OUTCOME STUDY OF GUTTA-PERCHA AND RESILON FILLED ROOT CANALS: A RADIOGRAPHIC AND CLINICAL ANALYSIS

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Abstract

ARYA M. TEHRANY: Outcome Study of Gutta-Percha and Resilon Filled Root Canals: A Radiographic and Clinical Analysis
(Under the direction of Eric M. Rivera, DDS, MS; Fabricio B. Teixeira DDS, MS, PhD; Daniel J. Caplan DDS, PhD)

The purpose of this retrospective study was to evaluate the radiographic and clinical outcome of teeth with chronic apical periodontitis receiving primary root canal therapy when obturated with gutta-percha and Roth's Eugenol Sealer compared to Resilon and Epiphany Sealer. Radiographic outcome was evaluated using the Periapical Index, while clinical outcome was evaluated with objective and subjective tests on 141 teeth. Univariate analysis found the presence of a permanent restoration, pre-operative PAI score, tooth type and age to be significant in predicting radiographic outcome. Univariate and multivariate analysis found age and presence of a permanent restoration as significant predictors of clinical outcome ($p<0.05$). Placement of full coverage restorations was found to significantly impact survival ($p=0.003$), especially in teeth with at least one compromised marginal ridge ($p=0.002$). Teeth filled with gutta-percha or Resilon had statistically indistinguishable differences in radiographic and clinical outcome, and are comparable to outcomes presented in the endodontic literature.

DEDICATIONS

To my family:

To my father: My hero, my inspiration and the one who I have modeled my life after

To my mother: My angel, my pride and the one who will always own my heart

To my brother: My best friend, my confidant and the one who has been there every step of the way with guiding arms.

ACKNOWLEDGEMENTS

To the casual observer, a thesis dissertation may appear to be solitary work. However, to complete a project of this magnitude requires a network of support, and I am indebted to many people. I would like to thank my faculty advisors Dr. Eric Rivera, Dr. Fabricio Teixeira and Dr. Daniel Caplan for their persistence and dedication to this project. I would also like to thank my research assistants Nurica Good, Laura Davies-Ludlow and Chris Yi. Their tireless efforts and countless hours made this project possible. Additional thanks to the additional radiographic examiners, Dr. Marcus Curry and Dr. Nozomu Yamauchi for their assistance. A special thanks to Dr. Fang Gu for her assistance in the data analysis. Finally, I am most especially grateful to my parents, Kia and Nina Tehrany, for their guidance and support.

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CHAPTER I
INTRODUCTION

Background

Endodontics is the branch of dentistry which is concerned with the morphology, physiology and pathology of the human dentin pulp and periradicular tissues. The principle aim of endodontics is the prevention and/or treatment of apical periodontitis. The importance of bacteria and their by-products in the development of apical periodontitis has been well documented throughout the literature (1-3). Prevention or healing of apical periodontitis involves a combination of disinfection of the root canal space through chemo-mechanical means (4, 5) and sealing both the root canal and access cavity with materials that will prevent re-infection (6-15).

After the microbial control phase of endodontic therapy, a root canal filling is placed to seal the root canal system. This filling should serve 3 principle functions: a) entomb most surviving bacteria b) stop the influx of periapical tissue-derived fluid from reaching surviving bacteria in the root canal system c) act as a barrier, thereby preventing re-infection of the root canal (16). Requirements for instrumentation of the root canal that will result in predictable success are well established (17-20). However, the present filling materials and techniques using gutta-percha fail in achieving the requirement of providing a suitable seal to further challenge by bacteria (7, 19). Torabinejad *et al*. showed that when gutta-percha filled canals were challenged by bacteria, 50% allowed

penetration through the entire length of the canal within 30 days (21). Several other articles have suggested that gutta-percha may be a weak point in endodontic therapy (22-24).

For these reasons, attention has been given to developing a new root filling material that better seals the canals. In 2004, Shipper and Trope showed that when using the FibreFill™ obturator (a resin fiber post with 5-8mm of gutta-percha apically) and a resin bonding sealer, there was a 50% improvement in prevention of bacterial leakage compared to the standard gutta-percha techniques (25). They suggested that a resin core root canal filling which could bond to the root canal walls would be desirable. The material should have an excellent apical fit, be bonded with a dentin-bonding system to a resin sealer, and the sealer itself should bond to the canal wall. Thus, should the coronal seal of the root canal system be lost or broken, another barrier to the coronal bacterial challenge may be achieved with a bonded filling material. The only drawback to this concept would be the ability to retreat such a root canal filling.

Many different materials have been proposed as root canal fillings, but have not replaced gutta-percha as the "gold standard" root filling material. Many of the bonding agents and resins studied to date have all had problems in working properties, radiopacity and retreatability (26-28). More recently, however, a resin-based root filling material has been developed. Resilon (Resilon Research LLC, Madison, CT) is a thermoplastic synthetic polymer based root canal filling material. Based on polymers of polyester, Resilon contains bioactive glass and radiopaque fillers. It performs like gutta-percha, has the same handling properties, and for retreatment purposes may be softened with heat or dissolved with solvents like chloroform (29, 30). It is to be utilized with Epiphany™

Sealer (Pentron Clinical Technologies, Wallingford, CT), which is a dual curable dental resin composite sealer.

Many researchers have evaluated the various properties of Resilon. A number of studies have focused on the biocompatibility of Resilon (31-38). Other studies have researched the ease of retreatability of the Resilon obturation system (29, 39-43). Other researchers have investigated the claim that Resilon filling material may increase the fracture resistance of teeth (44-51). The push-out bond strengths of Resilon have also been evaluated (52-57) as have the dentin bond strengths (58-60). However, by far the most research on the Resilon system has involved *in-vitro* and *in-vivo* animal studies that have investigated and evaluated the sealing ability of roots filled with Resilon (25, 61-101).

In an *in-vitro* study by Shipper *et al*. evaluating microbial leakage in roots filled with Resilon compared to gutta-percha, one sample tooth from each group was taken, longitudinally sectioned and had Scanning Electron Micrographs (SEM) made (64). From their SEM micrograph of the gutta-percha filled tooth, they observed the gutta-percha core pulling away from the AH 26 sealer, which remained against the dentin wall, thereby leaving a gap. It was theorized that this gap between the gutta-percha and the sealer may create an avenue for microleakage. In their observation of the SEM micrograph of the Resilon treated tooth, they found the Resilon core closely adapting to the Epiphany^{TM} sealer and in turn the Epiphany^{TM} sealer adhering to the dentin walls via "resin tags". They referred to this as a "mono-block" and discussed the possibility that Resilon filled canals would be more able to withstand bacterial penetration as a result of this "Resin Monoblock System (RMS)" (64).

The theory of a true “Monoblock” system has since been debated. In 2007, Perdigao *et al*. performed an SEM study of Resilon and gutta-percha filled teeth and concluded that although Resilon does not result in a true “monoblock”, the system exhibited significantly less frequent gaps than did gutta-percha (59). In another study by Gharib *et al*. 2007, laser scanning microscopy was used to evaluate the sealer-dentin interface and compare the percentage and average depth of dentinal tubule sealer penetration in the coronal, middle and apical thirds of teeth obturated with the Epiphany Obturation System (102). They found that a consistent fluorescent sealer ring was seen around the canal wall in all sections, with no gaps or definitive hybrid layer observed in the sealer-dentin interface with the Resilon system. However, they did show significantly less percentage of sealer penetration in apical sections than middle or coronal sections.

Of these aforementioned studies, there still remain conflicting results and conclusions. Many of the studies do show statistically significant results of Resilon performing better than gutta-percha in the various properties measured. While others may not show *statistically* significant results of Resilon performing better than gutta-percha, the evidence in the majority of these studies does point to potential *clinically* significant results, such as increased resistance to bacterial leakage and decreased periapical periodontitis.

Although these *in-vitro* and *in-vivo* studies provide valuable information and insight, the ultimate test remains how well these translate into clinical success. While parameters for the determination of endodontic treatment success have varied in the endodontic literature, the vast majority of studies include some sort of radiographic interpretation by which the presence or absence of healing is measured. The Periapical

Index (PAI), originally described by Orstavik in 1986, is one method of radiographically evaluating the level of healing following endodontic therapy (103).

Outcome studies of teeth receiving primary endodontic treatment have consistently shown that teeth with pre-operative radiographic lesions have lower levels of success compared to teeth without pre-operative radiographic lesions (20, 104-108).

Additionally, other factors have also been found to have a significant effect on the endodontic outcome of root canal treated teeth. Some of these include: the presence of a definitive coronal restoration (8, 109, 110), length of follow-up time (20), length of instrumentation and fill (105, 106), bacteriological status at the time of root fill (111), host systemic disorders (110, 112), age (109, 110), and gender (113).

To date, there has been limited published clinical-based research on the treatment outcome of teeth root canal treated and filled with Resilon. In a study published in 2007, Conner *et al*. evaluated the clinical outcomes of teeth that were root canal treated and filled with Resilon in a private practice setting (114). Immediate postoperative radiographs were compared to follow-up radiographs of at least 1 year in 82 randomly selected primary endodontic cases treated according to a non-standardized protocol and root-filled with Resilon. The Periapical Index (PAI) and the Clinical Impression of Healing (CIH) quantification procedures were used to determine the status and change in the condition of the teeth. The PAI evaluation revealed that 90% of the teeth that were healthy at the initial reading (PAI, 1or 2) maintained the condition at follow-up evaluation. Of those teeth that were unhealthy (PAI, 3-5) at the initial reading, 73.3% were judged healthy at the last evaluation. They also found that the proportion of healing with the CIH evaluation was 89.4%. The findings of this study support the contention that

regardless of treatment protocol, healing rates for Resilon-filled teeth in private practice were within the range of success rates for studies with uniform treatment techniques mostly in university settings with gutta-percha root filling (114). Unfortunately, this study lacked a control group (i.e. teeth filled with gutta-percha) to compare their results with. Rather, they used previous endodontic studies with teeth filled with gutta-percha as historic controls. However, the historic controls they compared their results with utilized different instrumentation and irrigation techniques, and therefore are not a reliable comparison. Additionally, there was no standardization of the instrumentation and disinfection protocol among the dentists and endodontists within the study itself.

In 2008, Cotton *et al*. evaluated 103 teeth, both vital and necrotic, after being treated in a private endodontic practice(115). Fifty of the teeth were filled with gutta-percha and Kerr sealer, while fifty-three were filled with Resilon and Epiphany sealer. The teeth were recalled at various time points between 2-25 months. They found no significant difference in the outcome of teeth that were endodontically treated and filled with gutta-percha compared to those that were filled with Resilon. Within their study, they further evaluated a subset of patients that are similar to those subjects that are evaluated in this current study. Specifically, they evaluated 50 teeth (27 filled with gutta-percha and Kerr sealer, and 23 filled with Resilon and Epiphany sealer) with pre-operative radiographic radiolucencies that were recalled after a minimum of 12 months post-obturation. In this subset of patients, they also found no statistically significant difference in the outcome of teeth based on the obturation material used. However, the sample size of this subset of subjects was small (27 filled with gutta-percha versus 23 filled with Resilon) and lacks the power that would be necessary to show a statistically

meaningful difference in success rates attributed to the differing filling materials, especially when considering all treatment was performed by an experienced endodontist, which has been shown in the literature to significantly improve the outcome compared to teeth treated by general dentists (116, 117).

Purpose and Null Hypothesis

The purpose of this retrospective study was to evaluate the radiographic and clinical outcome of teeth diagnosed as having Necrotic Pulp with Chronic Apical Periodontitis after receiving primary root canal therapy when obturated with gutta-percha and Roth's Eugenol Sealer compared to Resilon and Epiphany Sealer. The null hypothesis that there is no difference in either the radiographic or clinical outcome of root canal treated teeth filled with either gutta-percha and Roth's Eugenol Sealer or Resilon and Epiphany Sealer.

Study Design

This is a retrospective, *in-vivo* study performed on human subjects who previously had root canal therapy performed by undergraduate students at the University of North Carolina at Chapel Hill, School of Dentistry, Department of Endodontics. Subjects were recalled after a minimum of 12 months since completion of endodontic treatment. The recall examination included a radiographic assessment comparing pre-operative and follow-up radiographs using the Periapical Index as well as a clinical assessment based on standard subjective and objective endodontic diagnostic tests.

Significance

This research will help bridge the gap between the promising *in-vitro* and *in-vivo* animal studies to clinical practice. Utilizing these results will allow clinicians performing root canal therapy to make a more informed, educated and judicious decision in their clinical practice on the material they choose to fill root canals. Additionally, this research will evaluate the effect of several pre- and post- operative factors on radiographic and clinical outcome. The factors evaluated included: gender, age, tooth type, presence of permanent restoration, time between RCT and permanent restoration, type of permanent restoration, follow-up time, hypertension, diabetes, history of tobacco use, pre-operative PAI score, length of fill, density of fill in apical 1/3, taper, and sealer extrusion. By utilizing these results, the clinician can better make a prediction of outcome for root canal treatment of patients in their clinical practice.

CHAPTER II
ENDODONTIC TREATMENT PROTOCOL FOR UNDERGRADUATE DENTAL STUDENTS AT THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL, SCHOOL OF DENTISTRY, DEPARTMENT OF ENDODONTICS

All subjects who were included in this retrospective study were previous patients who had presented to the undergraduate endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry (UNC SOD) between June 2003 – November 2007 for root canal treatment. During the time period spanning between June 2003- July 2005, the undergraduate endodontic clinic at UNC SOD was using gutta-percha as the filling material for completion of root canal treatment. In August 2005, Resilon became introduced to the undergraduate clinic at the UNC SOD as the root canal filling material. During this time period, the evaluation, diagnosis, instrumentation and disinfection protocol for teeth diagnosed as having a necrotic pulp with Chronic Apical Periodontitis remained nearly identical, with the major difference related to the filling materials. All 3rd and 4th years students performing endodontic treatment were standardized to the following protocol:

Under faculty supervision, the student subjectively and objectively evaluates the tooth in question. Subjective evaluation minimally includes discussions with the patient about past medical history, history of the present illness, and chief complaint. Objective evaluation includes the use of necessary diagnostic tests. The diagnostic tests minimally include a thermal test using EndoIce^{TM}, an electric pulp test (EPT), percussion, palpation,

mobility and probing depths for the tooth in question along with adjacent teeth (at least one tooth on either side). A straight-on periapical radiograph is then made using intraoral Photostimulable Phosphor Plates (Gendex: DenOptix QST PSP #2 Plates), using various exposure times, and are scanned in to the subjects electronic record using the company recommended laser scanning device (Gendex: DenOptix QST Class 1 Laser Scanner). This initial pre-operative radiograph is made using a custom bite stent to ensure reproducible angulations of radiographs during follow-up visits. Stents were made using Rinn XCP precision instrument (Rinn Corp., Elgin, IL) bite tabs coated with adhesive and Regisil 2x (Dentsply Caulk, Milford, DE) impression material to capture an initial reproducible orientation of film to the pathological tooth and periradicular tissue.
The radiographs are examined for any signs of decay, pulp anatomy and root morphology, curvature, lamina dura and periodontal ligament (PDL) space, and any signs of periradicular pathology as evidenced by a radiolucency. After evaluation, a working diagnosis is made and confirmed by attending faculty. After discussing risks, benefits and alternatives to treatment with the patient, a treatment plan for the tooth is developed and written consent is obtained, and root canal treatment is initiated.

The tooth to be root canal treated is anesthetized, if applicable, and isolated with a rubber dam. If the seal is deemed to not be adequate by attending faculty, Cavit is placed around the neck of the tooth to serve as a barrier and improve isolation. The crown and adjacent rubber dam and clamp are disinfected by swabbing the area with either Betadine or 2.2% Chlorhexidine (CHX) and allowed to dry.

Gross caries removal and initial access form are accomplished with sterile high-speed carbide burs and low speed burs. After adequate access is achieved, a definitive

diagnosis is established and confirmed by attending faculty. The canals are negotiated by sterile stainless steel (SS) .02 taper K-files to the estimated working length (EWL) as measured on the digital radiograph (EWL = length of tooth from reference point to tip of radiographic apex minus 1mm). 2.6% Sodium Hypochlorite (NaOCl) serves as the irrigant during this process and is used after the use of each file. Working length radiographs are then made with .02 taper SS K-files to confirm the corrected working length.

After the corrected working length is confirmed by attending faculty, the coronal and middle thirds are prepared using a crown-down technique with variable taper Nickel-Titanium (NiTi) rotary files. During the time period from June 2003 to July 2005, Profile Series 29 rotary files were used for crown-down. Between August 2005 – November 2007, K3 rotary files were implemented. Both systems are NiTi rotary files and only used to achieve flaring of the coronal and middle thirds, with files never progressing any further than within 2mm of the working length. After flaring and shaping of middle third is achieved to within 2mm of the working length, the apical third is prepared with the use of .04 taper, NiTi Hand ProFiles. The apical third is instrumented up to minimal standardized sizes (Figure 1). During this process, 2.6% NaOCl is constantly used as the irrigant, along with constant recapitulation with SS .02 taper ISO 10 or 15 K-files. Upon achieving the minimal standardized sizes, the canals receive a final flush of 2.6% NaOCl and are dried with paper points (PP).

At this point, a calcium hydroxide Ca(OH)2) intracanal inter-appointment medication is mixed. This is achieved by mixing Ca(OH)2 with 2.2% CHX on a paper pad until a slurry is achieved. The Ca(OH)2 slurry is then transferred and spun into each

canal using a lentulo spiral on a slow speed handpiece. The chamber is then cleaned and dried. A cotton pellet is soaked with CHX, the excess is squeezed out, and is placed in the pulp chamber. A temporary restoration (either Cavit G or Intermediate Restoration Material (IRM)) at least three millimeters in depth is placed between the chamber and the external aspect of the tooth. The occlusion is checked and adjusted accordingly. The patient is dismissed and scheduled after a minimum of at least one week time with the Ca(OH)2 intracanal inter-appointment medication in place. In instances when the student is not able to accomplish all of these steps in one appointment, they progress as far along the aforementioned process as possible. When the clinic time is over, they stop at whatever step they have reached and prepare and place the Ca(OH)2 medication and temporary as previously described.

During the next visit, after adequate anesthesia, if applicable, and rubber dam isolation and disinfection is achieved as previously mentioned, the temporary is removed using carbide burs in high and low speed handpieces. The chamber is re-accessed and the canals are re-located. The Ca(OH)2 medication is removed using copious 2.6% NaOCl irrigation along with recapitulation using a smaller file then reached at the last appointment. Once the canals are thoroughly cleaned, each canal receives a 3ml rinse of 17% ethylenediamine tetraacetic acid (EDTA) with constant replenishment for 1-3 minutes. The canals are then dried with PP's. Each canal then receives a final 3-5ml rinse of 2.2% CHX. After the canals are dried again with PP's, the tooth is ready to be filled.

During the time period from June 2003 to July 2005, gutta-percha was the root filling material that was implemented. In this technique, a master cone of gutta-percha was snugly fitted to the achieved working length and a radiograph made to ensure correct

working length. Once this step is confirmed and approved by faculty, the roots are filled with a lateral condensation technique utilizing the master gutta-percha cone, Roth's Eugenol Sealer and multiple gutta-percha accessory cones. NiTi finger spreaders are used during lateral condensation. A trial pack radiograph is made to ensure adequate fill and is evaluated by the attending faculty.

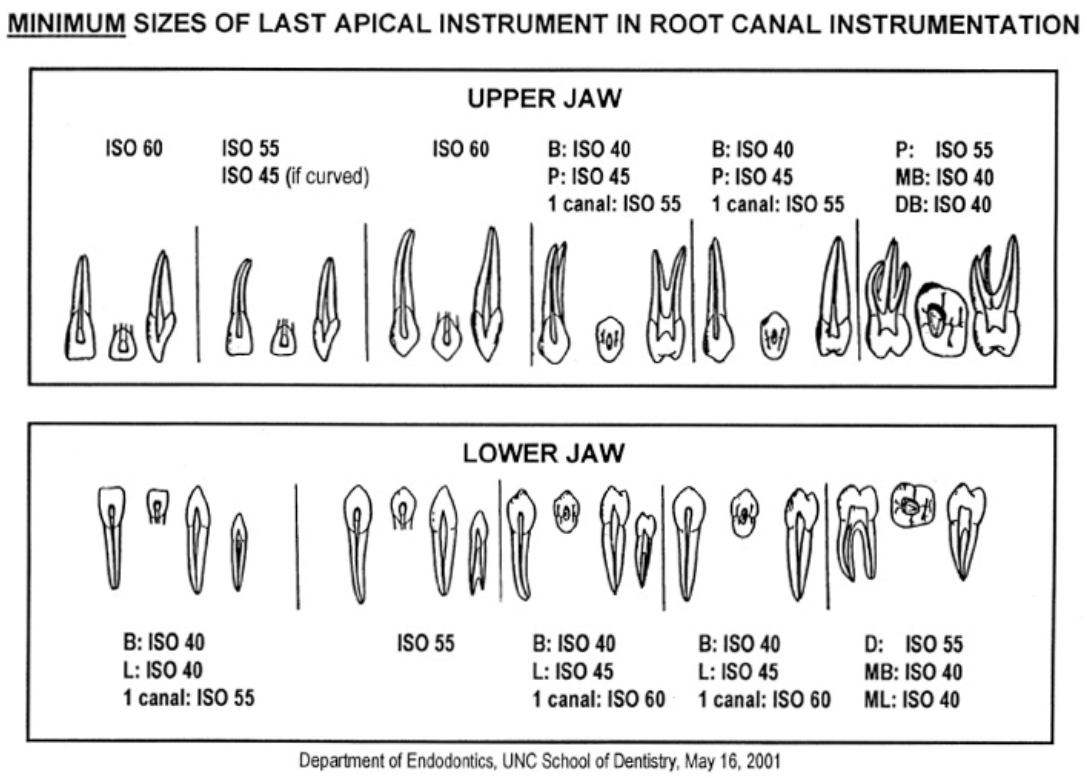
During the time period from August 2005 to November 2007, Resilon was the filling material used. In this technique, Epiphany^{TM} primer is placed on PP's and transferred into the dried canals to coat the walls. The self-etch primer is used to expose the collagen matrix that increases the surface area for bonding (hybrid layer) and allows for sealer to penetrate into the dentinal tubules. The primer is then dried with the use of PP's. A master cone of Resilon is snugly fitted to the achieved working length and a radiograph is made just the same as previously discussed with the gutta-percha technique. The roots are then filled with a lateral condensation technique utilizing the master Resilon cone, Epiphany^{TM} sealer, and multiple Resilon accessory cones. NiTi finger spreaders are used during lateral condensation just the same as with the gutta-percha technique. A trial pack radiograph is made to ensure adequate fill and is checked by the attending faculty.

After the attending faculty has given approval to continue, the excess material is seared at the canal orifices with size 5-7 pluggers. In esthetic areas, the filling is seared 2mm below the gingival margin to reduce possibility of staining from the sealer. The chamber is then adequately cleaned, a CP is placed in the chamber and a temporary is placed as previously described. A final straight on radiograph is made. The patient is advised of obtaining a permanent restoration on the tooth as soon as possible. The patient

is given all necessary post-operative instructions and recommendations and given time to ask any questions.

FIGURES

Figure 1 – Minimum Sizes of Apical Instrumentation



CHAPTER III
LONG-TERM RADIOGRAPHIC OUTCOME OF PERIAPICAL HEALING OF TEETH WITH CHRONIC APICAL PERIODONTITIS FOLLOWING ROOT CANAL TREATMENT AND FILLING WITH EITHER GUTTA-PERCHA OR RESILON

Abstract

The purpose of this retrospective study was to evaluate the radiographic outcome of teeth with chronic apical periodontitis receiving primary root canal therapy when obturated with gutta-percha and Roth's Eugenol Sealer compared to Resilon and Epiphany Sealer. All treatment was performed by dental students at the University of North Carolina at Chapel Hill. Radiographic outcome was evaluated using the Periapical Index after a minimum of 12 months post-obturation on 141 teeth. Univariate analysis found presence of a permanent restoration, pre-operative PAI score, tooth type and age to be significant in predicting radiographic outcome ($p < 0.05$). Teeth filled with gutta-percha or Resilon had statistically indistinguishable differences in radiographic outcome (81.1% versus 78.4%, respectively), and are comparable to outcomes presented in the endodontic literature.

Introduction

Endodontics is the branch of dentistry which is concerned with the morphology, physiology and pathology of the human dentin pulp and periradicular tissues. The principle aim of endodontics is the prevention and/or treatment of apical periodontitis. The importance of bacteria and their by-products in the development of apical periodontitis has been well documented throughout the literature (1-3). Prevention or healing of apical periodontitis involves a combination of disinfection of the root canal space through chemo-mechanical means (4, 5) and sealing both the root canal and access cavity with materials that will prevent re-infection (6-15).

After the microbial control phase of endodontic therapy, a root canal filling is placed to seal the root canal system. This filling should serve 3 principle functions: a) entomb most surviving bacteria b) stop the influx of periapical tissue-derived fluid from reaching surviving bacteria in the root canal system c) act as a barrier, thereby preventing re-infection of the root canal (16). Requirements for instrumentation of the root canal that will result in predictable success are well established (17-20). However, the present filling materials and techniques using gutta-percha fail in achieving the requirement of providing a suitable seal to further challenge by bacteria (7, 19). Torabinejad *et al*. showed that when gutta-percha filled canals were challenged by bacteria, 50% allowed penetration through the entire length of the canal within 30 days (21). Several other articles have suggested that gutta-percha may be a weak point in endodontic therapy (22-24).

Recently a resin-based root filling material has been developed. Resilon (Resilon Research LLC, Madison, CT) is a thermoplastic synthetic polymer based root canal

filling material. Based on polymers of polyester, Resilon contains bioactive glass and radiopaque fillers. It performs like gutta-percha, has the same handling properties, and for retreatment purposes may be softened with heat or dissolved with solvents like chloroform (29, 30). It is to be utilized with Epiphany^{TM} Sealer (Pentron Clinical Technologies, Wallingford, CT), which is a dual curable dental resin composite sealer.

Many researchers have evaluated the various properties of Resilon in both in-vitro and in-vivo studies, including Resilon's biocompatibility (31-38), ease of retreatability (29, 39-43), effect on the fracture resistance of teeth filled with Resilon (44-51), push-out bond strength, and sealing ability (25, 61-101). Unfortunately, there has been limited published clinical-based research on the treatment outcome of teeth root canal treated and filled with Resilon. In 2007, Conner *et al*. reported healing rates of teeth filled with Resilon in a private practice setting were within the range of success rates reported in university-based outcome studies using gutta-percha as the root filling (114). In 2008, Cotton *et al*. evaluated 103 teeth, both vital and necrotic, after being treated in a private endodontic practice and filled with either gutta-percha and Kerr sealer or Resilon and Epiphany Sealer. (115). They found no statistically significant difference in the outcome based on the obturation material used.

The present retrospective study was designed to further evaluate the radiographic outcome of teeth diagnosed as having Necrotic Pulps with Chronic Periradicular Periodontitis (CPP) when root canal treated and filled with either gutta-percha or Resilon using a standardized protocol. All treatment was rendered by undergraduate dental students in the endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry under direct supervision of an endodontic faculty member. Both

univariate and multivariable regression analyses were performed to determine any significance that the filling material had on the radiographic outcome of these teeth. Additionally, other pre- and post- operative factors were evaluated for their potential significant effects on radiographic outcome. The preoperative factors evaluated were gender, age, tooth type, pre-operative PAI score, length of recall times, presence of hypertension, presence of diabetes, and/or history of tobacco use. Postoperative factors evaluated were the presence of a permanent restoration, type of permanent restoration, and time elapsed between completion of root canal treatment and placement of permanent coronal restoration.

Materials and Methods

This retrospective study was approved by the Institutional Review Board of the University of North Carolina at Chapel Hill. The subject population was obtained from previous patients who had presented to the undergraduate endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry (UNC SOD) between June 2003 – November 2007 for root canal treatment. During the time period spanning between June 2003- July 2005, the undergraduate endodontic clinic at UNC SOD was using gutta-percha as the filling material for completion of root canal treatment. In August 2005, Resilon became introduced to the undergraduate clinic at the UNC SOD as the root canal filling material. During this time period, the evaluation, diagnosis, instrumentation and disinfection protocol for teeth diagnosed as having a necrotic pulp with Chronic Apical Periodontitis remained nearly identical, with the major difference related to the filling materials. All 3rd and 4th years students performing endodontic treatment were standardized to the protocol described in Chapter II.

Selection of Subjects and Recruitment Process

Selection of subjects to be recruited for the study was based on specific inclusion criteria. Inclusion criteria included: 1) Treatment performed by undergraduate dental students in the endodontic clinic at UNC SOD under direct supervision of faculty between June 2003 and November 2007, 2) Root canal treated tooth having a pre-operative diagnosis of a Necrotic Pulp with Chronic Periradicular Periodontitis with a radiographic lesion, 3) Complete root development at time of completion of root canal

treatment, and 4) At least 12 months since completion of root canal at time of follow-up evaluation.

After carefully reviewing the database of treated patients between June 2003 and November 2007, 1,584 root canal treated teeth were identified, with 610 teeth filled with gutta-percha and Roth's Eugenol Sealer and 974 teeth filled with Resilon and Epiphany Sealer. From this total, 492 root canal treated teeth that met the inclusion criteria were identified. Of those, 204 teeth were filled with gutta-percha, while 288 teeth were filled with Resilon. Starting in March 2008 and ending in January 2009, attempts to contact and enroll the qualified subjects were made in the following order: 1) Phone calls with messages explaining the research project and requesting follow-up examination. Three phone calls were attempted. 2) If a subject was unable to be contacted using the phone number on file, a study enrollment letter was sent to the address on file. 3) If still no contact was made, a phone call was made to the emergency contact person listed in the patients previously completed UNC School of Dentistry Registration form in an attempt to receive updated contact information for the subject. A financial incentive of $10 per tooth used were offered to subjects for their participation. The final subject population was comprised of 120 subjects with 141 teeth, with 53 teeth filled with Gutta-Percha and Roth's Eugenol Sealer and 88 teeth filled with Resilon and Epiphany Sealer.

Radiographic Interpretation and Assessment

During the recall examination, a follow-up radiograph was made. The custom bite stents made during the initial visit were either misplaced or lost for the vast majority of treated teeth, while others were not organized properly and therefore unable to be located

in an efficient manner. Therefore, a straight-on radiograph was made in place of using the custom bite stents that were previously made, with attention given to trying to accurately reproduce the same straight-on angle that was taken for the pre-operative radiograph. At the completion of the project, all of the pre-operative and follow-up radiographs from all the subjects were randomly arranged and independently assessed by each of three examiners (A.T., M.C., N.Y.) using the Periapical Index (PAI), a visual scoring index originally described by Orstavik 1986 based on histological analysis by Brynolf 1967 (103, 118). All radiographic images were viewed under similar viewing and lighting conditions on an IBM T60 laptop computer monitor (15-inch LCD screen, 1024x768 pixel resolution). Each examiner was blinded to the treatment group, gutta-percha or Resilon, of the radiograph that they were analyzing. The following specific instructions were given to the observers, according to Orstavik 1986(103):

1. Find the reference radiograph (Figure 1) in which the periapical area most closely resembles the periapical area you are studying. Assign the corresponding score to the observed root.

2. When in doubt, assign a higher score

3. For multi-rooted teeth, use the highest of the scores given to the individual roots

4. All endodontically treated teeth must be given a score

Additionally, the following written criteria for scoring the radiographs were also given according to Orstavik 1988 and Delano 2001 (119, 120):

1 = normal apical periodontium

2 = bone structural changes indicating, but not pathognomonic for, apical periodontitis

3 = bone structural changes with some mineral loss characteristics of apical

periodontitis

4 = well-defined radiolucency

5 = radiolucency with radiating expansions of bone structural changes

For teeth that were extracted at time of recall, the reason for extraction was determined by either reviewing the electronic notes for the patient if the tooth was extracted at the UNC SOD, or by contacting the dentist/oral surgeon if the extraction was performed in private practice. Pre-extraction radiographs, with at least one-year post obturation, were able to be obtained for each of these subjects, and these were used as the follow-up radiographs for outcome analysis.

Prior to scoring the pre-operative and follow-up radiographs, the examiners were each calibrated by three times scoring the standard set of 100 cases of individual radiographs, supplied by Dr. Dag Orstavik, on separate dates. After each scoring session, a discussion of results in comparison with “true scores”, which were previously determined by Dr. Orstavik, was made prior to the next scoring. After the final scoring of reference teeth, the scores were compared to the authoritative “true” scores, and Cohen's inter-examiner kappa scores were obtained. Additionally, the scores from the third scoring set were compared to the second scoring set and intra-examiner kappa scores were obtained for each examiner. This process was repeated until all examiners had inter- and intra- examiner kappa score greater than 0.61, which indicated good reproducibility (121).

Each pre-operative and follow-up radiograph was independently scored by all three examiners. The comparison of the follow-up (F/U) PAI scores to the pre-operative

(Pre-Op) PAI scores determined the radiographic outcome of each tooth. The outcome of each tooth was classified as either healed, healing or not healed according to the following:

PAI comparison of F/U to Pre-Op	**Healed**	**Healing**	**Not Healed**
F/U < Pre-Op **and** F/U = 1	X		
F/U < Pre-Op **and** F/U > 1		X	
F/U ≥ Pre-Op			X

Specifically, teeth were classified as healed, healing or not healed according to the following comparison of pre-operative to post-operative PAI Scores:

		Post-Operative PAI Score				
Pre-Operative PAI Score		1	2	3	4	5
	1	N/A	N/A	N/A	N/A	N/A
	2	Healed	Not Healed	Not Healed	Not Healed	Not Healed
	3	Healed	Healing	Not Healed	Not Healed	Not Healed
	4	Healed	Healing	Healing	Not Healed	Not Healed
	5	Healed	Healing	Healing	Healing	Not Healed

As there were three examiners, there were instances in which different PAI scores were given to pre-operative and post-operative radiographs by the different examiners. These situations were handled by assigning the score that the majority of the three examiners gave (i.e. if two examiners scored a radiograph as 2, and the other scored it a 3, a final score of 2 was recorded for that radiograph). If a different score was given by each of the three examiners, the examiners met together and discussed the radiographs and a consensus score was agreed upon.

In addition to assigning a PAI score to each radiograph, each of the examiners also interpreted and recorded the technical quality of the root canal filling. The factors of the root filling material that were assessed included: length of fill (within 1mm of the radiographic apex or not), extrusion of sealer evident (yes or no), density of fill (presence of voids in apical 1/3 or not), and taper of fill (adequate taper or not).

Prognostic Factors

In addition to the data generated from the radiographic examination, other pre- and post-operative data were collected from the subject and their dental record. These data were recorded and categorized as follows:

- Age of subject at time of treatment
    - Recorded in years (rounded up to nearest year)
- Gender
    - Male versus Female
- Tooth type
    - Anterior (centrals, laterals and canines) versus Premolar versus Molar
- Permanent Coronal Restoration
    - Present versus Not Present
- Type of final coronal restoration (if present)
    - Amalgam versus Composite versus Full Coverage Restoration versus Other
- Time elapsed from completion of RCT and placement of final restoration (if present)

    - Recorded in months (round up to nearest month)
    - This was determined by:
        - Documented records from UNC charts if the subject had the final restoration placed at UNC SOD
        - If the patient obtained the permanent restoration at a private dental office, the dentist was contacted to determine the exact date of placement of the permanent restoration
- Presence of Hypertension
    - Diagnosed with hypertension versus Not Diagnosed
- Presence of Diabetes
    - Diagnosed with Diabetes (type I or II) versus Not Diagnosed
- History of Tobacco use
    - Yes versus No
- Pre-Operative PAI score
    - Scores ranged from 2 to 5
        - Score of 1 was not used, as the inclusion criteria limited teeth to those diagnosed with a necrotic pulp and chronic apical periodontitis
- Presence of sealer extrusion at time of obturation
    - Present versus Not Present
- Length of Fill
    - Ideal (0-2mm of radiographic apex) versus Short (>2mm) versus Long (out of radiographic apex)

- Adequate density in Apical Third
    - Yes versus No
- Adequate Taper of Fill (continuous, smooth flowing taper)
    - Yes versus No

All of the data was recorded on a Subject Assessment Form (Figure 2). These forms were utilized for data analysis.

Data Analysis

The primary analysis was to determine the association between the filling materials used and radiographic outcome. Univariate and multivariate logistic regression analysis were used in this study to evaluate the association between radiographic outcome of primary root canal treated teeth and obturation method (gutta-percha and Roth's Eugenol Sealer versus Resilon and Epiphany Sealer). To account for the fact that the 141 teeth evaluated were from 120 subjects, logistic regression analysis was performed using the PROC GENMOD procedure with repeated statements within the SAS program. The odds ratio and associated 95% confidence intervals were used to represent the association with radiographic outcome. Other potential prognostic factors (previously listed) were also included in the analysis. They were analyzed as covariates, and the treatment effects were estimated as the adjusted odds-ratio with a CI of 95%. When using the multivariable logistic regression analysis model, effects that were not significant were consecutively eliminated until only significant variable remained. For univariate analysis, Chi-square test, Fisher exact test and ANOVA were used with the level of significance at $p < 0.05$.

Results

The PAI calibration exercise yielded kappa statistics that ranged from 0.69-0.78 for interexaminer reliability between the 3 examiners, while intraexaminer reliability ranged from 0.70-0.86 (Table 1). All weighted kappa statistics indicated substantial agreement (121).

Overall, 1584 teeth were root canal treated between June 2003 and November 2007, with 610 teeth filled with gutta-percha and Roth's Eugenol Sealer and 974 teeth filled with Resilon and Epiphany Sealer. From this total, 492 teeth (204 filled with gutta-percha and 288 filled with Resilon) met the inclusion criteria and were found to be eligible for participation in this study. The final sample size included in this study comprised of 141 teeth from 120 subjects, with 53 teeth being filled with gutta-percha and Roth's Eugenol Sealer and 88 teeth filled with Resilon and Epiphany Sealer. This yielded an overall recall rate of 28.7% (26.0% for the gutta-percha group and 30.6% for the Resilon group). After completion of the recruitment process, 277 teeth were unable to be recalled due to an inability to contact the subjects (phone number not in service/disconnected, wrong number, left message that was never returned, no response to recruitment letters that were mailed, returned recruitment letters due to change of address, emergency contact person listed was not able to be contacted). Of the 215 teeth belonging to subjects that were able to be contacted, 75 teeth were unable to be recalled due to refusal of subjects to participate in the research, resulting in a recall rate of 65.6% of contacted subjects, with a recall rate of 59.6% for the gutta-percha group and 69.3% for the Resilon group (Table 2). The most common reason given for refusal of participation was that the subject was not having any problems on the tooth in question.

Of those subjects that denied participation in the study, all reported still having their root canal treated tooth in their mouth and being asymptomatic on that tooth.

All of the pre- and post-operative variables were recorded and compared between the two treatment groups, gutta-percha or Resilon, to evaluate for any difference in baseline values (Table 3). It was determined that the mean follow-up time was significantly different between the two treatment groups ($p < 0.0001$). Gutta-percha filled teeth had a mean follow-up time of 52.14 months while Resilon filled teeth had a mean follow-up time of 23.82 months. No other recorded variable showed any statistically significant difference in baseline values between the two treatment groups.

Radiographic evaluation of teeth filled with gutta-percha and Roth's Eugenol Sealer showed 50.9% of teeth to be healed, 30.2% to be healing and 18.9% to be not healed. Teeth filled with Resilon and Epiphany Sealer were found to have 36.4% of teeth healed, 42.0% healing and 21.6% not healed. This difference was not statistically significant. Both presence of a permanent restoration and pre-operative PAI score showed a significant relationship with the radiographic outcome. There was no significant relationship observed between the radiographic outcome and any of the other independent variables: gender, age, tooth type, time between RCT and permanent restoration, type of permanent restoration, follow-up time, hypertension, diabetes, history of tobacco use, or sealer extrusion (Table 4). The length of fill, density in apical third and taper of fill were not able to be statistically evaluated with respect to radiographic outcome due to a lack of variability of these factors with very little deviation from ideal. Specifically, all teeth were found to have adequate density in the apical third, only three

teeth were found to lack adequate taper and only six teeth were found to have inadequate length of fill (three were short and three were long).

When combining the radiographic outcome of healed and healing as one category and comparing to those that were not healed, it was found that teeth filled with gutta-percha and Roth's Eugenol Sealer showed 81.1% of teeth were radiographically healing or healed, compared to 78.4% of teeth filled with Resilon and Epiphany Sealer. This difference was not statistically significant. Of the independent variables, tooth type, presence of a permanent restoration, and pre-operative PAI score showed a significant relationship with the radiographic outcome. There was no significant relationship observed between the radiographic outcome and any of the other variables: gender, age, time between RCT and permanent restoration, follow-up time, hypertension, diabetes, history of tobacco use, or sealer extrusion (Table 5).

Overall, 17 teeth were determined to have been previously extracted at the time of recall. All teeth were extracted a minimum of 12 months post-obturation. These included seven teeth filled with gutta-percha and ten teeth filled with Resilon. It was found that six of the seven extracted teeth filled with gutta-percha were extracted solely for restorability concerns, while the seventh was extracted due to pain and a confirmed vertical root fracture at time of extraction. Similarly, eight of the ten previously extracted teeth filled with Resilon were extracted solely for restorability concerns, while one was extracted due to abscess and the other for severe pain and a confirmed vertical root fracture at the time of extraction. The radiographic outcomes of the 17 extracted teeth are shown in Table 6. There was no significant difference in the scores of the extracted teeth between the two treatment groups. Each of the three teeth which were extracted due to reasons other than

restorability, i.e. pain, abscess and/or vertical root fracture, were each found to be not-healed radiographically.

Odds-Ratio estimates using univariate logistic regression analysis using a combination of various outcomes were performed. When comparing outcomes of healing vs. not healed (Table 7) showed tooth type to be significant in predicting outcome, with anteriors being 5.33 times as likely to be healing compared to molars, while premolars were 3.86 times as likely to be healing compared to molars. When comparing outcome groups of healed vs. not healed (Table 8), age was found to be significant, with treated teeth being 1.03 times as likely to be healed than not healed for every year increase in age after 18. Finally, when comparing outcomes of healed vs. healing (Table 9), pre-operative PAI score was found to be significant, with pre-operative PAI scores of 5 being .086 times as likely to be healed compared to teeth with PAI scores of 3.

Multivariable regression analysis was also performed, but showed no significant relationship between obturation material and any of the independent variables.

Discussion

When comparing treatment outcomes of endodontically treated teeth, either a prospective or retrospective study design can be utilized, each with certain advantages and disadvantages (115). Some of the advantages of a prospective study design are that it allows for blinded randomized treatment allocation, prior standardization of techniques, and simultaneous study of multiple variables. However, they require long follow-up times, which can become costly and can lead to attrition of subjects over time. Retrospective studies have the advantage of having larger study populations and longer follow-up times. However, they lack the randomization of treatment allocation and standardization of methods that a prospective design offers. This study determined the association between the filling materials used and radiographic outcome of teeth receiving primary endodontic treatment. Recent studies evaluating the outcome of Resilon treated teeth show success rates comparable to teeth treated with gutta-percha (114, 115). To show a statistically significant difference between the outcome of endodontically treated teeth with very similar success rates, a large sample of subjects would be necessary to allow for enough power to do so. For this reason, a retrospective study design was chosen in this study.

To minimize the effect of a lack of standardization in endodontic treatment that occurs in retrospective studies, this study utilized a subject population obtained from previous patients who had presented to the undergraduate endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry (UNC SOD) between June 2003 – November 2007 for root canal treatment. During this time, the evaluation, diagnosis, instrumentation and disinfection protocol for root canal treatment remained

nearly identical, with two exceptions. The first change was the filling material used to obturate the canal systems. From June 2003 – July 2005, gutta-percha and Roth's Eugenol sealer was used to obturate root canals, while Resilon and Epiphany Sealer was used from August 2005 – November 2007. The second change was related to the file system used for crown-down of the root canal system. Between June 2003 and July 2005, Profile Series 29 rotary files were used for crown-down, while K3 rotary files were used between August 2005 – November 2007. However, because both file systems are made of Nickel-Titanium and used only to achieve flaring of the coronal and middle third, with files never progressing any further than 2mm of the working length, it was not expected that the differing file systems would affect the outcome of the root canal treated teeth. A study by Gonzalez-Rodriquez and Ferrer-Luque evaluated the changes of cross-sectional area morphology of mesial mandibular curved canals in the coronal, middle and apical third after instrumentation with K3, Profile, or Hero 642 rotary files (122). They showed no significant difference in dentine removal between the K3 and Profile rotary instruments at any level in the root canal and therefore provides support for our contention that outcome would not be affected by the change in crown-down instrumentation, especially considering crown down was used only in the coronal and middle 1/3, while the apical 1/3 was instrumented using the same technique and same file system.

Outcome studies evaluating primary endodontic therapy have consistently shown that the presence of pre-operative periapical lesions significantly affect outcome, with success being significantly higher in teeth without periapical lesions (20, 104, 105, 107, 108, 113, 115, 123, 124). With reported success rates in these studies ranging from 88-

100% for primary endodontic treatment in teeth without periapical lesions (Table 10), few failures are seen, making it increasingly difficult to show a significant effect of any treatment variable on outcome. For this reason, this study focused on teeth diagnosed as having a necrotic pulp with chronic apical periodontitis, which would presumably result in a larger number of treatment failures and allow for more room to show a potentially significant effect of filling materials on outcome.

For the present study, the primary outcome was radiographic healing. The Periapical Index (PAI) was employed as the preferred method for evaluating the periapical structures of the treated teeth. The utilization of the PAI and subsequent assignment of scores is subjective. One of the major concerns in conducting research that requires judgments on the part of an observer is the reliability of ratings assigned. For this reason, prior to scoring any radiographs involved in the study, each examiner received extensive calibration. All examiners had inter- and intra- examiner kappa scores greater than 0.61 indicating substantial agreement (121). Additionally, all pre-operative and follow-up radiographs were randomly arranged and independently scored by each examiner, who were blinded to the filling material used. The scores of the follow-up radiographs were then compared to the scores of the pre-operative radiograph, which is in contrast with comparing the follow-up radiograph directly to the pre-operative radiograph and making a determination of the extent of healing. Employing this latter method may result in bias, and comparisons may not be “true” due to changes in angulations between films. However, by independently scoring pre-operative and follow-up radiographs in random order, slight changes in angulations between the radiographs do not have as dramatic impact on the detection of healing, resulting in a highly predictable model for

detecting healing of apical periodontitis (119). For this reason, along with the substantial agreement between examiners which was obtained after extensive calibration and the blindedness of examiners to the filling material, bias in scoring was minimized and made for a more objective radiographic evaluation.

Although significant efforts were made to minimize bias as much as possible, the potential for observer bias was still present. This bias can be attributed to two factors. The first factor is due to the increased radioopacity that is evident with Resilon and Epiphany Sealer compared to Gutta-Percha and Roth's Eugenol Sealer. Although this difference is apparent when comparing the filling materials side by side, it is not as apparent when evaluating radiographs individually as was done in the present study. Nevertheless, there is potential for the experienced observer to detect a difference in radioopacity and therefore know what material was used in filling the root canal system, which may introduce user bias when assigning PAI scores. Secondly, although PAI scores are assigned based on the radiographic lesion at the apex of the tooth, examiners see the entire tooth during their radiographic evaluation. As a result, examiners may observe factors such as the quality and type of coronal restoration, presence of recurrent decay, quality of root canal filling, as well as other radiographically discernible factors that may affect endodontic outcome. The presence or absence of these factors in the radiograph may introduce a subconscious bias in the assignment of PAI scores.

As mentioned earlier, the vast majority of custom bite stents that were made for the initial pre-operative radiographs during the initial treatment appointment were either misplaced or lost, while others were not organized properly and therefore unable to be located in an efficient manner. To address this matter, a straight-on radiograph was made

in place of using the custom bite stents that were previously made, with attention given to trying to accurately reproduce the same straight-on angle that was taken for the pre-operative radiograph. Although this was not ideal as this may introduce variations in angulations of follow-up radiographs compared to pre-operative radiographs, Orstavik showed that even when different radiographs are exposed with different angulations of the beam and/or different intraoral placements of films, more than 93% of scores were either identical or deviated from each other by only one step (120). Relating this finding to our study shows that although it was not ideal that we were not able to utilize the pre-operative stents, the vast majority of scores would have been either identical or deviated by only one score had the stents been used for the follow-up radiograph.

Our overall tooth recall rate was 28.7%, with a recall rate of 26.0% for the gutta-percha group and 30.6% for the Resilon group. As the recall rates for both treatment groups are very similar, it can be assumed that differences in outcome are not due to differences in recall rate. Our overall recall rate compares favorably to the recall rate of other recent outcome studies, ranging from 18.7 – 37.3% (108, 113-115, 123). Specifically, Conner *et al*. evaluated the same population of subjects – previous patients receiving primary endodontic therapy for teeth diagnosed as having Necrotic Pulp with Chronic Apical Periodontitis by dental students at the University of North Carolina at Chapel Hill – and obtained a recall rate of 33.6% (114). The recall rates from the Conner study and the present study can be attributed to the highly transient nature of the Triangle area of North Carolina, from which University patients are drawn. This is in part evidenced by the large number of subjects whose telephone numbers and/or addressed has changed. In fact, the major factor for non-participation was an inability to contact the

subjects. In total, 277 teeth belonged to subjects who were unable to be contacted, and therefore did not have the opportunity to either accept or decline participation. This is in contrast to non-participation due to subjects' decision to decline, which may likely be due to characteristics associated with recall (i.e. tooth being symptomatic or not) and could therefore have an effect on the results. Therefore, we further evaluated the recall rate with respect to those teeth from subjects that were able to be contacted, and had the opportunity to either participate or decline. Of the 215 teeth from subjects that were able to be contacted, 75 teeth were unable to be recalled due to refusal of subjects to participate in the research, resulting in a recall rate of 65.6% of contacted teeth, with recall rates of 59.6% for the gutta-percha group and 69.3% for the Resilon group. All subjects that refused participation in the study reported that their root canal treated tooth was still in their mouth and were asymptomatic at the time of contact.

The difference in recall rates of contacted subjects between the gutta-percha and Resilon groups may be in part explained by the fact that subjects from the Resilon group had their treatment performed much more recently, 23.8 months ago on average, compared to 52.1 months for the gutta-percha group. Therefore, the subjects from the Resilon group may have been more likely to want to follow-up with their more recent treatment to make sure everything was healing as it should be. Subjects from the gutta-percha group may not have been so eager to return for follow-up considering on average more than 4 years had passed, so if they were asymptomatic, they may have not felt the same need to return for follow-up. Additionally, it is likely that more of the subjects from the gutta-percha group may have already had some sort of follow-up in the past 4 years.

Despite the low follow-up rate, the composition of the two treatment groups was very similar with respect to pre- and post- treatment variables. In fact, an evaluation of the composition of pre- and post- treatment variables within the two treatment groups revealed the only variable for which there was a significant difference was follow-up time, with gutta-percha filled teeth having a mean follow-up time of 52.1 months compared to 23.8 months in teeth filled with Resilon. This is important in that longer follow-up times have been associated with more definitive healing patterns by some researchers (104, 124, 125). However, Orstavik *et al.* showed that while complete healing of preoperative CAP in some instances required 4 years for completion, signs of initiated healing are evident in at least 89% of all healing roots after 1 year (126). Given the mean follow-up time was nearly 2 years for even the Resilon treated teeth, the vast majority of teeth that were going to heal should have shown at least signs of healing at time of recall. At best, this difference in follow-up time suggests that greater potential exists among teeth filled with Resilon to resolve if a longer follow-up time was available.

Radiographic outcome was originally evaluated in three separate categories of healed, healing and not healed. Subsequent to this evaluation, outcomes of healed and healing were combined as one category and compared to the not-healed group. The rationale for combining healing and healed teeth into one group was based on findings in the endodontic literature that show although the vast majority of teeth that are going to heal show signs of healing in the first year, some teeth can take several years to see complete resolution of periapical lesions (124-127). These studies also revealed that some teeth that show minimal or no signs of radiographic healing initially, if followed for 10-17 years, will begin to heal, and others required as much as 20-28 years to show

radiographic healing. Applying these findings to the current study, lead to the belief that teeth that show radiographic signs of healing have a biologic environment that is conducive to healing, and may be a matter of time until complete healing is evidenced, contingent that other factors such as coronal seal or periodontal status are not compromised. Therefore, an additional evaluation of radiographic outcome was made comparing the combined outcomes of healing and healed to the outcome of not-healed. In addition to combining outcomes, odds-ratio estimates using univariate logistic regression analysis evaluated the effect of all variables to separate outcomes of healing vs. not healed (Table 7), healed vs. not healed (Table 8), and healed vs. healing (Table 9), to see if any differences were evident within outcome groups.

Overall, teeth filled with gutta-percha were found to have radiographic signs of success in 81.1% (healed = 50.9%, healing = 30.2%), while teeth filled with Resilon were found to have radiographic signs of success in 78.4% of cases (healed = 36.4%, healing = 42.0%). This difference proved to be non-significant in both univariate and multivariate regression analysis. The overall radiographic success rate reported in this study for primary non-surgical root canal treatment in teeth with a necrotic pulp and chronic apical periodontitis compares favorably to those reported in the endodontic literature for both teeth treated with gutta-percha and Resilon as shown in Table 9 (20, 104, 105, 107, 108, 113-115, 123, 124). These results reinforce the works of Conner *et al*. and Cotton *et al*., by showing that teeth filled with Resilon have success rates that are comparable to those teeth filled with gutta-percha (114, 115).

It should be mentioned that the teeth selected to be treated in the UNC undergraduate endodontic clinic by 3rd and 4th year dental students may be predisposed to

have better healing due to the fact that they are individually screened and determined to be suitable for treatment by dental students. Teeth with restricted chamber and/or canal anatomy, moderate to severe curvatures of canals, difficult access due to presence of crown or limited mouth opening, as well as those teeth that are deemed to have difficulty with rubber dam isolation due to loss of coronal tooth structure are not selected to be treated by undergraduate students, but rather referred to either the graduate endodontic clinic for an endodontic resident to treat or to an endodontic specialist in private practice. Teeth selected for treatment by undergraduate students are typically limited to those with open and unrestricted chamber and/or canal anatomy with only mild curvatures in canal anatomy. For these reasons, these teeth are more likely to be adequately instrumented, debrided and filled and therefore be predisposed to a greater likelihood of healing compared to those which are referred to endodontic residents or endodontic specialists. However, an argument can also be made that although teeth that are deemed to be more difficult to treat are referred to endodontic residents or endodontic specialists, they are better trained and better equipped to treat those teeth, and therefore as likely to adequately instrument, debride and fill the teeth to allow for a greater potential of healing.

Univariate analysis, including odds-ratio estimates of pre- and post- treatment variables showed several significant findings, dependant on which outcomes were evaluated. The presence of a permanent restoration at time of recall was found to be a significant predictor of outcome when separate outcomes of healed, healing and not healed were compared, as well as when the outcome of healing and healed were combined and compared to not healed. This finding is consistent with the endodontic

literature and has been attributed to an improved coronal seal with permanent restorations resulting in reduced coronal microleakage (6-15, 109, 110).

Pre-operative PAI scores were found to be significant when separate outcomes of healed, healing and not healed were evaluated. Additionally, odds-ratio estimates revealed that teeth with a pre-operative PAI score of 5 were 0.086 times as likely to be fully healed compared to teeth with PAI scores of 3, when the outcomes compared were healed vs. healing, although the model validation is in question due to small sample size in certain categories, as shown in Table 1. While pre-operative PAI scores have been shown to be significantly associated with outcome in at least two studies (128, 129), many studies have shown the size of a periapical radiolucency is significant in predicting outcome, with small lesions ($\leq$ 5mm in diameter) being associated with better outcomes (16, 113, 124, 129-132). Hoskinson argued this may be explained by the findings that both the presence and size of periapical lesions are measures of the root canal infection (1, 20, 133), therefore, teeth with larger periapical lesions may be more difficult to treat (131). However, because the PAI does not measure lesion size, results from this study cannot directly support those conclusions.

Reports in the endodontic literature regarding success rates for different tooth types have been controversial (134). In the current study, tooth type was shown to be significant when comparing teeth with combined outcomes of healed and healing versus those that were not healed. It also had a tendency to predict outcome when separate outcomes of healed, healing and not healed were evaluated ($p = 0.0647$). Additionally, odds-ratio estimates evaluating the outcome of healing versus not healed showed tooth type to be significant, with anteriors being 5.333 times as likely as molars to be healing

and premolars being 3.857 times as likely to be healing. These findings seem to agree with those that have shown multi-rooted teeth to be associated with decreased success rates (107, 123, 130). This difference may possibly be attributed to the increased complexity of the root canal system that can exist in multi-rooted teeth, making it more difficult to adequately disinfect the root canal system. It is also possible that the criteria for radiographic outcome used in this study multiple the chances of persistent disease by the number of roots, as the whole tooth was considered a unit of evaluation, as opposed to roots.

Age was only found to be significant when comparing outcomes of healed versus not healed, and odds-ratio estimates showed that for every year increase in age after 18, teeth are 1.03 times more likely to be radiographically healed. A possible explanation of this finding was described by Orstavik *et al*., who also found this same correlation of increased success with increased age and speculated that the progressive reduction of pulp space, diversities and ramifications with age limits the volume available for infection and makes it easier to provide adequate canal debridement and root filling (129). Other studies which have shown an inverse relationship with age and the prognosis of endodontic treatment, with increased age resulting in decreased prognosis (109, 110, 115). However, the majority of the evaluated endodontic literature appears to show no significant effect of age on endodontic outcome (104, 105, 107, 114, 123, 131).

The density of fill in apical third, taper of fill and length of fill were not able to be statistically evaluated with respect to effect on radiographic outcome due to a lack of variability of these factors with very little deviation from ideal. Specifically, all teeth were found to have adequate density in the apical third, only three teeth were found to

lack adequate taper and only six teeth were found to have inadequate length of fill (three were short and three were long). Adequate length of fill in this study was defined as the apical extent of the filling material being within 0-2mm of the radiographic apex according to the findings of Sjogren *et al* (105). According to Sjogren *et al*, teeth with necrotic pulps and apical periodontitis showed significantly higher success when root canal treated teeth were filled to within 0-2mm of the radiographic apex. The fact that there was such little variation from ideal with respect to length, density and taper of fill can be attributed to the close faculty supervision and several faculty check-steps during the treatment process. If either the master cone and/or trial pack film shows a lack of adequate density in the apical third, lack of adequate taper or inadequate length of fill and cannot be rectified by the student, the faculty member assists in assuring these standards are met prior to completion of the filling.

In conclusion, this study found through univariate and multivariate analysis that the type of obturation material, gutta-percha and Roth's Eugenol Sealer or Resilon and Epiphany Sealer, had no significant effect on radiographic outcome. Univariate analysis showed the presence of a permanent restoration, pre-operative PAI score, tooth type and age to be significantly associated with specific radiographic outcomes. Multivariate analysis however, showed no significant association between any factor and radiographic outcome.

TABLES

Table 1. Summary of Inter- and Intra- Examiner Reliability Kappa Scores After Calibration of Three Examiners to the Use of the Periapical Index Scoring Index.

	Interexaminer[*1] Reliability Kappa[*2]	Intraexaminer Reliability Kappa[*2]
Examiner 1	0.74	0.80
Examiner 2	0.78	0.70
Examiner 3	0.69	0.86

*[1] Interexaminer reliability was between observer scores and "true" scores as defined by Orstavik for the standard set of 100 radiographs

*[2] Landis & Kock 1977: Kappa > 0.61 = "substantial agreement"

Table 2. Identification, Recruitment, and Enrollment of Study Teeth.

	Gutta- Percha	**Resilon**	**Total**
Total Number of Root Canal Treated Teeth	610	974	1584
Eligible Teeth	204	288	492
Unable to be contacted	115	161	276
Contacted	89	127	216
Denied Participation	36	39	75
Participated	53	88	141
Contacted / Eligible (%)	43.6%	44.1%	43.9%
Overall Recall Rate: Participated / Eligible (%)	26.0%	30.6%	28.7%
Contacted Recall Rate:: Participated / Contacted (%)	59.6%	69.3%	65.3%

Table 3. Univariate analysis summary of variables by obturation material for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

	Obturation Material			Difference
	Gutta-Percha (N=53) [*N1]	**Resilon (N=88)** [*N2]	**Total (N=141)** [*N3]	**P value** [†]
Gender, n(%)				0.8415
Male	27 (50.9)	42 (47.7)	69 (48.9)	
Female	26 (49.1)	46 (52.3)	72 (51.1)	
Age (years)				0.7497[*]
N (%)	53 (100)	88 (100)	141 (100)	
Mean (SD)	50.8 (11.8)	49.9 (13.9)	50.3 (13.1)	
Tooth type, n(%)				0.4339
Anterior	21 (39.6)	42 (47.7)	63 (44.7)	
Premolar	17 (32.1)	29 (33.0)	46 (32.6)	
Molar	15 (28.3)	17 (19.3)	32 (22.7)	
Presence of permanent restoration, n(%)				0.8875
Yes	46 (86.8)	77 (87.5)	123 (87.2)	
No	7 (13.2)	11 (12.5)	18 (12.8)	
Type of Restoration, n(%)				0.7816 [#]
Full Coverage Crown	23 (43.4)	31 (35.2)	54 (38.3)	
Amalgam	3 (5.7)	8 (9.1)	11 (7.8)	
Composite	15 (28.3)	31 (35.2)	46 (32.6)	
Other	5 (9.4)	7 (8.0)	12 (8.5)	
Temporary (IRM, Cavit, etc)	7 (13.2)	11 (12.5)	18 (12.8)	
Type of Permanent Restoration, n(%)				0.3865
Intra-coronal	23 (50.0)	46 (59.7)	69 (56.1)	
Cuspal coverage	23 (50.0)	31 (40.3)	54 (43.9)	
Time (in months) between RCT and permanent restoration				0.4502[*]
N (%)	46 (100)	77 (100)	123 (100)	
Mean (SD)	4.0 (8.2)	3.0 (13.5)	3.4 (11.5)	
Follow-up time (months)				<0.0001[*]
N (%)	53 (100)	88 (100)	141 (100)	
Mean (SD)	52.1 (10.9)	23.8 (10.6)	34.4 (17.2)	
Diagnosis of Hypertension, n(%)				0.8231
No	38 (71.7)	66 (75.0)	104 (73.8)	
Yes	15 (28.3)	22 (25.0)	37 (26.2)	
Diagnosis of Diabetes, n(%)				0.6315
No	48 (90.6)	76 (86.4)	124 (87.9)	
Yes	5 (9.4)	12 (13.6)	17 (12.1)	
History of tobacco use, n(%)				0.7773
No	44 (83.0)	70 (79.5)	114 (80.9)	
Yes	9 (17.0)	18 (20.5)	27 (19.1)	
Sealer extrusion evident at completion of RCT, n(%)				0.9203
No	43 (81.1)	72 (81.8)	115 (81.6)	
Yes	10 (18.9)	16 (18.2)	26 (18.4)	
Pre-op PAI Score, n(%)				0.0954
2	6 (11.3)	2 (2.3)	8 (5.7)	
3	19 (35.9)	26 (29.5)	45 (31.9)	
4	21 (39.6)	47 (53.4)	68 (48.2)	
5	7 (13.2)	13 (14.8)	20 (14.2)	

[†] Chi-Square test used unless otherwise noted

[#] Fisher exact test

[*] t-test applied

[*N1, N2, and N3] For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Gutta-Perhca N = 46, Resilon N = 77, and Total N = 123, respectively

Table 4. Univariate analysis summary of variables by radiographic outcome of not healed, healing or healed for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

	Radiographic Outcome				
	Not healed (N=29)*N1	Healing (N=53)*N2	Healed (N=59)*N3	Total (N=141)*N4	P value †
Obturation material, n(%)					0.1786
GP	10 (18.9)	16 (30.2)	27 (50.9)	53 (100)	
Resilon	19 (21.6)	37 (42.0)	32 (36.4)	88 (100)	
Gender, n(%)					0.4909
Male	17 (24.6)	24 (34.8)	28 (40.6)	69 (100)	
Female	12 (16.7)	29 (40.3)	31 (43.0)	72 (100)	
Age (in years)					0.1187*
N (%)	29 (20.6)	53 (37.6)	59 (41.8)	141 (100)	
Mean (SD)	46.0 (14.3)	49.6 (15.9)	53.0 (14.7)	50.3 (15.1)	
Tooth type, n(%)					0.0647
Anterior	9 (14.3)	28 (44.4)	26 (41.3)	63 (100)	
Premolar	8 (17.4)	18 (39.1)	20 (43.5)	46 (100)	
Molar	12 (37.5)	7 (21.9)	13 (40.6)	32 (100)	
Presence of permanent restoration, n(%)					0.0039#
No	9 (50.0)	5 (27.8)	4 (22.2)	18 (100)	
Yes	20 (16.3)	48 (39.0)	55 (44.7)	123 (100)	
Type of permanent restoration, n(%)					0.5016
Intra-coronal	14 (20.3)	26 (37.7)	29 (42.0)	69 (100)	
Cuspal coverage	7 (13.0)	20 (37.0)	27 (50.00)	54 (100)	
Time (in months) between RCT and permanent restoration					0.8681*
N (%)	21 (17.1)	46 (37.4)	56 (45.5)	123 (100)	
Mean (SD)	2.9 (4.4)	3.71 (5.7)	3.25 (6.1)	3.4 (5.7)	
Follow-up time (months)					0.1441*
N (%)	29 (20.6)	53 (37.6)	59 (41.8)	141 (100)	
Mean (SD)	31.2 (16.5)	32.2 (17.8)	37.6 (17.1)	34.4 (17.2)	
Diagnosis of Hypertension, n(%)					0.9366
No	21 (20.2)	40 (38.5)	43 (41.3)	104 (100)	
Yes	8 (21.6)	13 (35.1)	16 (43.3)	37 (100)	
Diagnosis of Diabetes, n(%)					0.6087
No	26 (21.0)	48 (38.7)	50 (40.3)	124 (100)	
Yes	3 (17.6)	5 (29.4)	9 (52.9)	17 (100)	
History of tobacco use, n(%)					0.7119
No	25 (21.9)	42 (36.8)	47 (41.2)	114 (100)	
Yes	4 (14.8)	11 (40.7)	12 (44.4)	27 (100)	
Sealer extrusion evident at completion of RCT, n(%)					0.3463
No	25 (21.7)	40 (34.8)	50 (43.5)	115 (100)	
Yes	4 (15.4)	13 (50.0)	9 (34.6)	26 (100)	
Pre-op PAI Score, n(%)					<0.001#
2	2 (25.0)	0 (0.00)	6 (75.00)	8 (100)	
3	13 (28.9)	7 (15.6)	25 (55.5)	45 (100)	
4	11 (16.2)	33 (48.5)	24 (35.3)	68 (100)	
5	3 (15.0)	13 (65.0)	4 (20.0)	20 (100)	

† Chi-Square test used unless otherwise noted

*ANOVA test

Fisher exact test

*N1, N2, N3, and N4 For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Not Healed N = 21, Healing N = 46, Healed N = 56, and Total N = 123, respectively

Table 5. Univariate analysis summary of variables by radiographic outcome of not healed and healing/healed for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

	Radiographic Outcome			
	Not healed (N=29)[*N1]	Healing/Healed (N=112)[*N2]	Total (N=141)[*N3]	P value [†]
Obturation material, n(%)				0.8625
GP	10 (18.9)	43 (81.1)	53 (100)	
Resilon	19 (21.6)	69 (78.4)	88 (100)	
Gender, n(%)				0.3349
Male	17 (24.6)	52 (75.4)	69 (100)	
Female	12 (16.7)	60 (83.3)	72 (100)	
Age (in years)				0.0820*
N (%)	29 (20.6)	112 (79.4)	141 (100)	
Mean (SD)	46.00 (14.3)	51.27 (15.3)	50.27 (15.1)	
Tooth type, n(%)				0.0245
Anterior	9 (14.3)	54 (85.7)	63 (100)	
Premolar	8 (17.4)	38 (82.6)	46 (100)	
Molar	12 (37.5)	20 (62.5)	32 (100)	
Presence of permanent restoration, n(%)				0.0027[#]
No	9 (50.0)	9 (50.0)	18 (100)	
Yes	20 (16.3)	103 (83.7)	123 (100)	
Type of permanent restoration, n(%)				0.4062
Intra-coronal	14 (20.3)	55 (79.7)	69 (100)	
Cuspal coverage	7 (13.0)	47 (87.0)	54 (100)	
Time (in months) between RCT and permanent restoration				0.6800*
N (%)	21 (16.3)	102 (83.7)	123 (100)	
Mean (SD)	3.0 (4.4)	3.5 (6.0)	3.4 (5.7)	
Follow-up time (months)				0.2759*
N (%)	29 (20.6)	112 (79.4)	141 (100)	
Mean (SD)	31.2 (16.5)	35.1 (17.4)	34.4 (17.2)	
Diagnosis of Hypertension, n(%)				1.000
No	21 (20.2)	83 (79.8)	104 (100)	
Yes	8 (21.6)	29 (78.4)	37 (100)	
Diagnosis of Diabetes, n(%)				1.000
No	26 (21.0)	98 (79.0)	124 (100)	
Yes	3 (17.6)	14 (82.4)	17 (100)	
History of tobacco use, n(%)				0.5960
No	25 (21.9)	89 (78.1)	114 (100)	
Yes	4 (14.8)	23 (85.2)	27 (100)	
Sealer extrusion evident at completion of RCT, n(%)				0.5964
No	25 (21.7)	90 (78.3)	115 (100)	
Yes	4 (15.4)	22 (84.6)	26 (100)	
Pre-op PAI Score, n(%)				0.3632[#]
2	2 (25.0)	6 (75.0)	8 (100)	
3	13 (28.9)	32 (71.1)	45 (100)	
4	11 (16.2)	57 (83.8)	68 (100)	
5	3 (15.0)	17 (85.0)	20 (100)	

[†] Chi-Square test used unless otherwise noted

[*] ANOVA test

[#] Fisher exact test

[*N1, N2, and N3] For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Not Healed N = 21, Healing/Healed N = 102, and Total N = 123, respectively

Table 6. Radiographic outcome of 17 extracted teeth with respect to root filling material

	Healed	Healing	Not Healed	Total	P-value
Gutta-Percha, n(%)	2 (28.6)	2 (28.6)	3 (42.8)	7 (100)	1.000
Resilon, n(%)	2 (18.2)	3 (36.4)	5 (45.4)	10 (100)	

Table 7. Healing vs. Not Healed. Odds Ratio estimate using univariate logistic regression analysis using radiographic outcomes of healing (N=53) vs. not healed (N=29) for 82 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

Variable	Coding (0 vs. 1)	Odds Ratio Estimate	95% Confidence Interval		P value
Obturation material	GP vs. Resilon	0.822	0.313	2.155	0.6896
Gender	Male vs. Female	0.584	0.234	1.46	0.2500
Age	Unit = 1year	1.016	0.986	1.047	0.3055
Tooth type	Anterior vs. Molar	5.333	1.611	17.655*	0.0451
	Premolar vs. Molar	3.857	1.105	13.463*	
	Anterior vs Premolar	0.723	0.236	2.220	
Presence of Permanent Restoration	Without vs. With	0.521	0.127	2.143	0.3661
Type of permanent restoration[*N1]	Intra-coronal vs Cuspal coverage	1.538	0.523	4.523	0.4292
Time between RCT and permanent restoration[*N1]	Unit = 1 month	1.024	0.924	1.135	0.6493
Follow-up time	Unit = 1month	1.007	0.978	1.037	0.6355
Diagnosis of Hypertension	No vs. Yes	1.026	0.336	3.131	0.9645
Diagnosis of Diabetes	No vs. Yes	1.372	0.3	6.274	0.6837
History of tobacco use	No vs. Yes	0.764	0.216	2.698	0.6755
Sealer extrusion evident at completion of RCT	No vs. Yes	0.615	0.178	2.132	0.4439
Pre-op PAI Score	2 vs. 5	<0.001	<0.001	>999.9	0.9897
	3 vs. 5	0.147	0.03	0.708*	
	4 vs. 5	0.952	0.218	4.157	

*Statistically significant, however, model validation is in question due to small sample size in certain category shown in Table 1.

[*N1] For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Healing N=46, Not Healed N=21, Total N=67

Table 8. Healed vs. Not Healed. Odds Ratio estimate using univariate logistic regression analysis using radiographic outcomes of healed (N=59) vs. not healed (N=29) for 88 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

Variable	Coding (0 vs. 1)	Odds Ratio estimate	95% Confidence Interval		P value
Obturation material	GP vs. Resilon	1.603	0.638	4.027	0.3154
Gender	Male vs. Female	0.638	0.26	1.566	0.3262
Age	Unit = 1year	1.032	1.000	1.063	0.0451
Tooth type	Anterior vs. Molar	2.667	0.896	7.939	0.2441
	Premolar vs. Molar	2.308	0.742	7.179	
	Anterior vs Premolar	0.865	0.283	2.643	
Presence of Permanent Restoration	Without vs. With	0.364	0.083	1.593	0.1796
Type of permanent restoration[*N1]	Intra-coronal vs Cuspal coverage	1.862	0.653	5.310	0.2374
Time between RCT and permanent restoration[*N1]	Unit = 1 month	1.01	0.910	1.122	0.8473
Follow-up time	Unit = 1month	1.026	0.997	1.056	0.0830
Diagnosis of Hypertension	No vs. Yes	0.896	0.302	2.658	0.8429
Diagnosis of Diabetes	No vs. Yes	0.794	0.195	3.227	0.7470
History of tobacco use	No vs. Yes	0.783	0.225	2.725	0.7011
Sealer extrusion evident at completion of RCT	No vs. Yes	1.111	0.307	4.024	0.8723
Pre-op PAI Score	2 vs. 5	2.25	0.251	20.131	0.6782
	3 vs. 5	1.705	0.325	8.933	
	4 vs. 5	2.25	0.412	12.284	

[*N1] For variables “Type of permanent restoration” and “Time (in months) between RCT and permanent restoration”, Healed N=56, Not Healed=21, Total N=77

Table 9. Healed vs. Healing. Odds Ratio estimate using univariate logistic regression analysis using radiographic outcomes of healed (N=59) vs. healing (N=53) for 112 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

Variable	Coding (0 vs. 1)	Odds Ratio estimate	95% Confidence Interval		P value
Obturation material	GP vs. Resilon	0.513	0.235	1.116	0.0893
Gender	Male vs. Female	0.916	0.435	1.928	0.8175
Age	Unit = 1year	0.985	0.961	1.010	0.2385
Tooth type	Anterior vs. Molar	2.000	0.691	5.788	0.2162
	Premolar vs. Molar	1.671	0.546	5.112	
	Anterior vs Premolar	1.197	0.521	2.747	0.6719
Presence of Permanent Restoration	Without vs. With	1.432	0.364	5.639	0.1289
Type of permanent restoration[*N1]	Intra-coronal vs Cuspal coverage	1.210	0.553	2.651	0.6329
Time between RCT and permanent restoration[*N1]	Unit = 1 month	1.013	0.949	1.083	0.6912
Follow-up time	Unit = 1month	0.982	0.961	1.004	0.0985
Diagnosis of Hypertension	No vs. Yes	1.145	0.49	2.676	0.7545
Diagnosis of Diabetes	No vs. Yes	1.728	0.54	5.527	0.3487
History of tobacco use	No vs. Yes	0.975	0.389	2.441	0.9566
Sealer extrusion evident at completion of RCT	No vs. Yes	0.554	0.215	1.427	0.2171
Pre-op PAI Score	2 vs. 5	<0.001	<0.001	>999.999	<0.001
	3 vs. 5	0.086	0.021	0.349[*]	
	4 vs. 5	0.423	0.123	1.459	

*Statistically significant, however, model validation is in question due to small sample size in certain category shown in Table 1.

[*N1] For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Healed N=56, Healing=46, Total N=102

Table 10. Reported Success Rates from Endodontic Literature for Primary Non-Surgical Root Canal Treatment for Teeth With and Without Apical Radiolucency

	No Apical Radiolucency	Apical Radiolucency
Strindberg 1956	89%	68%
Kerekes 1979	94%	84%
Bystrom 1987	94%	85%
Sjogren 1990	96%	86%
Chugal 2001	88%	60%
Friedman 2003	92%	74%
Farzaneh 2004	93%	79%
Marquis 2006	88%	76%
Cotton 2007	100%	66%

FIGURES

Figure 1 – PAI Diagrammatic & Radiographic Reference

(Reproduced from Orstavik D, Kerekes K, Eriksen HM. The periapical index: a scoring system for radiographic assessment of apical periodontitis. Endodontics & dental traumatology 1986;2(1):20-34.)

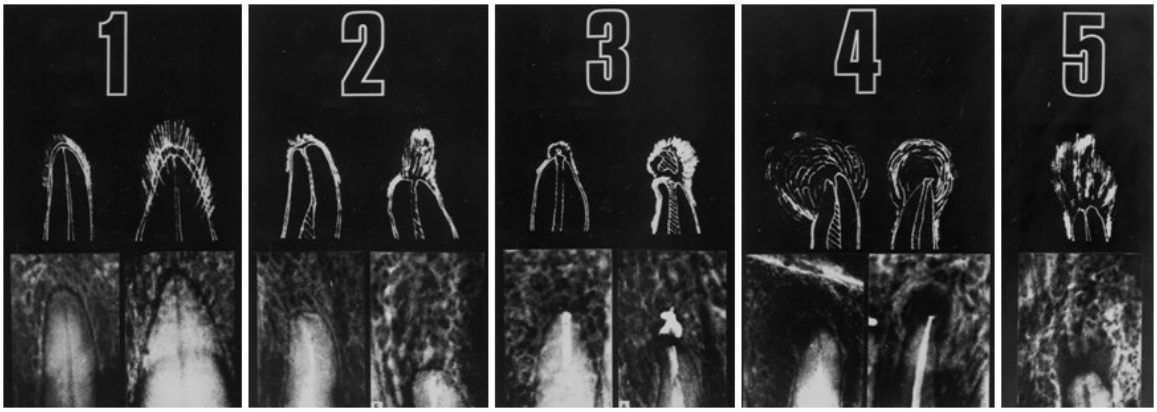


Figure 2 – Subject Assessment Form

Subject Assessment Form

1. Subject number: _____
2. Age of subject at initial treatment: _____
3. Gender: ☐ Male ☐ Female
4. Past Medical Hx: ☐ Hypertension ☐ Diabetes ☐ History of Tobacco Use
5. Tooth #: _____
6. Tooth Type:

   ☐ Maxillary ☐ Mandibular

   ☐ Central ☐ Lateral ☐ Canine ☐ 1st Premolar ☐ 2nd Premolar ☐ 1st Molar ☐ 2nd Molar
7. Date of Completion of root canal treatment: _____
8. Date permanent restoration was placed (if exact date known from record): _____
9. Time elapsed from completion of root canal treatment and placement of final restoration:

   ☐ 0 months (restoration placed at completion of root canal) ☐ < 1 month ☐ 1-3 months

   ☐ 4-6 months ☐ 7-9 months ☐ 10-12 months ☐ > 12 months ☐ No final coronal restoration present
10. Type of permanent coronal restoration (if present):

    ☐ Amalgam ☐ Composite ☐ Full coverage crown ☐ Onlay ☐ Post ☐ Other _____
11. Marginal Ridges:

    ☐ Intact ☐ At least one marginal ridge lost
12. Type of temporary material if not permanently restored:

    ☐ Cavit ☐ IRM ☐ Other _____
13. Clinical Evaluation (check all that apply):

    ☐ patient reports presence of pain associated with tooth ☐ pain upon percussion

    ☐ pain upon palpation ☐ attachment loss greater than 5mm ☐ tooth mobility greater than grade +1

    ☐ presence of sinus tract ☐ present of swelling
14. Radiographic Examination (check all that apply):
    a. Pre-Operative PAI score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
    b. Post-Operative PAI score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
    c. Presence of sealer extrusion: ☐ Yes ☐ No
    d. Length of fill: ☐ Ideal (0-2mm of radiographic apex) ☐ Short (>2mm) ☐ Long
    e. Adequate density of fill with no voids seen in apical 1/3: ☐ Yes ☐ No
    f. Adequate taper of fill: ☐ Yes ☐ No

CHAPTER IV
LONG-TERM CLINICAL OUTCOME OF TEETH WITH CHRONIC APICAL PERIODONTITIS FOLLOWING ROOT CANAL TREATMENT AND FILLING WITH EITHER GUTTA-PERCHA OR RESILON

Abstract

The purpose of this retrospective study was to evaluate the clinical outcome of teeth with chronic apical periodontitis receiving primary root canal therapy when obturated with gutta-percha and Roth's Eugenol Sealer compared to Resilon and Epiphany Sealer. All treatment was performed by dental students at the University of North Carolina at Chapel Hill. Clinical outcome was evaluated objectively and subjectively using standard diagnostic tests on 141 teeth. Success was defined as absence of all clinical signs and symptoms that indicate persistent inflammation/infection. Univariate and multivariate analysis found presence of a permanent restoration and age to be significant in predicting clinical outcome ($p < 0.05$). Univariate analysis found placement of full coverage restorations to significantly affect survival ($p = 0.003$), especially in teeth with at least one compromised marginal ridge ($p = 0.002$). Teeth filled with gutta-percha or Resilon had statistically indistinguishable differences in clinical outcome, 90.08% versus 89.8%, respectively.

Introduction

Endodontics is the branch of dentistry which is concerned with the morphology, physiology and pathology of the human dentin pulp and periradicular tissues. The principle aim of endodontics is the prevention and/or treatment of apical periodontitis. The importance of bacteria and their by-products in the development of apical periodontitis has been well documented throughout the literature (1-3). Prevention or healing of apical periodontitis involves a combination of disinfection of the root canal space through chemo-mechanical means (4, 5) and sealing both the root canal and access cavity with materials that will prevent re-infection (6-15).

After the microbial control phase of endodontic therapy, a root canal filling is placed to seal the root canal system. This filling should serve 3 principle functions: a) entomb most surviving bacteria b) stop the influx of periapical tissue-derived fluid from reaching surviving bacteria in the root canal system c) act as a barrier, thereby preventing re-infection of the root canal (16). Requirements for instrumentation of the root canal that will result in predictable success are well established (17-20). However, the present filling materials and techniques using gutta-percha fail in achieving the requirement of providing a suitable seal to further challenge by bacteria (7, 19). Torabinejad *et al*. showed that when gutta-percha filled canals were challenged by bacteria, 50% allowed penetration through the entire length of the canal within 30 days (21). Several other articles have suggested that gutta-percha may be a weak point in endodontic therapy (22-24).

Recently a resin-based root filling material has been developed. Resilon (Resilon Research LLC, Madison, CT) is a thermoplastic synthetic polymer based root canal

filling material. Based on polymers of polyester, Resilon contains bioactive glass and radiopaque fillers. It performs like gutta-percha, has the same handling properties, and for retreatment purposes may be softened with heat or dissolved with solvents like chloroform (29, 30). It is to be utilized with Epiphany^{TM} Sealer (Pentron Clinical Technologies, Wallingford, CT), which is a dual curable dental resin composite sealer.

Many researchers have evaluated the various properties of Resilon in both *in-vitro* and *in-vivo* studies, including Resilon's biocompatibility (31-38), ease of retreatability (29, 39-43), effect on the fracture resistance of teeth filled with Resilon (44-51), push-out bond strength, and sealing ability (25, 61-101). Unfortunately, there has been limited published clinical-based research on the treatment outcome of teeth root canal treated and filled with Resilon. In 2007, Conner *et al*. reported healing rates of teeth filled with Resilon in a private practice setting were within the range of success rates reported in university-based outcome studies using gutta-percha as the root filling (114). In 2008, Cotton *et al*. evaluated 103 teeth, both vital and necrotic, after being treated in a private endodontic practice and filled with either gutta-percha and Kerr sealer or Resilon and Epiphany Sealer. (115). They found no statistically significant difference in the outcome based on the obturation material used.

The purpose of this retrospective study was to evaluate the clinical outcome of teeth with chronic apical periodontitis receiving primary root canal therapy when obturated with gutta-percha and Roth's Eugenol Sealer compared to Resilon and Epiphany Sealer.All treatment was rendered by undergraduate dental students in the endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry under direct supervision of an endodontic faculty member. Both univariate and

multivariable regression analyses were performed to determine any significance that the filling material had on the clinical outcome of these teeth. Additionally, other pre- and post- operative factors were evaluated for their potential significant effects on clinical outcome. The preoperative factors evaluated were gender, age, tooth type, pre-operative PAI score, length of recall times, presence of hypertension, presence of diabetes, and/or history of tobacco use. Postoperative factors evaluated were the presence of a permanent restoration, type of permanent restoration, and time elapsed between completion of root canal treatment and placement of permanent coronal restoration.

Materials and Methods

This retrospective study was approved by the Institutional Review Board of the University of North Carolina at Chapel Hill. The subject population was obtained from previous patients who had presented to the undergraduate endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry (UNC SOD) between June 2003 – November 2007 for root canal treatment. During the time period spanning between June 2003- July 2005, the undergraduate endodontic clinic at UNC SOD was using gutta-percha as the filling material for completion of root canal treatment. In August 2005, Resilon became introduced to the undergraduate clinic at the UNC SOD as the root canal filling material. During this time period, the evaluation, diagnosis, instrumentation and disinfection protocol for teeth diagnosed as having a necrotic pulp with Chronic Apical Periodontitis remained nearly identical, with the major difference related to the filling materials. All 3rd and 4th years students performing endodontic treatment were standardized to the protocol described in Chapter II.

Selection of Subjects and Recruitment Process

Selection of subjects to be recruited for the study was based on specific inclusion criteria. Inclusion criteria included: 1) Treatment performed by undergraduate dental students in the endodontic clinic at UNC SOD under direct supervision of faculty between June 2003 and November 2007, 2) Root canal treated tooth having a pre-operative diagnosis of a Necrotic Pulp with Chronic Periradicular Periodontitis with a radiographic lesion, 3) Complete root development at time of completion of root canal

treatment, and 4) At least 12 months since completion of root canal at time of follow-up evaluation.

After carefully reviewing the database of treated patients between June 2003 and November 2007, 1,584 root canal treated teeth were identified, with 610 teeth filled with gutta-percha and Roth's Eugenol Sealer and 974 teeth filled with Resilon and Epiphany Sealer. From this total, 492 root canal treated teeth that met the inclusion criteria were identified. Of those, 204 teeth were filled with gutta-percha, while 288 teeth were filled with Resilon. Starting in March 2008 and ending in January 2009, attempts to contact and enroll the qualified subjects were made in the following order: 1) Phone calls with messages explaining the research project and requesting follow-up examination. Three phone calls were attempted. 2) If a subject was unable to be contacted using the phone number on file, a study enrollment letter was sent to the address on file. 3) If still no contact was made, a phone call was made to the emergency contact person listed in the patients previously completed UNC School of Dentistry Registration form in an attempt to receive updated contact information for the subject. A financial incentive of $10 per tooth used were offered to subjects for their participation. The final subject population was comprised of 120 subjects with 141 teeth, with 53 teeth filled with Gutta-Percha and Roth's Eugenol Sealer and 88 teeth filled with Resilon and Epiphany Sealer.

Clinical Examination

During the recall examination, a clinical examination mirroring those that were done on the initial visit was performed. This included a subjective evaluation of subjects'

report of pain as well as an objective evaluation that includes inspection for the presence of a sinus tract and/or abscess, an assessment of subjects' response to percussion and palpation, as well as an evaluation of the mobility and probing depths for the treated tooth as well as adjacent teeth (at least one tooth on either side). As these clinical parameters serve as an indication of persistent inflammation/infection of the tooth and associated periodontal tissues, if any are noted the case will be documented clinically as failed, otherwise it will be classified clinically as healed.

For teeth that were extracted at time of recall, the reason for extraction was determined by either reviewing the electronic notes for the patient if the tooth was extracted at the UNC SOD, or by contacting the dentist/oral surgeon if the extraction was performed in private practice. The reason for extraction of all teeth was able to be determined. Teeth that were extracted due to continued signs of infection, pain, or vertical root fractures were classified as clinical failures. However, teeth that were extracted solely for restorability concerns due to crown fracture, while at the same time not showing any of the described clinical parameters of failure were documented as clinically successful.

Prognostic Factors

In addition to the data generated from the clinical examination, other pre- and post-operative data were collected from the subject and their dental record. These data were recorded and categorized as follows:

- Age of subject at time of treatment
    - Recorded in years (rounded up to nearest year)

- Gender
    - Male versus Female
- Tooth type
    - Anterior (centrals, laterals and canines) versus Premolar versus Molar
- Permanent Coronal Restoration
    - Present versus Not Present
- Type of final coronal restoration (if present)
    - Amalgam versus Composite versus Full Coverage Restoration versus Other
- Time elapsed from completion of RCT and placement of final restoration (if present)
    - Recorded in months (round up to nearest month)
    - This was determined by:
        - Documented records from UNC charts if the subject had the final restoration placed at UNC SOD
        - If the patient obtained the permanent restoration at a private dental office, the dentist was contacted to determine the exact date of placement of the permanent restoration
- Presence of Hypertension
    - Diagnosed with hypertension versus Not Diagnosed
- Presence of Diabetes
    - Diagnosed with Diabetes (type I or II) versus Not Diagnosed
- History of Tobacco use

    - Yes versus No
- Pre-Operative PAI score
    - Scores ranged from 2 to 5
        - Score of 1 was not used, as the inclusion criteria limited teeth to those diagnosed with a necrotic pulp and chronic apical periodontitis
- Presence of sealer extrusion at time of obturation
    - Present versus Not Present
- Length of Fill
    - Ideal (0-2mm of radiographic apex) versus Short (>2mm) versus Long (out of radiographic apex)
- Adequate density in Apical Third
    - Yes versus No
- Adequate Taper of Fill (continuous, smooth flowing taper)
    - Yes versus No

All of the data was recorded on a Subject Assessment Form (Figure 1). These forms were utilized for data analysis.

Data Analysis

The primary analysis was to determine the association between the filling materials used and clinical outcome. Univariate and multivariate logistic regression analysis were used in this study to evaluate the association between radiographic outcome of primary root canal treated teeth and obturation method (gutta-percha and Roth's

Eugenol Sealer versus Resilon and Epiphany Sealer). To account for the fact that the 141 teeth evaluated were from 120 subjects, logistic regression analysis was performed using the PROC GENMOD procedure with repeated statements within the SAS program. The odds ratio and associated 95% confidence intervals were used to represent the association with clinical outcome. Other potential prognostic factors (previously listed) were also included in the analysis. They were analyzed as covariates, and the treatment effects were estimated as the adjusted odds-ratio with a CI of 95%. When using the multivariable logistic regression analysis model, effects that were not significant were consecutively eliminated until only significant variable remained. For univariate analyses, Fisher exact test, t-test and Chi-square test were used, with the level of significance set at $p < 0.05$.

The survival rate of root canal treated teeth was also evaluated within each of the treatment groups. Survival in this study was defined as the tooth being present and functional in the subjects' mouth. Additionally, teeth were analyzed to determine any association between the survival or root canal treated teeth and the presence of a full coverage restoration as well as presence of intact marginal ridges. For these univariate analyses, Fisher exact test was used, with the level of significance set at $p < 0.05$.

Results

Overall, 1584 teeth were root canal treated between June 2003 and November 2007, with 610 teeth filled with gutta-percha and Roth's Eugenol Sealer and 974 teeth filled with Resilon and Epiphany Sealer. From this total, 492 teeth (204 filled with gutta-percha and 288 filled with Resilon) met the inclusion criteria and were found to be eligible for participation in this study. The final sample size included in this study comprised of 141 teeth from 120 subjects, with 53 teeth being filled with gutta-percha and Roth's Eugenol Sealer and 88 teeth filled with Resilon and Epiphany Sealer. This yielded an overall recall rate of 28.7% (26.0% for the gutta-percha group and 30.6% for the Resilon group). After completion of the recruitment process, 277 teeth were unable to be recalled due to an inability to contact the subjects (phone number not in service/disconnected, wrong number, left message that was never returned, no response to recruitment letters that were mailed, returned recruitment letters due to change of address, emergency contact person listed was not able to be contacted). Of the 215 teeth belonging to subjects that were able to be contacted, 75 teeth were unable to be recalled due to refusal of subjects to participate in the research, resulting in a recall rate of 65.6% of contacted subjects, with a recall rate of 59.6% for the gutta-percha group and 69.3% for the Resilon group (Table 1). The most common reason given for refusal of participation was that the subject was not having any problems on the tooth in question. Of those subjects that denied participation in the study, all reported still having their root canal treated tooth in their mouth and being asymptomatic on that tooth.

All of the pre- and post-operative variables were recorded and compared between the two treatment groups, gutta-percha or Resilon, to evaluate for any difference in

baseline values (Table 2). It was determined that the mean follow-up time was significantly different between the two treatment groups ($p < 0.0001$). Gutta-percha filled teeth had a mean follow-up time of 52.1 months while Resilon filled teeth had a mean follow-up time of 23.8 months. No other recorded variable showed any statistically significant difference in baseline values between the two treatment groups.

Teeth filled with gutta-percha and Roth's Eugenol Sealer showed 90.8% of teeth were clinically successful, compared to 89.8% of teeth filled with Resilon and Epiphany Sealer. This difference was not statistically significant. Of the independent variables, both age and presence of a permanent restoration showed a significant bivariate relationship with the clinical outcome. There was no significant relationship observed between the clinical outcome and any of the other independent variables: gender, tooth type, time between RCT and permanent restoration, type of permanent restoration, follow-up time, hypertension, diabetes, history of tobacco use, sealer extrusion or pre-operative PAI score (Table 3). The length of fill, density in apical third and taper of fill were not able to be evaluated with respect to radiographic outcome due to a lack of variability of these factors with very little deviation from ideal. Specifically, all teeth were found to have adequate density in the apical third, only three teeth were found to lack adequate taper and only six teeth were found to have inadequate length of fill (three were short and three were long).

Overall, 17 teeth were determined to have been previously extracted at the time of recall. All teeth were extracted a minimum of 12 months post-obturation. These included seven teeth filled with gutta-percha and ten teeth filled with Resilon. It was found that six of the seven extracted teeth filled with gutta-percha were extracted due solely to

restorability concerns and showed none of the clinical parameters of failure. Similarly, this finding was found to be true for eight of the ten previously extracted teeth filled with Resilon. There was no significant difference between the two treatment groups (Table 4).

The survival rates of the 141 treated teeth were evaluated with respect to filling material. Survival was defined as the tooth being present and functional in the subjects' mouth. It was found that teeth filled with gutta-percha had a survival rate of 87.0% compared to 88.5% for Resilon filled teeth (Table 5). This difference was not statistically significant. Survival of root canal treated teeth was also evaluated with respect to the presence of a full coverage restoration and it was found that the presence of full coverage restorations significantly affected survival rates (Table 6). Further analysis of the survival rate of the subset of 87 teeth that did not receive full coverage restorations with respect to the presence of intact marginal ridges revealed that the presence of intact marginal ridges was also significant in predicting survival (Table 7).

Odds-Ratio estimates using univariate logistic regression analysis showed age and presence of permanent restoration to be significant in predicting the outcome of clinical success (Table 8). Specifically, for every year increase in a patient's age after 18 years, treated teeth are 0.96 times as likely to be clinically successful. Compared to the teeth without a permanent coronal restoration, teeth with restorations are 4.90 times likely to be clinically successful.

Multivariate logistic regression analysis also showed that age and presence of a permanent restoration were statistically significant in predicting the clinical success (Table 9).

Discussion

When comparing treatment outcomes of endodontically treated teeth, either a prospective or retrospective study design can be utilized, each with certain advantages and disadvantages (115). Some of the advantages of a prospective study design is that it allows for blinded randomized treatment allocation, prior standardization of techniques, and simultaneous study of multiple variables. However, they require long follow-up times, which can become costly and can lead to attrition of subjects over time. Retrospective studies have the advantage of having larger study populations and longer follow-up times. However, they lack the randomization of treatment allocation and standardization of methods that a prospective design offers. This study determined the association between the filling materials used and clinical outcome of primary endodontic treatment. Recent studies evaluating the outcome of Resilon treated teeth show success rates comparable to teeth treated with gutta-percha (114, 115). To show a statistically significant difference between the outcome of endodontically treated teeth with similar success rates, a large sample of subjects would be necessary to allow for enough power to do so. For this reason, a retrospective study design was chosen in this study.

To minimize the effect of a lack of standardization in endodontic treatment that occurs in retrospective studies, this study utilized a subject population obtained from previous patients who had presented to the undergraduate endodontic clinic at the University of North Carolina at Chapel Hill, School of Dentistry (UNC SOD) between June 2003 – November 2007 for root canal treatment. During this time, the evaluation, diagnosis, instrumentation and disinfection protocol for root canal treatment remained nearly identical, with two exceptions. The first change was the filling material used to

obturate the canal systems. From June 2003 – July 2005, gutta-percha and Roth's Eugenol sealer was used to obturate root canals, while Resilon and Epiphany Sealer was used from August 2005 – November 2007. The second change was related to the file system used for crown-down of the root canal system. Between June 2003 and July 2005, Profile Series 29 rotary files were used for crown-down, while K3 rotary files were used between August 2005 – November 2007. However, because both file systems are made of Nickel-Titanium and used only to achieve flaring of the coronal and middle third, with files never progressing any further than 2mm of the working length, it was not expected that the differing file systems would affect the outcome of the root canal treated teeth. A study by Gonzalez-Rodriquez and Ferrer-Luque evaluated the changes of cross-sectional area morphology of mesial mandibular curved canals in the coronal, middle and apical third after instrumentation with K3, Profile, or Hero 642 rotary files (122). They showed no significant difference in dentine removal between the K3 and Profile rotary instruments at any level in the root canal and therefore provides support for our contention that outcome would not be affected by the change in crown-down instrumentation, especially considering crown down was used only in the coronal and middle 1/3, while the apical 1/3 was instrumented using the same technique and same file system.

Outcome studies evaluating primary endodontic therapy have consistently shown that the presence of pre-operative periapical lesions significantly affect outcome, with success being significantly higher in teeth without periapical lesions (20, 104, 105, 107, 108, 113, 115, 123, 124). With reported success rates in these studies ranging from 88-100% for primary endodontic treatment in teeth without periapical lesions (Table 10),

few failures are seen, making it increasingly difficult to show a significant effect of any treatment variable on outcome. For this reason, this study focused on teeth diagnosed as having a necrotic pulp with chronic apical periodontitis, which would presumably result in a larger number of treatment failures and allow for more room to show a potentially significant effect of filling materials on outcome.

Our overall tooth recall rate was 28.7%, with a recall rate of 26.0% for the gutta-percha group and 30.6% for the Resilon group. As the recall rates for both treatment groups are very similar, it can be assumed that differences in outcome are not due to differences in recall rate. Our overall recall rate compares favorably to the recall rate of other recent outcome studies, ranging from 18.7 – 37.3% (108, 113-115, 123). Specifically, Conner *et al*. evaluated the same population of subjects – previous patients receiving primary endodontic therapy for teeth diagnosed as having Necrotic Pulp with Chronic Apical Periodontitis by dental students at the University of North Carolina at Chapel Hill – and obtained a recall rate of 33.6% (114). The recall rates from the Conner study and the present study can be attributed to the highly transient nature of the Triangle area of North Carolina, from which University patients are drawn. This is in part evidenced by the large number of subjects whose telephone numbers and/or addressed has changed. In fact, the major factor for non-participation was an inability to contact the subjects. In total, 277 teeth belonged to subjects who were unable to be contacted, and therefore did not have the opportunity to either accept or decline participation. This is in contrast to non-participation due to subjects' decision to decline, which may likely be due to characteristics associated with recall (i.e. tooth being symptomatic or not) and could therefore have an effect on the results. Therefore, we further evaluated the recall rate with

respect to those teeth from subjects that were able to be contacted, and had the opportunity to either participate or decline. Of the 215 teeth from subjects that were able to be contacted, 75 teeth were unable to be recalled due to refusal of subjects to participate in the research, resulting in a recall rate of 65.6% of contacted teeth, with recall rates of 59.6% for the gutta-percha group and 69.3% for the Resilon group. All subjects that refused participation in the study reported that their root canal treated tooth was still in their mouth and were asymptomatic at the time of contact. Unfortunately, these teeth could not be utilized in our study due to inability to evaluate the teeth clinically, which may have revealed sinus tracts, sensitivity to percussion and/or palpation although subjects reported being asymptomatic.

The difference in recall rates of contacted subjects between the gutta-percha and Resilon groups may be in part explained by the fact that subjects from the Resilon group had their treatment performed much more recently, 23.8 months ago on average, compared to 52.1 months for the gutta-percha group. Therefore, the subjects from the Resilon group may have been more likely to want to follow-up with their more recent treatment to make sure everything was healing as it should be. Subjects from the gutta-percha group may not have been so eager to return for follow-up considering on average more than 4 years had passed, so if they were asymptomatic, they may have not felt the same need to return for follow-up. Additionally, it is likely that more of the subjects from the gutta-percha group may have already had some sort of follow-up in the past 4 years.

An evaluation of frequency of pre- and post- treatment variables between the two treatment groups revealed that there was a significant difference in the follow-up time between the two treatment groups, with gutta-percha filled teeth having a mean follow-up

time of 52.14 months compared to 23.82 months in teeth filled with Resilon. This is important in that longer follow-up times have been associated with more definitive healing patterns by some researchers (104, 124, 125), although others have found that signs of initiated healing are evident in at least 89% of all healing roots after 1 year (126). However, these researchers were evaluating radiographic healing and not clinical healing, which would likely not take as long to show evidence of healing. At best, this difference in follow-up time suggests that greater potential exists among teeth filled with Resilon to resolve if a longer follow-up time was available, although it is the opinion of the authors that this would not be the case for signs of clinical healing, which would take considerably less time to heal.

For the present study, the primary outcome was clinical healing. During the recall examination, a clinical examination mirroring those that were done on the initial visit was performed as previously described. The clinical criteria for treatment failure follow those described by Rahbaran *et al*. 2001 and included: report of pain by the subject, pain upon percussion, pain upon palpation, attachment loss greater than 5mm, tooth mobility greater than pre-treatment mobility, and presence of a sinus tract and/or swelling (135). The overall clinical success rate of 90.8% and 89.8% for gutta-percha and Resilon, respectively, was consistent with the clinical success rates shown in the literature (104, 105, 114). This finding, along with the findings of other recent outcome studies of Resilon filled teeth (114, 115) compared to radiographic outcome studies of gutta-percha filled teeth (Table 10) support the contention that success rates for Resilon-filled teeth are within the range of success rates for gutta-percha filled teeth.

It should be mentioned that the teeth selected to be treated in the UNC undergraduate endodontic clinic by 3rd and 4th year dental students may be predisposed to have better healing due to the fact that they are individually screened and determined to be suitable for treatment by dental students. Teeth with restricted chamber and/or canal anatomy, moderate to severe curvatures of canals, difficult access due to presence of crown or limited mouth opening, as well as those teeth that are deemed to have difficulty with rubber dam isolation due to loss of coronal tooth structure are not selected to be treated by undergraduate students, but rather referred to either the graduate endodontic clinic for an endodontic resident to treat or to an endodontic specialist in private practice. Teeth selected for treatment by undergraduate students are typically limited to those with open and unrestricted chamber and/or canal anatomy with only mild curvatures in canal anatomy. For these reasons, these teeth are more likely to be adequately instrumented, debrided and filled and therefore be predisposed to a greater likelihood of healing compared to those which are referred to endodontic residents or endodontic specialists. However, an argument can also be made that although teeth that are deemed to be more difficult to treat are referred to endodontic residents or endodontic specialists, they are better trained and better equipped to treat those teeth, and therefore as likely to adequately instrument, debride and fill the teeth to allow for a greater potential of healing.

For teeth that were extracted at time of recall, the reason for extraction was determined by either reviewing the electronic notes for the patient if the tooth was extracted at the UNC SOD, or by contacting the dentist/oral surgeon if the extraction was performed in private practice. The reason for extraction of all teeth was able to be

determined. For those teeth that were extracted solely for restorability concerns due to crown fracture, while at the same time not showing any of the described clinical parameters of failure were documented as clinically successful. Teeth documented as showing evidence of any of the clinical parameters of failure at the time of extraction, regardless of the reason for extraction, were documented as clinically failed. The rationale for scoring in this manner was attributed to our assumption that it was the lack of an adequate restoration that resulted in the tooth being extracted as opposed to a failure of the root canal treatment.

To evaluate the validity of our assumption, the survival rates of the 141 treated teeth were evaluated with respect to full coverage restorations and it was found that the presence of full coverage restorations significantly affected survival rates ($p = 0.003$). Further evaluation of the subset of 87 teeth that did not receive full coverage restorations with respect to the presence of intact marginal ridges revealed that the presence of intact marginal ridges was significant in predicting survival ($p = 0.002$). Interestingly, it was found that all of the teeth that were extracted due to coronal fracture rendering the tooth non-restorable had at least one marginal ridge which was compromised, while none of the 28 teeth with intact marginal ridges were extracted. These findings support our contention that teeth extracted solely due to restorability concerns as a result of crown fracture following endodontic treatment could have been largely avoided with the placement of adequate permanent restorations, and were therefore a failure of an adequate restoration, rather than a failure of endodontic treatment. This finding is supported in the endodontic literature by Reeh *et al.*, who showed the largest losses in stiffness of root canal treated teeth were related to the loss of marginal ridge integrity

(136). This finding may help us to better improve the survival rates of root canal treated teeth by recommending full coverage restorations for root canal treated teeth that have lost at least one of their marginal ridges.

Survival rates of gutta-percha filled teeth was found to be 87.0% compared to 88.5% for Resilon filled teeth. This difference was not statistically significant. The overall survival rate was 87.9%. These numbers compare to those presented in the endodontic literature, although they are on the lower range of the spectrum of 92.9 – 97.0% (109, 116, 137, 138). This can in part be attributed to difference in methodology employed in this study compared to those which found higher survival rates. In the current study, only subjects who had presented to our clinic were included for analysis, resulting in a loss of subjects due to follow-up. However, the referenced studies were based on insurance databases, which can affect the survival rate in at least two ways. Firstly, in insurance database studies, all patients receiving treatment are able to be evaluated, which contrasts with this study, in which only subjects returning for follow-up were evaluated. Specifically, all 65 subjects accounting for 75 teeth that refused participation in our study stated that their previous root canal treated tooth was still in their mouths and were asymptomatic. If these patients were included for survival analysis, the overall survival rate would have been 92.1%, which would compare more favorably to numbers presented in the literature. Secondly, the fact that the referenced studies were based on insurance databases means that the patients had dental insurance, and therefore were likely to receive permanent restoration after the completion of their root canal as covered by their dental insurance. This is in contrast to the university clinic patients evaluated in this study, who for the most part present to the dental school due to

lack of dental insurance and are seeking seeking reduced dental fees. These subjects may therefore more likely to either have more time elapse between the completion of root canal treatment and the placement of restoration while they gather the necessary finances, while others may never seek permanent restorations due to lack of finances. For these reasons, the survival rate is likely to be reduced in our study. In fact 16 of the 17 teeth that were extracted lacked a permanent restoration and may likely have been prevented with an adequate restoration. Additionally, the majority of previous survival studies incorporated root canals performed by both endodontists and general dentists. One study performed by Alley *et al*. compared survival rates of teeth endodontically treated by general dentists and endodontists (116). Although they found an overall survival rate of 93.4%, they found a survival rate of 89.7% for teeth treated by general dentists, compared to 98.1% for teeth treated by endodontists. This difference proved to be significant and could help explain why our survival rate was on the lower range of the spectrum of the reported studies, considering all endodontic treatment was performed by undergraduate dental students.

Evaluation of the pre- and post-treatment variables showed age and presence of permanent restoration to be significant in predicting the clinical outcome. Specifically, with age, odds-ratio estimate showed that for every year increase in age after 18 years, primary endodontic treatment of teeth with necrotic pulps and chronic apical periodontitis were 0.96 times less likely to be clinically successful. Only a few other outcome studies have shown an inverse relationship with age and the prognosis of endodontic treatment (109, 110, 115). It may be assumed that in older individuals, healing processes are slower and less effective in the young. Additionally, older individuals are more likely to have

systemic disease, such as hypertension, diabetes, or other immunocompromisation which may serve as risk factors for healing (110, 112, 139). One study showed that increased age is associated with increased success rates (129). However, the majority of the evaluated endodontic literature appears to show no significant effect of age on endodontic outcome (104, 105, 107, 114, 123, 131).

The importance of a permanent restoration on endodontic outcome was reiterated in this study. Odds-ratio estimate showed that primary root canal treated teeth with permanent restorations at time of recall were 4.90 times as likely to be clinically successful as their counterparts without permanent restorations. This finding further solidifies the importance of permanent restorations on the prognosis of endodontic treatment and is consistent with what has been repeatedly shown to be true in the endodontic literature (6-15, 109, 110).

The length of fill, density in apical third and taper of fill were not able to be evaluated with respect to radiographic outcome due to a lack of variability of these factors with little deviation from ideal. Specifically, all teeth were found to have adequate density in the apical third, only three teeth were found to lack adequate taper and only six teeth were found to have inadequate length of fill (three were short and three were long). Adequate length of fill in this study was defined as the apical extent of the filling material being within 0-2mm of the radiographic apex according to the findings of Sjogren *et al* (105). According to Sjogren *et al,* teeth with necrotic pulps and apical periodontitis showed significantly higher success when root canal treated teeth were filled to within 0-2mm of the radiographic apex. The fact that there was such little variation from ideal with respect to length, density and taper of fill can be attributed to the close faculty

supervision and several faculty check-steps during the treatment process. If either the master cone and/or trial pack film shows a lack of adequate density in the apical third, lack of adequate taper or inadequate length of fill and cannot be rectified by the student, the faculty member assists in assuring these standards are met prior to completion of the filling.

In conclusion, this study found through univariate and multivariate regression analysis that the type of obturation material, gutta-percha and Roth's Eugenol Sealer or Resilon and Epiphany Sealer, had no significant effect on clinical outcome or survival. Both univariate and multivariate analysis showed that age and presence of a permanent restoration were significant predictors of clinical outcome. Furthermore, univariate analysis showed that placement of a full coverage restoration significantly reduces the number of extracted teeth due to crown fracture, with teeth which have lost at least one of their marginal ridges receiving the greatest benefit.

TABLES

Table 1. Identification, Recruitment, and Enrollment of Study Teeth.

	Gutta- Percha	**Resilon**	**Total**
Total Number of Root Canal Treated Teeth	610	974	1584
Eligible Teeth	204	288	492
Unable to be contacted	115	161	276
Contacted	89	127	216
Denied Participation	36	39	75
Participated	53	88	141
Contacted / Eligible (%)	43.6%	44.1%	43.9%
Overall Recall Rate: Participated / Eligible (%)	26.0%	30.6%	28.7%
Contacted Recall Rate:: Participated / Contacted (%)	59.6%	69.3%	65.3%

Table 2. Univariate analysis summary of variables by obturation material for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

	Obturation Material			Difference
	Gutta-Percha (N=53)[*N1]	**Resilon (N=88)[*N2]**	**Total (N=141)[*N3]**	**P value [†]**
Gender, n(%)				0.8415
Male	27 (50.9)	42 (47.7)	69 (48.9)	
Female	26 (49.1)	46 (52.3)	72 (51.1)	
Age (years)				0.7497[*]
N (%)	53 (100)	88 (100)	141 (100)	
Mean (SD)	50.81 (11.84)	49.96 (13.87)	50.3 (13.1)	
Tooth type, n(%)				0.4339
Anterior	21 (39.6)	42 (47.7)	63 (44.7)	
Premolar	17 (32.1)	29 (33.0)	46 (32.6)	
Molar	15 (28.3)	17 (19.3)	32 (22.7)	
Presence of permanent restoration, n(%)				0.8875
Yes	46 (86.8)	77 (87.5)	123 (87.2)	
No	7 (13.2)	11 (12.5)	18 (12.8)	
Type of Restoration, n(%)				0.7816 [#]
Full Coverage Crown	23 (43.4)	31 (35.2)	54 (38.3)	
Amalgam	3 (5.7)	8 (9.1)	11 (7.8)	
Composite	15 (28.3)	31 (35.2)	46 (32.6)	
Other	5 (9.4)	7 (8.0)	12 (8.5)	
Temporary (IRM, Cavit, etc)	7 (13.2)	11 (12.5)	18 (12.8)	
Type of Permanent Restoration, n(%)				0.3865
Intra-coronal	23 (50.0)	46 (59.7)	69 (56.1)	
Cuspal coverage	23 (50.0)	31 (40.3)	54 (43.9)	
Time (in months) between RCT and permanent restoration				0.4502[*]
N (%)	46 (100)	77 (100)	123 (100)	
Mean (SD)	4.01 (8.24)	3.03 (13.52)	3.4 (11.5)	
Follow-up time (months)				<0.0001[*]
N (%)	53 (100)	88 (100)	141 (100)	
Mean (SD)	52.14 (10.86)	23.82 (10.56)	34.4 (17.2)	
Diagnosis of Hypertension, n(%)				0.8231
No	38 (71.7)	66 (75.0)	104 (73.8)	
Yes	15 (28.3)	22 (25.0)	37 (26.2)	
Diagnosis of Diabetes, n(%)				0.6315
No	48 (90.6)	76 (86.4)	124 (87.9)	
Yes	5 (9.4)	12 (13.6)	17 (12.1)	
History of tobacco use, n(%)				0.7773
No	44 (83.0)	70 (79.5)	114 (80.9)	
Yes	9 (17.0)	18 (20.5)	27 (19.1)	
Sealer extrusion evident at completion of RCT, n(%)				0.9203
No	43 (81.1)	72 (81.8)	115 (81.6)	
Yes	10 (18.9)	16 (18.2)	26 (18.4)	
Pre-op PAI Score, n(%)				0.0954
2	6 (11.3)	2 (2.3)	8 (5.7)	
3	19 (35.9)	26 (29.5)	45 (31.9)	
4	21 (39.6)	47 (53.4)	68 (48.2)	
5	7 (13.2)	13 (14.8)	20 (14.2)	

[†] Chi-Square test used unless otherwise noted

[#] Fisher exact test

[*] t-test applied

[*N1, N2, N3] For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Gutta-Perhca N = 46, Resilon N = 77, Total N = 123, respectively

Table 3. Univariate analysis summary of variables by outcome of clinical success or failure for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

	Clinical outcome			
	Failure (N=14)[*N1]	Success (N=127)[*N2]	Total (N=141)[*N1]	P value [†]
Obturation material, n(%)				1.000
GP	5 (9.4)	48 (90.6)	53 (100)	
Resilon	9 (10.2)	79 (89.8)	88 (100)	
Gender, n(%)				0.4008
Male	5 (7.2)	64 (92.8)	69 (100)	
Female	9 (12.5)	63 (87.5)	72 (100)	
Age (in years)				0.0263[*]
N (%)	14 (9.9)	127 (90.1)	141 (100)	
Mean (SD)	41.7 (14.0)	53.9 (15.1)	50.3 (15.0)	
Tooth type, n(%)				0.5867
Anterior	7 (11.1)	56 (88.9)	63 (100)	
Premolar	3 (6.5)	43 (93.5)	46 (100)	
Molar	4 (12.5)	28 (87.5)	32 (100)	
Presence of permanent restoration, n(%)				0.0186
No	9 (7.3)	114 (92.7)	123 (100)	
Yes	5 (27.78)	13 (72.22)	18 (100)	
Type of permanent restoration, n(%)				0.3102
Intra-coronal	7 (10.1)	62 (89.9)	69 (100)	
Cuspal coverage	2 (3.7)	52 (96.3)	54 (100)	
Time (in months) between RCT and permanent restoration				0.6402*
N (%)	9 (7.3)	114 (92.7)	123 (100)	
Mean (SD)	2.5 (3.1)	3.5 (5.9)	3.4 (5.7)	
Follow-up time (months)				0.8046*
N (%)	14 (9.9)	127 (90.1)	141 (100)	
Mean (SD)	35.4 (18.2)	34.1 (17.3)	34.4 (17.4)	
Diagnosis of Hypertension, n(%)				0.1365[#]
No	8 (7.7)	96 (92.3)	104 (100)	
Yes	6 (16.2)	31 (83.8)	37 (100)	
Diagnosis of Diabetes, n(%)				0.6773
No	12 (9.7)	112 (90.3)	124 (100)	
Yes	2 (11.8)	15 (88.2)	17 (100)	
History of tobacco use, n(%)				1.000
No	12 (10.5)	102 (89.5)	114 (100)	
Yes	2 (7.4)	25 (92.6)	27 (100)	
Sealer extrusion evident at completion of RCT, n(%)				0.4667
No	13 (11.3)	102 (88.7)	115 (100)	
Yes	1 (3.9)	25 (96.1)	26 (100)	
Pre-op PAI Score, n(%)				0.8542
2	1 (12.5)	7 (87.5)	8 (100)	
3	4 (8.9)	41 (91.1)	45 (100)	
4	6 (8.8)	62 (91.2)	68 (100)	
5	3 (15.0)	17 (85.0)	20 (100)	

[†]Fisher exact test applied unless otherwise noted

*t-test applied

[#]Chi-square test applied

[*N1, N2, and N3] For variables "Type of permanent restoration" and "Time (in months) between RCT and permanent restoration", Failure N = 9, Success N = 114, and Total N = 123, respectively

Table 4. Univariate analysis of 17 extracted teeth with respect to root filling material and presence or absence of clinical parameters of failure.

	No clinical parameter(s) of failure noted at time of extraction – extracted solely due to restorability concerns	Clinical parameter(s) of failure noted at time of extraction – extracted for any reason	Total	P-value
Gutta-Percha, n(%)	6 (85.7)	1 (14.3)	7 (100)	1.00
Resilon, n(%)	8 (80.0)	2 (20.0)	10 (100)	

Table 5. Univariate analysis of Survival of 141 Teeth With Respect to Obturation Material

	Survival			
	Yes	**No**	**Total**	**P value**
Gutta-Percha, n(%)	47 (87.0)	7 (13.0)	54 (100)	1.000
Resilon, n(%)	77 (88.5)	10 (11.5)	87 (100)	

Table 6. Univariate analysis of Survival of 141 Teeth With Respect to Presence of Full Coverage Restorations

	Survival			
	Yes	**No**	**Total**	**P value**
Intact Full Coverage Restoration, n(%)	53 (98.1)	1 (1.9)	54 (100)	0.003
No Full Coverage Restoration, n(%)	71 (81.6)	16 (18.4)	87 (100)	

Table 7. Univariate analysis of Survival of 87 Teeth Without Full Coverage Restorations With Respect to Presence of Intact Marginal Ridges

	Survival			
	Yes	**No**	**Total**	**P value**
Marginal Ridges Not Intact, n(%)	43 (72.9)	16 (27.1)	59 (100)	0.002
Marginal Ridges Intact, n(%)	28 (100)	0 (0)	28 (100)	

Table 8. Odds-Ratio estimate using univariate logistic regression analysis using outcomes of clinical success (N=127) vs. failure (N=14) for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

Variable	Coding (0 vs. 1)	Odds Ratio estimate	95% Confidence Interval		P value
Obturation material	GP vs. Resilon	0.620	0.157	2.448	0.5220
Gender	Male vs. Female	0.364	0.092	1.432	0.3155
Age (Categorized)	<35 vs. >65	>999.99	<0.001	>999.99	0.7091
	35-65 vs. >65	>999.99	<0.001	>999.99	
Age	Unit = 1 year	0.958	0.922	0.996	0.0309
Tooth type	Anterior vs. Molar	0.833	0.186	3.731	0.6166
	Premolar vs. Molar	0.674	0.127	3.576	
	Anterior vs Premolar	1.792	0.438	7.336	
Presence of Permanent Restoration	Without vs. with	4.897	1.417	16.745	0.0088
Type of permanent restoration[*N1]	Intra-coronal vs Cuspal coverage	2.935	0.584	14.745	0.1587
Time between RCT and permanent restoration[*N1]	Unit = 1 month	0.982	0.834	1.156	0.8262
Follow-up time	Unit = 1month	1.004	0.973	1.038	0.8030
Diagnosis of Hypertension	No vs. Yes	0.431	0.139	1.337	0.1450
Diagnosis of Diabetes	No vs. Yes	0.587	0.116	2.978	0.5202
History of tobacco use	No vs. Yes	2.500	0.306	20.409	0.3925
Sealer extrusion evident at completion of RCT	No vs. Yes	2.381	0.291	19.465	0.4185
Pre-op PAI Score	2 vs. 5	1.286	0.100	16.537	0.8461
	3 vs. 5	0.900	0.151	5.370	
	4 vs. 5	0.563	0.095	3.323	

[*N1] For variables “Type of permanent restoration” and “Time (in months) between RCT and permanent restoration”, N=123

Table 9. Multivariate logistic regression analysis summary of variables using outcomes of clinical success vs. failure for 141 teeth with Necrotic Pulp and Chronic Periradicular Periodontitis with recall time of at least 12 months.

Variable		Odds Ratio Estimates	95% Confidence Interval		P value
Obturation	GP vs. Resilon	1.02	0.314	3.312	0.8906
Age	Unit = 1year	0.958	0.921	0.996	0.0487
Restoration	Without vs. With	4.758	1.319	17.166	0.0172

Table 10. Reported Success Rates from Endodontic Literature for Primary Non-Surgical Root Canal Treatment for Teeth With and Without Apical Radiolucency

	No Apical Radiolucency	Apical Radiolucency
Strindberg 1956	89%	68%
Kerekes 1979	94%	84%
Bystrom 1987	94%	85%
Sjogren 1990	96%	86%
Chugal 2001	88%	60%
Friedman 2003	92%	74%
Farzaneh 2004	93%	79%
Marquis 2006	88%	76%
Cotton 2007	100%	66%

FIGURES

Figure 1 – Subject Assessment Form

Subject Assessment Form

1. Subject number: _____
2. Age of subject at initial treatment: _____
3. Gender: ☐ Male ☐ Female
4. Past Medical Hx: ☐ Hypertension ☐ Diabetes ☐ History of Tobacco Use
5. Tooth #: _____
6. Tooth Type:

   ☐ Maxillary ☐ Mandibular

   ☐ Central ☐ Lateral ☐ Canine ☐ 1st Premolar ☐ 2nd Premolar ☐ 1st Molar ☐ 2nd Molar
7. Date of Completion of root canal treatment: _____
8. Date permanent restoration was placed (if exact date known from record): _____
9. Time elapsed from completion of root canal treatment and placement of final restoration:

   ☐ 0 months (restoration placed at completion of root canal) ☐ < 1 month ☐ 1-3 months

   ☐ 4-6 months ☐ 7-9 months ☐ 10-12 months ☐ > 12 months ☐ No final coronal restoration present
10. Type of permanent coronal restoration (if present):

    ☐ Amalgam ☐ Composite ☐ Full coverage crown ☐ Onlay ☐ Post ☐ Other _____
11. Marginal Ridges:

    ☐ Intact ☐ At least one marginal ridge lost
12. Type of temporary material if not permanently restored:

    ☐ Cavit ☐ IRM ☐ Other _____
13. Clinical Evaluation (check all that apply):

    ☐ patient reports presence of pain associated with tooth ☐ pain upon percussion

    ☐ pain upon palpation ☐ attachment loss greater than 5mm ☐ tooth mobility greater than grade +1

    ☐ presence of sinus tract ☐ present of swelling
14. Radiographic Examination (check all that apply):
    a. Pre-Operative PAI score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
    b. Post-Operative PAI score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
    c. Presence of sealer extrusion: ☐ Yes ☐ No
    d. Length of fill: ☐ Ideal (0-2mm of radiographic apex) ☐ Short (>2mm) ☐ Long
    e. Adequate density of fill with no voids seen in apical 1/3: ☐ Yes ☐ No
    f. Adequate taper of fill: ☐ Yes ☐ No

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