complete caries removal performed 2=No exposure expected pre-operatively if complete caries removal performed
GRP	Treatment group: 1=Indirect pulp cap 2=Complete caries removal, non exposed 3=Direct pulp cap
SYMP	Pre-operative symptomatology: 1=Symptomatic before treatment 2=Asymptomatic before treatment
EXP	Exposure size: 1=none 2= ≤ 0.5 mm 3> > 0.5 mm
MED	Medicament (liner) used: 1=Life ^R 2=Dycal ^R 3=Cavitec ^R
MAT	Restorative materials used: 1=Liner + varnish + base + amalgam 2=Liner + varnish + amalgam 3=Liner + bonding agent + composite

PTPER1 Initial history of sensitivity to:
 PTHOT1 PER=Percussion HOT=Heat COLD=Cold
 PTCOLD1 1=none 2=slight 3=moderate 4=severe

TPER1 Initial tested sensitivity to:
 THOT1 Percussion=PER Heat=HOT Cold=COLD
 TCOLD1 1=none 2=slight 3=moderate 4=severe

T1EPT1
 T2EPT1 Five consecutive pre-operative electric pulp
 T3EPT1 tester readings of the treated tooth
 T4EPT1
 T5EPT1

C1EPT1
 C2EPT1 Five consecutive pre-operative electric pulp
 C3EPT1 tester readings of the control tooth
 C4EPT1
 C5EPT1

PTPER2 3 day post-treatment history of sensitivity
 PTHOT2 to: PER=Percussion HOT=Heat COLD=Cold
 PTCOLD2 1=none 2=slight 3=moderate 4=severe

PTPER3 3 day post-treatment history of sensitivity
 PTHOT3 to: PER=Percussion HOT=Heat COLD=Cold
 PTCOLD3 1=none 2=slight 3=moderate 4=severe

PTPER4 1 week post-treatment history of sensitivity
 PTHOT4 to: PER=Percussion HOT=Heat COLD=Cold
 PTCOLD4 1=none 2=slight 3=moderate 4=severe

TPER4 1 week post-treatment tested sensitivity
 THOT4 to: PER=Percussion HOT=Heat COLD=Cold
 TCOLD4 1=none 2=slight 3=moderate 4=severe

T1EPT4
 T2EPT4 Five consecutive 1 week post-operative electric
 T3EPT4 pulp tester readings of the treated tooth
 T4EPT4
 T5EPT4

C1EPT4
 C2EPT4 Five consecutive 1 week post-operative electric
 C3EPT4 pulp tester readings of the control tooth
 C4EPT4
 C5EPT4

PTPER5 6 month post-treatment history of sensitivity
 PTHOT5 to: PER=Percussion HOT=Heat COLD=Cold
 PTCOLD5 1=none 2=slight 3=moderate 4=severe

TPER5 6 month post-treatment history of sensitivity
THOT5 to: PER=Percussion HOT=Heat COLD=Cold
TCOLD5 1=none 2=slight 3=moderate 4=severe

T1EPT5
T2EPT5 Five consecutive 6 month post-treatment
T3EPT5 electric pulp tester readings of the
T4EPT5 treated tooth
T5EPT5

C1EPT5
C2EPT5 Five consecutive 6 month post-treatment
C3EPT5 electric pulp tester readings of the
C4EPT5 control tooth
C5EPT5

A zero (0) data entry denotes no data recorded.

CODE	SEQ	AGE	TXTTOOTH	CTRL	SEX	EXT	SURF	RD	SET	GRP	SYMP
EXP	MED	MAT	PTPER1	PTHOT1	PTCOLD1	TPER1	THOT1	TCOLD1	T1EPT1	T2EPT1	T3EPT1
T4EPT1	T5EPT1	C1EPT1	C2EPT1	C3EPT1	C4EPT1	C5EPT1	PTPER2	PTHOT2	PTCOLD2	PTPER3	PTHOT3
PTCOLD3	PTPER4	PTHOT4	PTCOLD4	TPER4	THOT4	TCOLD4	T1EPT4	T2EPT4	T3EPT4	T4EPT4	T5EPT4
C1EPT4	C2EPT4	C3EPT4	C4EPT4	C5EPT4	PTPER5	PTHOT5	PTCOLD5	TPER5	THOT5	TCOLO5	T1EPT5
T2EPT5	T3EPT5	T4EPT5	T5EPT5	C1EPT5	C2EPT5	C3EPT5	C4EPT5	C5EPT5			
1	1	23	29	21	2	1	6	2	1	3	2
2	1	1	1	1	1	1	1	1	60	34	40
64	54	32	27	27	25	29	1	1	1	1	1
1	1	1	1	1	1	1	42	57	46	41	51
39	40	39	38	38	1	1	2	1	2	2	72
80	67	68	44	42	41	40	39	37			
1	2	23	4	13	2	1	6	2	2	2	2
1	1	1	1	1	1	1	1	1	45	44	45
45	36	44	37	39	38	43	1	1	1	1	1
1	1	1	1	1	1	1	42	40	55	49	48
31	38	40	47	43	1	1	1	1	1	1	48
65	64	58	59	39	43	47	45	47			
1	3	23	3	14	2	1	6	2	2	2	2
1	3	1	1	1	1	1	1	1	33	41	38
41	40	28	59	41	40	37	1	1	1	1	1
1	1	1	1	1	1	1	45	43	46	41	40
17	15	15	17	17	1	1	1	1	1	1	36
45	35	34	32	15	17	17	15	16			
2	1	33	32	18	1	1	7	1	2	2	2
1	2	1	1	1	1	1	1	1	54	49	49
53	52	50	53	68	72	68	1	1	1	1	1
1	1	1	1	1	1	2	80	80	80	80	80
49	51	57	56	61	1	1	1	1	1	1	61
76	78	60	69	45	45	50	44	46			
2	2	33	17	31	1	1	9	1	2	2	2
1	1	1	1	1	1	1	1	1	41	40	24
43	49	32	34	31	33	34	1	1	1	1	1
1	1	1	1	1	1	1	50	52	68	67	59
41	40	39	36	45	1	1	1	1	1	1	45
43	48	44	45	42	42	40	44	48			
2	3	33	13	4	1	1	6	2	2	2	1
1	2	1	1	1	2	1	1	2	47	55	51
47	48	32	37	34	28	26	1	1	1	1	1
1	1	1	1	1	1	1	23	27	32	32	30
28	29	28	29	28	1	1	1	1	1	1	34
31	35	38	38	33	40	39	34	29			

2	4	33	2	4	1	1	9	2	2	2	2
1	1	1	1	1	1	1	1	1	71	62	64
67	75	32	37	34	28	26	1	1	1	1	1
1	1	1	1	1	1	1	55	46	41	54	49
28	29	28	29	28	1	1	1	1	1	1	56
61	59	70	70	33	40	39	34	29			
3	2	24	29	20	2	1	6	2	1	2	1
1	1	1	1	3	3	2	2	2	44	38	37
39	37	43	46	43	44	44	4	4	4	1	1
2	1	1	1	1	1	1	42	43	58	50	50
48	48	49	47	43	1	1	1	1	1	1	42
30	44	37	42	36	21	25	36	39			
3	3	24	30	18	2	1	6	2	2	2	2
1	1	1	1	1	1	1	1	1	31	36	39
35	36	35	42	49	39	43	1	1	1	1	1
1	1	1	1	1	1	1	39	43	29	23	25
33	38	35	36	31	1	1	1	1	1	2	72
55	59	48	53	39	35	34	31	33			
3	4	24	28	21	2	1	2	2	2	2	2
1	2	1	1	1	1	1	1	1	39	34	35
34	38	30	27	28	27	24	1	1	1	1	1
1	1	1	1	1	1	1	38	35	26	21	36
38	36	37	35	35	1	1	1	1	1	2	38
32	37	38	35	30	28	28	38	22			
3	5	24	32	18	2	1	5	2	2	2	2
1	2	1	1	1	1	1	1	1	40	52	52
64	48	35	42	49	39	43	1	1	1	1	1
1	1	1	3	1	1	2	24	24	23	24	23
33	38	35	36	31	1	1	1	1	1	1	43
70	49	41	49	39	35	34	31	33			
4	1	24	2	14	2	1	7	1	1	1	1
1	1	1	1	2	2	2	2	1	35	31	31
31	31	48	56	49	55	44	2	1	1	1	1
2	1	1	1	2	1	1	49	47	18	37	27
45	49	34	49	53	1	1	1	1	1	1	65
80	39	34	38	50	52	56	40	47			
4	2	24	15	3	2	1	9	2	2	2	2
1	2	1	1	1	1	1	1	1	65	52	53
51	50	51	46	50	50	48	1	1	2	1	1
2	1	1	1	2	1	1	54	31	54	54	50
34	31	23	32	37	1	1	1	1	1	1	41
37	43	51	49	41	40	32	40	40			
4	3	24	11	5	2	1	3	2	2	2	2
1	2	3	1	1	1	1	1	1	35	35	34
27	10	32	31	31	28	29	1	1	1	1	1
1	1	1	1	1	2	2	25	26	25	25	24
26	26	28	27	26	1	1	1	1	1	1	41
33	31	31	31	33	27	26	30	28			
4	4	24	26	23	2	1	3	2	2	2	2
1	2	3	1	1	1	1	1	1	15	17	17
18	17	35	26	25	25	26	1	1	1	1	1
2	1	1	1	1	1	1	22	19	19	21	21
23	28	31	25	35	1	1	1	1	1	1	19
13	11	20	19	27	31	23	30	30			

4	5	24	27	21	2	1	3	2	2	2	2
1	1	3	1	1	1	1	1	1	41	39	38
37	34	36	34	26	16	12	1	1	1	1	1
2	1	1	1	1	1	2	15	25	38	36	40
39	38	35	22	16	1	1	1	1	1	1	18
17	16	6	2	25	22	21	22	20			
4	6	24	28	21	2	1	3	2	2	2	2
1	1	3	1	1	1	1	1	1	22	22	21
18	16	36	34	26	16	12	1	1	1	1	1
2	1	1	1	1	1	2	37	22	37	24	31
39	38	35	22	16	1	1	1	1	1	1	14
17	18	18	20	25	22	21	22	20			
4	7	24	6	11	2	1	3	2	2	2	2
1	1	3	1	1	1	1	1	1	39	30	21
18	20	25	26	25	25	24	1	1	1	1	1
1	1	1	1	1	1	1	39	31	36	25	38
25	24	25	25	25	1	1	1	1	1	1	35
34	34	35	34	41	33	31	31	31			
4	8	24	7	10	2	1	3	2	2	2	1
1	2	3	1	2	1	1	2	1	18	17	12
9	12	22	22	21	22	16	1	1	1	1	1
1	1	1	1	1	1	1	23	21	20	21	20
21	21	20	19	26	1	1	1	1	1	1	20
19	19	20	18	29	22	23	26	30			
4	9	24	22	27	2	1	3	2	1	2	2
1	2	3	1	1	1	1	1	1	28	25	25
26	24	15	25	38	36	40	1	1	1	1	1
1	1	1	1	1	1	2	26	25	23	23	22
36	32	33	31	30	1	1	1	1	1	2	26
24	26	25	26	18	17	16	6	2			
4	10	24	9	8	2	1	1	2	1	2	2
1	1	3	1	1	1	1	1	1	26	24	25
21	20	24	21	17	17	16	1	1	1	1	1
1	1	1	1	1	1	1	24	22	23	23	24
18	15	16	13	4	1	1	1	1	1	1	21
25	25	26	22	18	21	22	19	18			
5	1	28	3	2	1	1	8	2	1	1	1
1	1	1	1	1	2	1	2	2	78	79	73
72	72	80	80	80	80	80	1	1	1	1	1
1	1	1	1	1	1	1	65	54	55	56	54
33	78	72	67	35	1	1	1	1	2	1	43
41	57	30	64	48	40	73	53	52			
5	2	28	5	12	1	1	2	2	2	2	2
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44	42	52	52	48	48	50	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0

7	4	21	17	31	1	2	0	1	2	4	2
0	0	0	1	1	1	1	1	1	64	57	56
55	60	52	40	37	38	36	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
15	1	31	17	31	2	2	5	2	2	3	2
2	2	1	1	1	1	1	1	1	41	44	45
45	47	52	46	43	35	23	1	1	1	1	1
1	1	1	1	1	1	1	43	38	41	35	17
36	22	12	14	18	1	1	1	1	1	1	17
18	16	17	9	17	12	26	12	11			
17	1	28	17	31	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	42	41	39
37	36	44	40	37	37	36	1	1	1	1	1
1	1	1	1	1	1	1	46	37	27	30	28
44	30	33	33	31	1	1	1	1	1	1	39
19	37	46	37	34	44	39	37	46			
17	2	28	32	18	1	2	5	1	2	3	2
2	2	1	1	1	1	1	1	1	32	34	36
36	39	47	80	47	42	38	1	1	1	1	1
1	1	1	2	1	1	1	59	37	37	44	44
34	35	38	42	37	1	1	1	1	1	1	52
33	42	37	43	51	47	44	44	42			
18	1	30	1	15	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	31	31	31
30	30	30	26	26	28	41	1	1	3	1	1
3	1	1	1	1	1	1	46	40	56	42	40
43	40	44	45	43	1	1	1	1	1	1	44
44	45	46	45	30	29	27	28	28			
18	2	30	16	2	1	2	5	1	2	3	2
2	2	1	1	1	1	1	1	1	37	41	46
50	51	32	31	30	31	30	1	1	3	1	1
3	1	1	1	1	1	1	43	47	42	43	50
26	35	31	39	39	1	1	1	1	1	1	39
38	40	41	62	28	27	28	27	28			
21	4	29	16	15	2	2	5	1	2	2	2
1	3	2	1	1	1	1	1	1	20	9	19
34	16	20	13	20	12	26	1	1	1	1	1
1	1	1	1	1	1	1	30	27	24	14	16
40	30	38	14	33	1	1	1	1	1	1	18
12	13	9	20	32	10	15	8	9			
22	1	35	1	15	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	58	42	41
37	40	51	48	58	56	66	1	1	1	2	1
1	2	1	1	1	1	1	46	48	48	32	34
32	31	30	30	32	1	1	1	1	1	1	39
40	43	40	40	36	30	34	28	38			
22	2	35	32	18	1	2	5	1	2	3	2
2	2	2	1	1	1	1	1	1	48	43	42
45	33	40	39	31	32	30	1	1	3	1	1
3	1	1	3	2	1	2	42	40	37	36	45
36	38	38	41	37	1	1	1	1	1	1	46
45	50	47	52	51	39	50	36	52			

22	3	35	16	2	1	2	5	1	2	3	2
3	2	2	1	1	1	1	1	1	55	58	59
47	46	52	49	47	52	52	1	1	3	1	1
3	1	1	3	2	1	1	58	52	50	64	61
39	42	42	39	53	1	1	1	1	1	1	20
29	19	22	31	50	52	47	48	42			
22	4	35	17	31	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	75	72	56
57	53	39	35	35	28	31	1	1	3	1	1
3	1	1	3	2	1	1	40	44	42	44	44
41	44	49	45	51	1	1	1	1	1	1	44
43	46	45	49	39	51	60	50	34			
33	1	60	32	18	1	2	5	1	2	2	2
1	2	1	1	1	1	1	1	1	32	28	29
25	31	29	26	25	28	34	1	1	1	1	1
1	1	1	1	1	1	1	39	31	36	35	35
37	45	40	40	33	1	1	1	1	1	1	34
34	32	38	36	30	29	30	28	30			
43	1	25	16	15	2	2	0	1	2	4	1
0	0	0	1	1	2	1	1	1	37	37	43
37	51	47	40	41	41	42	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
43	2	25	17	15	2	2	0	1	2	4	1
0	0	0	1	1	3	1	1	1	18	20	27
34	35	47	40	41	41	42	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
46	1	27	1	15	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	38	42	38
46	43	46	42	41	42	30	1	2	1	1	2
1	1	2	1	1	1	1	24	27	28	32	34
70	80	55	55	58	1	1	1	1	1	1	53
51	50	50	50	54	67	68	76	58			
46	2	27	16	15	1	2	5	1	2	3	2
2	2	2	1	1	1	1	1	1	44	44	57
71	57	46	42	41	42	30	1	2	1	1	2
1	1	2	1	1	1	1	48	46	52	80	36
70	80	55	55	58	1	1	1	1	1	1	80
80	80	80	80	54	67	68	76	58			
47	1	26	1	2	2	2	5	1	2	3	1
2	1	2	1	1	3	1	1	2	32	17	16
31	46	24	13	19	55	25	1	1	1	1	1
1	1	1	1	1	1	1	51	44	47	49	45
38	41	35	36	32	1	1	1	1	1	1	58
62	61	69	75	58	53	62	65	51			
47	2	26	16	2	2	2	0	1	2	4	1
0	0	0	1	1	2	1	1	1	48	7	61
55	46	24	13	19	55	25	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0

50	1	26	1	2	1	2	5	1	2	3	2
3	2	2	1	1	1	1	1	1	33	34	34
33	35	30	28	26	27	28	1	1	1	1	1
1	1	1	1	1	1	1	33	34	37	38	37
35	33	32	32	31	1	1	1	1	1	1	32
37	37	40	41	40	41	40	37	40			
50	2	26	32	31	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	40	33	29
23	21	47	47	46	49	51	1	1	1	1	1
1	1	1	1	1	1	1	25	23	24	29	25
45	48	38	40	41	1	1	1	1	1	1	30
33	27	27	35	45	39	36	43	51			
50	3	26	16	2	1	2	5	1	2	3	2
2	1	2	1	1	1	1	1	1	49	49	48
50	46	35	33	32	32	31	1	1	1	1	1
1	1	1	1	1	1	1	38	47	50	49	48
31	31	29	30	30	1	1	1	1	1	1	43
41	50	47	44	40	41	40	37	40			
50	4	26	17	31	1	2	5	1	2	3	2
3	2	2	1	1	1	1	1	1	30	29	29
29	37	45	48	38	40	41	1	1	1	1	1
1	1	1	1	1	1	1	42	38	42	42	45
44	54	51	38	42	1	1	1	1	1	1	43
41	38	39	39	45	39	36	43	51			
51	1	23	16	15	1	2	5	1	2	3	2
3	1	2	1	1	1	1	1	1	70	34	51
50	66	58	46	30	24	31	1	1	3	1	1
3	1	1	3	1	1	1	15	42	31	6	24
34	15	38	36	19	1	1	1	1	2	2	21
38	36	27	33	45	46	39	39	29			
51	2	23	17	18	1	2	5	1	2	3	2
2	2	2	1	1	1	1	1	1	61	20	37
47	32	42	23	37	49	54	1	1	3	1	1
3	1	1	3	1	1	1	33	17	16	27	16
34	32	24	28	23	1	1	1	1	2	1	32
32	32	22	28	33	27	29	24	27			

Appendix V

HISTOLOGICAL DATA

Code	Seq	Tooth	Tx Type	Med	Time Tx	Inflam Resp.	* Soft Tissue	* Hard Tissue
7	3	16	Ctl			1	1	1
7	4	17	Ctl			1	1	1
17	3	1	Ctl			1	1	1
17	4	16	Ctl			1	1	3
43	1	16	Ctl			1	1	2
43	2	17	Ctl			1	1	1
47	2	16	Ctl			1	1	1
3	5	32	CCR	D	6m	1	1	1
15	1	17	CCR	D	6m	1	1	2
21	4	16	CCR	C	6m	1	1	2
7	2	32	DPC	L	6m	1	1	
17	1	17	DPC	L	6m	1	1	1
18	1	1	DPC	L	6m	1	1	1
22	1	1	DPC	L	6m	1	1	1
22	4	17	DPC	L	6m	1	1	1
46	1	1	DPC	L	6m	4	3	3
47	1	1	DPC	L	6m	1	1	1
51	1	16	DPC	L	6m	1	1	1
3	1	2	DPC	D	1w	2	2	3
7	1	1	DPC	D	6m	1	1	1
17	2	32	DPC	D	6m	2	1	2
18	2	16	DPC	D	6m	1	1	1
22	2	32	DPC	D	6m	1	1	1
22	3	16	DPC	D	6m	1	1	1
46	2	16	DPC	D	6m	4	3	3
51	2	17	DPC	D	6m	1	1	1

Legend: Code = Patient code number
 Seq = Treatment sequence (i.e. 3 = third tooth treated in that patient)
 Ctl = Untreated control
 CCR = Complete caries removal
 DPC = Direct pulp cap
 L = Life^R
 D = Dycal^R
 C = Cavitec^R
 1w = 1 week following treatment
 6m = 6 months following treatment

* See Table 2 for description of categories.

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