

A Retrospective Study Comparing Clinical Outcomes after Obturation with Resilon/Epiphany or Gutta-Percha/Kerr Sealer

Taylor P. Cotton, DDS,* William G. Schindler, DDS, MS,* Scott A. Schwartz, DDS,* William R. Watson, DDS, MS,[†] and Kenneth M. Hargreaves, DDS, PhD*^{‡,§||}

Abstract

The purpose of this retrospective study was to evaluate the treatment outcome of root canal systems obturated with gutta-percha and Kerr Pulp Canal Sealer compared with Resilon and Epiphany sealer. One hundred three teeth treated in a private endodontic practice were included in the study. Clinical outcomes (healed versus nonhealed) were assessed by using the Periapical Index determination and clinical evaluation at recall appointments. The magnitude of the association between obturation materials used and outcome measured was evaluated with univariate and multivariate logistic regression analysis. Univariate analysis indicated that pulpal vitality, presence of a preoperative lesion, and length of recall times were statistically significant in predicting the outcome. Logistic regression analysis showed that age, tooth position, and length of recall times were statistically significant in predicting the outcome. Root canal systems obturated with gutta-percha and Kerr Pulp Canal Sealer or Resilon and Epiphany sealer had statistically indistinguishable differences in clinical outcome. (*J Endod* 2008;xx:xxx)

Key Words

Clinical, endodontic, Epiphany, gutta-percha, outcome assessment, Resilon, sealer

From the Departments of *Endodontics, [†]Pharmacology, [§]Physiology, and ^{||}Surgery, University of Texas Health Science Center, San Antonio, Texas; and [‡]private practice in Wichita, Kansas.

Address requests for reprints to Dr Taylor P. Cotton, Department of Endodontics, UTHSCSA School of Dentistry, 7703 Floyd Curl Dr, Mail Code 7892, San Antonio, TX 78229-3900. E-mail address: cottont@uthscsa.edu. 0099-2399/\$0 - see front matter

Copyright © 2008 American Association of Endodontists. doi:10.1016/j.joen.2008.03.018

Bacteria and their by-products have been shown to be a cause of pulpal necrosis and apical periodontitis (1). A primary objective of endodontic therapy is to debride and clean the root canal system through mechanical and chemical means (2, 3). After thorough chemomechanical debridement, the canal system is obturated with a filling material, and this treatment regimen sets the stage for postoperative healing (4). As a major part of this therapeutic treatment, the obturation ideally confers 3 main functions: prevention of coronal ingress of bacteria, entombment of remaining bacteria, and prevention of accumulation of fluid apically that could serve as nutrients for bacteria (5).

Gutta-percha used with various sealers is the standard with which other obturating materials are compared (6). Recently a thermoplastic synthetic polymer-based root canal filling material has been developed that might be used as an alternative core obturation material. This material, Resilon (Resilon Research LLC, Madison, CT), is made of polycaprolactone and contains bioactive glass, bismuth oxychloride, and barium sulfate. The corresponding sealer, Epiphany Root Canal Sealant (Pentron Clinical Technologies, Wallingford, CT), is a dual-cure dental resin composite sealer (7). These obturation materials have been compared with gutta-percha and various sealers in preclinical studies evaluating microleakage (7, 8), fluid filtration leakage (9), cytotoxicity (10), surface characteristics after exposure to enzymes (11), and differences in inflammation in dogs with apical periodontitis (12). Resilon has also been evaluated clinically in a nonstandardized protocol (13).

In prospective and retrospective studies the outcome of treatment has been evaluated for teeth obturated with gutta-percha, and many factors have been assessed for their relationship to treatment outcome. Pulpal vitality (14–16), presence of a preoperative lesion (14, 15, 17–23), and length of recall time (17, 24, 25) have been shown in many studies to be significant factors affecting the outcome of root canal treatment. Additional factors that might also affect outcome are age (23), gender (15), tooth location (26), number of canals obturated (20), and single or multiple visits (27). Assessment of treatment outcome can be accomplished through the use of radiographic and/or clinical evaluation. Radiographic evaluation can be assessed through strict criteria (17) or through the use of the Periapical Index (PAI) system (28), and clinical interpretation can be evaluated through presentation of symptoms (18–20) or functionality (29) of the tooth treated.

The present retrospective study was designed to compare radiographic and clinical outcomes of teeth obturated with either Resilon and Epiphany sealer or gutta-percha and Kerr Pulp Canal Sealer (Kerr Corporation, Orange, CA) by using a single private practice site in which patients were assigned to either treatment by using an allocation method of treatment room assignment as described below. Both univariate and multivariate logistic regression analyses were used to evaluate the impact of the obturation method and other preoperative prognostic features on the clinical outcomes. The additional preoperative factors assessed were age, gender, tooth location, pulpal vitality, presence of preoperative periapical radiolucency, number of canals obturated, single or multiple visits, and length of recall times.

Materials and Methods

Sample Size/Endodontic Treatment

This study was approved by the Institutional Review Board of the University of Texas Health Science Center at San Antonio. The sample population was initially composed of 276 endodontically treated teeth of patients who were referred by general practitioners to a single practitioner endodontic practice located in Wichita, KS. The patients were treated between August 2003 and May 2004. The endodontic office in this study provided 2 fully equipped rooms for treatment. One room was equipped for obturation with gutta-percha and Kerr Pulp Canal Sealer and the other with Resilon and Epiphany sealer. All other equipment and instruments were the same in each treatment room. Patient assessment, treatment data, and radiographs were obtained by both the practitioner and his staff, with the diagnosis and treatment being provided by a single endodontist with 18 years of private practice experience. Digital radiographs were taken with a Sirona Heliodont DS unit (60 kilovolts (peak), 7 mA) (Sirona Dental Systems, LLC, Charlotte, NC) with variable exposure times, and Schick sensors and software (Schick Technologies, Inc, Long Island City, NY) were used to capture the radiographic images.

At each appointment, patients were seated in the first available treatment room. This patient allocation method did not take into account any demographic or preoperative variables at the time of treatment room assignment. Canals were obturated with the material assigned to the treatment room that the patient was in at the time of obturation, independent of the treatment room occupied at any previous visit. Every patient was anesthetized, and a rubber dam was placed. Access was made, canals were located, and coronal flare was obtained with a rotary ProFile GT size 20, 0.06 taper (Dentsply Tulsa Dental, Tulsa, OK). Stainless steel FlexoFile (Dentsply Maillefer, Tulsa, OK) hand files and an Elements Apex Locator (Sybron Endo, Orange, CA) were used to determine working length (WL) as the point at which the apex locator read 0.0. Then rotary K3 size 15–25 with a 0.02 taper (Sybron Endo) and rotary ProTaper S1, S2, and F1 (Dentsply Tulsa Dental) nickel-titanium (NiTi) files were used to initially clean and shape the canals to WL. LightSpeed NiTi rotary instruments (LightSpeed Technology, Inc, San Antonio, TX) were then used without rotary power to determine the largest size that would go past WL. This size was recorded, and the canal was then prepped with a K3 0.04 or 0.06 taper to the previously determined LightSpeed size. After canal preparation to the size of the largest LightSpeed that would go past WL, larger LightSpeed instruments were inserted. If a LightSpeed of 2 sizes or greater easily fit to within 1 mm of the WL, the canal would then be prepped with a K3 0.04 or 0.06 taper to match the larger size at the shorter length determined by the LightSpeed instrument.

Throughout treatment the canals were irrigated with 5.25% NaOCl warmed in a beaker on a beverage warming device (The Holmes Group, Warrensburg, MO). A final flush of hydrogen peroxide followed by a rinse of 17% ethylenediaminetetraacetic acid to remove the smear layer completed the irrigation. All irrigants were dispensed with a monojet syringe through a 30-gauge Max-i-Probe (Dentsply Rinn, Elgin, IL) needle. The volume of irrigants was not recorded. Canals were then dried with sterile paper points. For multiple visit appointments, UltraCal XS (Ultradent Products, Inc, South Jordan, UT) calcium hydroxide was dispensed into the canal by using a 30-gauge needle followed by a sterile cotton pellet and a temporary restoration of Cavit or intermediate restorative material (IRM).

Before obturation, WL length was confirmed with the Elements Apex Locator. A master cone of the obturation material to be used was selected to match the final size and taper of the canal preparation to WL, placed to length for assessment, and then removed. For canals that were prepared to a larger size within 1 mm short of WL, a cone of corre-

sponding size and taper was selected, and the apical 3 mm of the cone was softened with chloroform. The cone was then fit to WL and removed.

For canals obturated with gutta-percha, Kerr Pulp Canal Sealer was mixed, and the gutta-percha master cone was coated and placed back to WL. For canals obturated with Resilon, a sterile paper point was used to apply the Epiphany primer to the walls of the canal. A dry paper point was then placed to length and used to absorb excess primer inside the root canal. The Resilon master cone was coated with Epiphany sealer and placed to length. Both obturation materials were then incrementally down packed by using a System B (Sybron Endo) and condensers. The goal was to down pack and condense to within 3 mm of WL or as close to that as possible. After the down pack, the canals were backfilled by using an Obtura II gun (Obtura Spartan, Fenton, MO) with the same obturation material as the master cone. The material was finally condensed at the orifice(s), with the Resilon and Epiphany sealer obturated canals being light-cured for 40 seconds.

After obturation, the chambers were closed with composite, amalgam, or a sterile cotton pellet followed by Cavit or IRM. The postobturation restoration was determined on the basis of the referring dentist's preference and the endodontist's judgment of maintaining a coronal seal.

After treatment, patients were mailed postcards and telephoned to set up a recall appointment. Also, if a patient was in the office for additional treatment of a different tooth, their previously treated tooth was recalled. A total of 117 treated teeth from 110 patients were recalled, with recall times ranging from 2–25 months. At the recall appointment, patients were seated, and a radiographic image was acquired. The treated tooth was percussed, the area was visually inspected and palpated, and any complaints by the patient were recorded. Asymptomatic/within normal limits (WNL) was recorded if no clinical symptoms were present. The type of restoration present at the time of recall was also recorded. Treatment and recall data were recorded and stored in the endodontic practice's TDO (Dog Breath Software, Inc, San Diego, CA) software. The data from the patients' charts were assessed retrospectively by independent observers consisting of a board-certified endodontist and an endodontic resident and analyzed by a statistician. None of the observers were involved in treatment of the teeth.

The data from 117 recalled teeth were subjected to various exclusion criteria without consideration as to the type of obturation material used. Initially, 3 teeth were eliminated from the study for various reasons. One tooth obturated with gutta-percha/Kerr sealer was extracted by a general dentist without being evaluated by the endodontist, another tooth obturated by gutta-percha/Kerr sealer was extracted as a result of a vertical root fracture confirmed on extraction, and a third tooth obturated with Resilon/Epiphany was re-treated as a result of an initial procedural error. Nine teeth (5 obturated with gutta-percha/Kerr sealer, 4 obturated with Resilon/Epiphany) were eliminated because either the immediate postoperative or the recall radiograph did not adequately show the apices and surrounding bone of the tooth being evaluated. In addition, 3 adjacent teeth in 1 patient had confluent periradicular radiolucencies, and all were obturated with Resilon/Epiphany at the same appointment. One tooth was selected randomly to be included in the study, and the other 2 were eliminated. After the exclusion criteria were applied, 103 endodontically treated teeth (50 obturated with gutta-percha/Kerr sealer, 53 obturated with Resilon/Epiphany) from 98 patients remained to be evaluated in the study. All teeth presented with permanent restorations at the time of recall. Eighty-three teeth (41 obturated with gutta-percha/Kerr sealer, 42 obturated with Resilon/Epiphany) were recalled at 12–25 months. The 12–25-month group was further divided into an intermediate recall group of 12–18 months having 15 teeth (8 obturated with gutta-percha/Kerr sealer, 7 obturated with Resilon/Epiphany) and a long recall group of more than 18 months

having 68 teeth (33 obturated with gutta-percha/Kerr sealer, 35 obturated with Resilon/Epiphany). Twenty teeth (9 obturated with gutta-percha/Kerr sealer, 11 obturated with Resilon/Epiphany) were recalled in less than 12 months. The data were evaluated for all 103 teeth (entire population), regardless of recall time, and then for the subset of 83 teeth (12–25-month recall group) with a recall of 12 months or greater. Finally, subsets of patients with preoperative lesions in the above 2 groups were analyzed.

Subjective Radiographic Assessment

The PAI was used for subjective radiographic assessment of all immediate postoperative and recall radiographs. The PAI allows evaluators to compare a radiograph with a set of 5 reference radiographs and their associated line drawings (28). Two additional board-certified endodontists not involved in the treatment of the teeth and not having analyzed the data from the patients' charts served as PAI evaluators in this study. Each evaluator was calibrated according to Delano et al (30) by using standardized radiographs provided by Professor Orstavik.

All of the immediate postoperative and recall digital radiographs were placed into separate PowerPoint (Microsoft Corp, Redmond, WA) presentations. Both PAI evaluators were blinded to preoperative variables to include the obturation material used in each tooth and the length of recall time. Each evaluator independently viewed each set of radiographs and assigned a PAI score for each tooth. A third investigator tabulated and compared assigned scores. For any disagreement on a PAI score for a particular tooth, the PAI evaluators jointly reevaluated the radiograph, and a consensus score was reached (31). A second PAI scoring for the same immediate postoperative and recall radiographs was performed 7–14 days later. After the second PAI scoring, intra-rater and inter-rater reliability was determined by using a weighted kappa statistic.

Prognostic Factors

The prognostic factors used in this study were determined on the basis of the data that were consistently recorded for each tooth treated. In addition, the prognostic factors or covariates evaluated were decreased compared with the total number collected as a result of the sample size's limitation of being unable to obtain statistically significant results with too many prognostic factors. The data recorded in each patient's chart regarding factors to be assessed were extracted and coded for logistic regression. The obturation material was coded as either gutta-percha or Resilon. Age was recorded and coded as the age provided by the patient at the initial appointment. Gender was coded as either male or female. Pulpal vitality was coded as 1 of 3 groups: (1) vital, (2) nonvital, which included necrotic pulps and previously accessed teeth, or (3) filled, which represented retreatments. The PAI scores for the immediate postoperative radiographs were used to determine the preoperative presence of a periapical lesion. For purposes of logistic regression analysis, the PAI scores of 1 or 2 were coded as no lesion, and PAI scores of 3 or greater were coded as a lesion. The teeth treated were grouped and coded as anterior teeth, premolar teeth, or molar teeth. The teeth were also coded as 1 canal obturated or 2 or more canals obturated. The number of appointments was coded as a single visit or multiple visits. The recall time was coded as <12 months (short), 12–18 months (intermediate), or >18 months (long).

Outcome Assessment

The outcome assessment for this study was modeled after the Toronto studies (18–20). Radiographic and clinical criteria were used to determine a dichotomized outcome of healed (18–20) and nonhealed for the recall radiographs. The radiographic criteria were determined through cutoffs within the PAI system developed by Orstavik et al (28),

and the clinical data were obtained from the recorded recall appointment information. Periapical tissues were classified as healed in the absence of radiographic signs of apical periodontitis (PAI score of 1 or 2) and the absence of clinical signs and symptoms other than tenderness to percussion as determined by the Toronto Studies (18–20). Any other condition was classified as nonhealed.

Data Analysis

The primary analysis was to determine the magnitude of association between the choice of obturation material and treatment outcome. Univariate and multivariate logistic regression were used in this retrospective study to compare the outcome of healed versus nonhealed root canal treatment with 2 different obturation methods of gutta-percha and Kerr Pulp Canal Sealer and Resilon and Epiphany sealer. The odds ratio and associated 95% confidence intervals (CIs) were used to represent the magnitude of association. Other potential prognostic factors considered for inclusion into the model included age, gender, tooth location, pulpal vitality, presence of a preoperative periapical lesion, number of canals obturated, number of appointments, and length of recall times. These were analyzed as covariates, and the treatment effect was estimated as the adjusted odds ratio (95% CI).

Because of the small data sets of 103 and 83 teeth, with each having small numbers of nonhealed outcomes, it was difficult to construct a stable logistic regression model. The model was limited to only a small number of covariates. Effects that were not statistically significant in the model were eliminated consecutively until an appropriate model could be constructed. To allow the logistic regression model to estimate results without ignoring confounding factors, exclusions were made with some of the factors because their results had 0 nonhealed outcomes (ie, vital pulp diagnosis and absence of preoperative lesion). In addition, 2 factors were consolidated (tooth position and number of canals) to streamline the regression model.

For univariate analysis, Fisher exact test and *t* test were used. Initially, the entire population was statistically analyzed, regardless of recall time, followed by the 12–25-month recall groups. Finally, subsets of teeth with a preoperative lesion were evaluated within the 2 groups. A weighted kappa statistic was used to assess each observer's agreement with the calibration radiographs, and it was used to assess intra-rater and inter-rater reliability of each observer with regard to the immediate postoperative and recall radiographs.

Results

The weighted kappa statistic for the calibration exercises ranged from 0.67–0.84 between the 2 observers. The weighted kappa statistics for the immediate postoperative and recall radiographs for intra-rater reliability ranged from 0.68–0.84 and ranged from 0.80–0.93 for inter-rater reliability between the 2 observers. All weighted kappa statistics indicated substantial agreement (32).

Univariate association of the outcome assessment of healed and nonhealed for age, gender, tooth position, obturation material, number of appointments, pulpal vitality, presence of a preoperative lesion, number of canals obturated, and length of recall time is presented for the entire population with recall times ranging from 2–25 months in Table 1 and for the 12–25-month recall group in Table 2. The overall healed rates for the entire population and the 12–25-month recall group were 78.6% and 85.5%, respectively. Both pulpal vitality ($p < .001$) and the presence of a preoperative lesion ($p < .005$) were significantly correlated with the clinical outcome for both the entire population and the 12–25-month recall group. Teeth with a positive response to vitality testing and the absence of a preoperative lesion showed a better outcome of healed. No statistically significant association was detected

TABLE 1. Univariate Analysis Summary of Variables by Outcome of Healed and Nonhealed for 103 Teeth with Recall Times Ranging from 2–25 Months

	Outcome			p Value
	Healed	Nonhealed	Total	
Age				.4*
N (%)	81 (78.6)	22 (21.4)	103 (100)	
Mean (SD)	51.1 (15.6)	54.3 (17.5)	51.8 (16)	
SEM	1.7	3.7	1.6	
Median	50	58.5	51	
Minimum, maximum	18, 84	12, 86	12, 86	
Gender, n (%)				.06†
Male	29 (69.0)	13 (31.0)	42 (100)	
Female	52 (85.2)	9 (14.8)	61 (100)	
Total	81	22	103	
Tooth position, n (%)				.31†
Anterior	9 (64.3)	5 (35.7)	14 (100)	
Premolar	17 (77.3)	5 (22.7)	22 (100)	
Molar	55 (82.1)	12 (17.9)	67 (100)	
Total	81	22	103	
Obturation material, n (%)				1†
Resilon	42 (79.2)	11 (20.8)	53 (100)	
Gutta-percha	39 (78.0)	11 (22.0)	50 (100)	
Total	81	22	103	
Appointments, n (%)				.07†
Single	68 (82.9)	14 (17.1)	82 (100)	
Multiple	13 (61.9)	8 (38.1)	21 (100)	
Total	81	22	103	
Pulp diagnosis, n (%)				<.001†
Vital	34 (97.1)	1 (2.9)	35 (100)	
Nonvital	34 (75.6)	11 (24.4%)	45 (100)	
Filled	13 (56.5)	10 (43.5)	23 (100)	
Total	81	22	103	
Preoperative lesion, n (%)				<.001†
Yes	43 (66.2)	22 (33.8)	65 (100)	
No	38 (100)	0 (0.0)	38 (100)	
Total	81	22	103	
No. of canals obturated, n (%)				1†
Single	20 (80.0)	5 (20.0)	25 (100)	
Multiple	61 (78.2)	17 (21.8)	78 (100)	
Total	81	22	103	
Recall time, n (%)				.003†
> 18 mo (long)	57 (83.8)	11 (16.2)	68 (100)	
12–18 mo (intermediate)	14 (93.3)	1 (6.7)	15 (100)	
< 12 mo (short)	10 (50.0)	10 (50.0)	20 (100)	
Total	81	22	103	

SD, standard deviation; SEM, standard error of the mean.

*t test.

†Fisher exact test.

between the type of obturation material ($p = 1.00$) and the outcomes of healed or nonhealed.

Univariate analysis of the subset of teeth with a preoperative lesion within the entire population (Table 3) showed length of recall time to be statistically significant in affecting the outcome ($p = .007$). Longer recalls demonstrated greater healed outcomes. No factors were statistically significant for the 12–25-month recall group with preoperative lesions in affecting the outcome (Table 4). In addition, the type of obturating material for both groups was not statistically significant.

Multivariate logistic regression for the 12–25-month recall group included the factors of age, obturation material, and tooth position (Table 5). Obturation material, tooth position, and recall time enabled stable estimation by using logistic regression for the entire population (Table 6). Interactions between the variables were evaluated, but none were found. Age (odds ratio, 0.96) within the 12–25-month recall group had a quadratic effect related to a nonhealed outcome. The probability of nonhealed plotted against age resulted in a parabolic graph that peaked around age 53. This indicated that the probability of having a nonhealed outcome increased to about age 53 and then decreased

afterwards. Within the 12–25-month recall group, tooth position was not significant ($p = .1$) but affected age in the model, indicating it might confound the effect for age and must be adjusted for. In the entire population, tooth position was significant ($p = .04$) for the outcome, with healed being more associated with anterior teeth compared with premolar teeth and molar teeth compared with premolar teeth. Obturation material was not significant in relation to healed, compared with nonhealed for either subject group. Length of recall time was statistically significant ($p = .008$) when the short time (<12 months) was included in the entire population.

Discussion

Assessment of treatment outcome can be accomplished through a prospective or retrospective study design, with both approaches having advantages and disadvantages (29). Prospective studies are considered higher levels of evidence because they permit blinded randomized treatment allocation, a priori standardization of techniques and sampling methods, and the simultaneous study of multiple variables. Disadvan-

TABLE 2. Univariate Analysis Summary of Variables by Outcome of Healed and Nonhealed for 83 Teeth with Recall Times Ranging from 12–25 Months

	Outcome			p Value
	Healed	Nonhealed	Total	
Age				.25*
N (%)	71 (85.5%)	12 (14.5%)	83 (100%)	
Mean (SD)	52.4 (15.4)	57.7 (9.6)	53.2 (14.7)	
SEM	1.8	2.8	1.6	
Median	51	59	51	
Minimum, maximum	18, 84	40, 77	18, 84	
Gender, n (%)				.06†
Male	26 (76.5)	8 (23.5)	34 (100)	
Female	45 (91.8)	4 (8.2)	49 (100)	
Total	71	12	83	
Tooth position, n (%)				.26†
Anterior	8 (72.7)	3 (27.3)	11 (100)	
Premolar	14 (82.4)	3 (17.6)	17 (100)	
Molar	49 (89.1)	6 (10.9)	55 (100)	
Total	71	12	83	
Obturation material, n (%)				1†
Resilon	36 (85.7)	6 (14.3)	42 (100)	
Gutta-percha	35 (85.4)	6 (14.6)	41 (100)	
Total	71	12	83	
Appointments, n (%)				.06†
Single	59 (89.4)	7 (10.6)	66 (100)	
Multiple	12 (70.6)	5 (29.4)	17 (100)	
Total	71	12	83	
Pulp diagnosis, n (%)				.001†
Vital	30 (100)	0 (0.0)	30 (100)	
Nonvital	31 (83.8)	6 (16.2)	37 (100)	
Filled	10 (62.5)	6 (37.5)	16 (100)	
Total	71	12	83	
Preoperative lesion, n (%)				.003†
Yes	38 (76.0)	12 (24.0)	50 (100)	
No	33 (100)	0 (0.0)	33 (100)	
Total	71	12	83	
No. of canals obturated, n (%)				1†
Single	16 (84.2)	3 (15.8)	19 (100)	
Multiple	55 (85.9)	9 (14.1)	64 (100)	
Total	71	12	83	
Recall time, n (%)				.68†
12–18 mo (intermediate)	14 (93.3)	1 (6.7)	15 (100)	
>18 mo (long)	57 (83.8)	11 (16.2)	68 (100)	
Total	71	12	83	

SD, standard deviation; SEM, standard error of the mean.

**t* test.

†Fisher exact test.

tages of prospective studies include the need for long follow-up times, potential problems with patients lost to follow-up, higher costs, and longer time for study completion. From this perspective, one advantage of retrospective studies is that they might enable longer follow-up periods and larger study populations. In addition, they can protect the study from some sources of bias because the data collected are usually for reasons other than research. Limitations of retrospective studies include the inability to randomize and standardize the methods, and the scope of analysis is limited to the data collected. Although prospective studies are desirable, many studies that evaluate endodontic treatment outcome are retrospective.

The terminology and criteria to assess the outcome of endodontic therapy vary across the literature. Strict radiographic criteria can be used to determine success, failure, and uncertainty (17). The PAI scoring system is another method used to radiographically interpret success and failure by using a cutoff within the scale to differentiate an outcome (28). Another categorization of treatment outcome is healed, healing, and disease (33). The Toronto studies (18–20) deemed treatment outcome to be healed or disease and used a combination of radiographic and clinical criteria to determine their results. A more recent

method of assessing outcome is through digital subtraction radiography. This technology is able to indicate periradicular changes and demonstrate healing (34), but no criteria have been validated for the determination of success and failure. Digital subtraction also requires standardized radiographs, which are often not feasible in a retrospective study. This study chose to modify the Toronto studies' (18–20) model so that a combination of radiographic and clinical data could be used to determine the outcome of healed compared with nonhealed. Factors assessed in this retrospective study were limited by the data that were recorded during treatment and at recall. Overall, the success rates are similar to other success failure studies (14–16, 18–22, 26, 33).

Given the relatively prolonged periods often required for the radiographic and clinical healing of apical periodontitis, it is not surprising that the 12–25-month recall group would have a higher outcome of healed (85.5%) compared with the entire population (78.6%), with recall times ranging from 2–25 months. It should be noted that the outcomes of this study are based on a small sample size from Midwest America, with treatment being provided by a single practitioner in a private practice setting. The results might not be completely repre-

TABLE 3. Univariate Analysis Summary of Variables by Outcome of Healed and Nonhealed for 65 Teeth with Preoperative Radiolucency and Recall Times Ranging from 2–25 Months

	Outcome			p Value
	Healed	Nonhealed	Total	
Age				.81*
N (%)	43 (66.2)	22 (33.8)	65 (100)	
Mean (SD)	53.3 (14.1)	54.3 (17.5)	53.7 (15.2)	
SEM	2.2	3.7	1.9	
Median	54	58.5	55	
Minimum, maximum	26, 83	12, 86	12, 86	
Gender, n (%)				.2†
Male	18 (58.1)	13 (41.9)	31 (100)	
Female	25 (73.5)	9 (26.5)	34 (100)	
Total	43	22	65	
Tooth position, n (%)				.19†
Anterior	3 (37.5)	5 (62.5)	8 (100)	
Premolar	10 (66.7)	5 (33.3)	15 (100)	
Molar	30 (71.4)	12 (28.6)	42 (100)	
Total	43	22	65	
Obturation material, n (%)				.79†
Resilon	24 (68.6)	11 (31.4)	35 (100)	
Gutta-percha	19 (63.3)	11 (36.7)	30 (100)	
Total	43	22	65	
Appointments, n (%)				.4†
Single	32 (69.6)	14 (30.4)	46 (100)	
Multiple	11 (57.9)	8 (42.1)	19 (100)	
Total	43	22	65	
Pulp diagnosis, n (%)				.15†
Vital	8 (88.9)	1 (11.1)	9 (100)	
Nonvital	24 (68.6)	11 (31.4)	35 (100)	
Filled	11 (52.4)	10 (47.6)	21 (100)	
Total	43	22	65	
No. of canals obturated, n (%)				1†
Single	10 (66.7)	5 (33.3)	15 (100)	
Multiple	33 (66.0)	17 (34.0)	50 (100)	
Total	43	22	65	
Recall time, n (%)				.007†
>18 mo (long)	33 (75.0)	11 (25.0)	44 (100)	
12–18 mo (intermediate)	5 (83.3)	1 (16.7)	6 (100)	
<12 mo (short)	5 (33.3)	10 (66.7)	15 (100)	
Total	43	22	65	

SD, standard deviation; SEM, standard error of the mean.

**t* test.

†Fisher exact test.

sentative of outcomes found in other areas of the country with differing patient populations and different endodontic treatment procedures.

Comparing the clinical outcomes between Resilon and Epiphany sealer and gutta-percha and Kerr Pulp Canal Sealer is important from a treatment perspective. Regardless of the reported outcomes from multiple *in vitro* studies evaluating Resilon (8–13), clinical decision making should be based on the outcomes of clinical research. A nonstandardized clinical evaluation of teeth obturated with Resilon showed healed and healing rates to be within the range evaluated for gutta-percha throughout the literature (13). This study contributes to that clinical knowledge base by evaluating teeth obturated with gutta-percha and Kerr Pulp Canal Sealer compared with teeth obturated with Resilon and Epiphany sealer. To ensure a robust conclusion, we evaluated the entire sample of 103 cases (entire population) as well as a subset of 83 cases with a 12–25-month follow-up period (12–25-month recall group). The healed rate for the entire population was 78.6%, and there was no difference in healed rates between the 2 obturation materials (Table 1). The 12–25-month recall group had a healed rate of 85.5%, and there was not a detectable difference in healed rates between the 2 obturation materials (Table 2). Similarly, the rates of nonhealed between Resilon and gutta-percha did not differ for either the entire pop-

ulation or the 12–25-month recall group. Next, we evaluated the subsets of teeth having preoperative periapical radiolucency. The healed rate for the subset of teeth with preoperative radiolucency within the entire population was 66.2%, and no difference was found between the healed rates of the 2 obturation materials (Table 3). The healed rate for the subset of teeth with preoperative periapical radiolucency within the 12–25-month recall group was 76%, and no difference was found between the healed rates of the 2 obturation materials (Table 4). Finally, we conducted multivariate logistic regression analysis, which indicated that the type of obturating material had no significant effect on the healed outcome for either the entire population of 103 cases (odds ratio, 0.74; $p = .66$) or for the 12–25-month recall group of 83 teeth (odds ratio, 0.48; $p = .42$). Thus, within the limitations of the present study design, our results indicated that the type of obturation material used had no detectable difference in the outcome of endodontic treatment.

In this study, age was shown to be significant only in the logistic regression model of the 12–25-month recall group. In this model, tooth position tended to interact with patient age. Age was shown to be a significant factor only when leaving tooth position in the model. However, the multivariate logistic regression model of the entire population did not show age to be a factor affecting the outcome. In addition,

TABLE 4. Univariate Analysis Summary of Variables by Outcome of Healed and Nonhealed for 50 Teeth with Preoperative Radiolucency and Recall Times Ranging from 12–25 Months

	Outcome			p Value
	Healed	Nonhealed	Total	
Age				.39*
N (%)	38 (76.0)	12 (24.0)	50 (100)	
Mean (SD)	53.8 (14.2)	57.7 (9.6)	54.8 (13.3)	
SEM	2.3	2.8	1.9	
Median	54.5	59	56.5	
Minimum, maximum	26, 83	40, 77	26, 83	
Gender, n (%)				0.19†
Male	16 (66.7)	8 (33.3)	24 (100)	
Female	22 (84.6)	4 (15.4)	26 (100)	
Total	38	12	50	
Tooth position, n (%)				0.2†
Anterior	3 (50.0)	3 (50.0)	6 (100)	
Premolar	9 (75.0)	3 (25.0)	12 (100)	
Molar	26 (81.3)	6 (18.7)	32 (100)	
Total	38	12	50	
Obturation material, n (%)				1†
Resilon	21 (77.8)	6 (22.2)	27 (100)	
Gutta-percha	17 (73.9)	6 (26.1)	23 (100)	
Total	38	12	50	
Appointments, n (%)				.47†
Single	28 (80.0)	7 (20.0)	35 (100)	
Multiple	10 (66.7)	5 (33.3)	15 (100)	
Total	38	12	50	
Pulp diagnosis, n (%)				.15†
Vital	7 (100)	0 (0.0)	7 (100)	
Nonvital	21 (77.8)	6 (22.2)	27 (100)	
Filled	10 (62.5)	6 (37.5)	16 (100)	
Total	38	12	50	
No. of canals obturated, n (%)				1†
Single	9 (75.0)	3 (25.0)	12 (100)	
Multiple	29 (76.3)	9 (23.7)	38 (100)	
Total	38	12	50	
Recall time, n (%)				1†
12–18 mo (intermediate)	5 (83.3)	1 (16.7)	6 (100)	
>18 mo (long)	33 (75.0)	11 (25.0)	44 (100)	
Total	38	12	50	

SD, standard deviation; SEM, standard error of the mean.

**t* test.

†Fisher exact test.

univariate analysis of both groups and subsets of the groups with a preoperative lesion did not show age to be a significant factor affecting the outcome. Thus, our results are similar to many studies (14, 18–21, 26), but not all (23), in which patient age had a weak or nondetectable effect on treatment outcome.

The Toronto Study, Phase 3 (20) reported a statistical difference in healed rates between teeth with 1 root (92%) versus 2 or more roots (83%). This result is similar to some (26) but not all (23) studies. In the present study, multivariate analysis demonstrated a significant effect

for tooth location, but only for the entire population. No detectable difference was noted in the 12–25-month recall group.

Single versus multiple visits have been evaluated, with no detectable significant differences in the success of treatment (27). The results of this study are similar in that the number of appointments was not statistically significant in affecting the outcome for either the entire population or the 12–25-month recall group.

Some studies have shown pulpal vitality to have no effect on the outcome of treatment (18–22), whereas other studies have shown it to

TABLE 5. Multivariate Logistic Regression Analysis Summary of Variables By Outcome of Healed for 83 Teeth with Recall Times Ranging from 12–25 Months*

Variable	Level	Odds Ratio†	95% CI‡	p Value
Age (per year increase)	Effect near 53 years	0.96	0.83–1.05	N/A§
Age squared (per year ² increase)		1.01	1–1.01	.02
Material	Gutta-percha vs Resilon	0.48	0.07–2.87	.42
Tooth position	Anterior vs premolar	0.2	0.01–4.44	.1
	Molar vs premolar	2.5	0.31–21.68	

*Logistic regression model is based on 38 subjects (26 healed, 12 nonhealed).

†Odds ratios are for probabilities of healed.

‡Profile-likelihood estimated CI.

§p value is not interpretable because of quadratic form of age effect.

TABLE 6. Multivariate Logistic Regression Analysis Summary of Variables By Outcome of Healed for 103 Teeth with Recall Times Ranging from 2–25 Months*

Variable	Level	Odds Ratio†	95% CI‡	p Value
Tooth position	Anterior vs premolar	0.82	0.07–9.16	.04
	Molar vs premolar	4.85	0.83–32.65	
Obturation material	Gutta-percha vs Resilon	0.74	0.18–2.85	.66
Recall time	Long vs short	8.47	2.1–41.78	.008
	Intermediate vs short	9.88	0.78–291.54	

*Logistic regression model is based on 58 subjects (36 healed, 22 nonhealed).

†Odds ratios are for probabilities of healed.

‡Profile-likelihood estimated CI.

make a difference in the outcome (14–16). In addition, retreatment of teeth has been shown to have a lower outcome of success as compared with initial endodontic treatment (21, 35). In this study, evaluation of both the entire population and the 12–25-month recall group showed through univariate analysis that pulpal vitality was a significant factor in affecting the outcome of treatment. The majority of nonhealed teeth for both groups were either nonvital or root-filled. Interestingly, the evaluation of vitality as a factor affecting the outcome of the subsets of teeth with a preoperative lesion indicated that there were vital pulps with preoperative lesions. This occurred as a result of the blinded assignment of PAI scores to each tooth for determining the presence of preoperative radiolucency.

The presence or absence of preoperative periapical radiolucency has been shown to be significant, with success being higher in teeth without a lesion (13–23). Univariate analysis of the entire population and the 12–25-month recall group determined that the presence of a preoperative lesion can affect the outcome. All nonhealed teeth had preoperative radiolucencies. However, multivariate analysis did not detect a statistical association of the presence of preoperative periapical radiolucency with the clinical outcome.

Recall times vary throughout the literature. Time is required for the body to heal, and healing might not be visualized, or it might be incomplete if a recall appointment is too soon. Complete healing, as well as improved healing, has been shown to increase as recall times become longer, and cases that are to fail as a result of the development of a lesion can mostly be detected by 24 months (24). The present study showed through univariate analysis and logistic regression that the length of recall time made a difference in the outcome of healed compared with nonhealed. The overall healed rate for the entire population with recall times of 2–25 months was 78.6%, and for the 12–25-month recall group, it was 85.5%. Univariate analysis of the entire population showed that 50% of the teeth with recall times of less than 12 months were considered nonhealed. Multivariate analysis of the entire population showed that recall times of 12 months and longer had significantly higher odds ratios of being healed when compared with recall times of less than 12 months.

In conclusion, the endodontic literature that evaluates success and failure is diverse. The parameters and methods of evaluation for determining the outcome of treatment vary among studies. In addition, the factors evaluated for prognostic purposes also vary among studies, as does the statistical method for evaluation. This makes assessment of the literature difficult in regards to what is deemed success and what factors might influence the outcome of treatment. This study found through univariate and multivariate analysis that the type of obturation material, gutta-percha and Kerr Pulp Canal Sealer or Resilon and Epiphany sealer, had no detectable difference in the outcome of endodontic treatment as assessed by PAI radiographic scoring and clinical symptoms. Univariate analysis indicated pulpal vitality, presence of a preoperative lesion, and length of recall times were statistically significant in affecting the out-

come, and multivariate logistic regression analysis showed age, tooth position, and length of recall times were also statistically significant in affecting the outcome.

References

1. Kakehashi S, Stanley H, Fitzgerald R. The effect of surgical exposures of dental pulps in germ-free and conventional laboratory rats. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 1965;20:340–9.
2. Bystrom A, Sundqvist G. Bacteriologic evaluation of the efficacy of mechanical root canal instrumentation in endodontic therapy. *Scand J Dent Res* 1981;89:321–8.
3. Bystrom A, Sundqvist G. Bacteriologic evaluation of the effect of 0.5% sodium hypochlorite in endodontic therapy. *Oral Surg Oral Med Oral Pathol* 1983;55:307–12.
4. Bystrom A, Happonen R-P, Sjogren U, Sundqvist G. Healing of periapical lesions of pulpless teeth after endodontic treatment with controlled asepsis. *Endod Dent Traumatol* 1987;3:58–63.
5. Sundqvist G, Figdor D. Endodontic treatment of apical periodontitis. In: Orstavik D, Pitt Ford TR, eds. *Essential endodontology: prevention and treatment of apical periodontitis*. Oxford: Blackwell Science Ltd, 1998:253.
6. Walton RE, Torabinejad M. *Principles and practice of endodontics*. 3rd ed. Philadelphia: WB Saunders, 2002:246.
7. Shipper G, Orstavik D, Teixeira F, Trope M. An evaluation of microbial leakage in roots filled with a thermoplastic synthetic polymer-based root canal filling material (Resilon). *J Endod* 2004;30:342–7.
8. Pitout E, Oberholzer TG, Blignaut E, Molepo J. Coronal leakage of teeth root-filled with gutta-percha or Resilon root canal filling material. *J Endod* 2006;32:879–81.
9. Biggs S, Knowles K, Ibarrola J, Pashley DH. An in vitro assessment of the sealing ability of resilon/epiphany using fluid filtration. *J Endod* 2006;32:759–61.
10. Key J, Rahemtulla F, Eleazer P. Cytotoxicity of a new root canal filling material on human gingival fibroblasts. *J Endod* 2006;32:756–8.
11. Tay FR, Pashley DH, Yiu CKY, et al. Susceptibility of a polycaprolactone-based root canal filling material to degradation: II—gravimetric evaluation of enzymatic hydrolysis. *J Endod* 2005;31:737–41.
12. Shipper G, Teixeira F, Arnold R, Trope M. Periapical inflammation after coronal microbial inoculation of dog roots filled with gutta-percha or resilon. *J Endod* 2005;31:91–6.
13. Conner DA, Caplan DJ, Teixeira FB, Trope M. Clinical outcome of teeth treated endodontically with a nonstandardized protocol and root filled with resilon. *J Endod* 2007;33:1290–2.
14. Kojima K, Inamoto K, Nagamatsu K, et al. Success rate of endodontic treatment of teeth with vital and nonvital pulps: a meta-analysis. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2004;97:95–9.
15. Chugal NM, Clive JM, Spangberg ISW. A prognostic model for assessment of the outcome of endodontic treatment: effect of biologic and diagnostic variables. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2001;91:342–52.
16. Hoskinson SE, Ng YL, Hoskinson AE, Moles DR, Gulabivala K. A retrospective comparison of outcome of root canal treatment using two different protocols. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2002;93:705–15.
17. Strindberg LZ. The dependence of the results of pulp therapy on certain factors: an analytic study based on radiographic and clinical follow-up examinations. *Acta Odontol Scand* 1956;14(Suppl 21):2–175.
18. Friedman S, Abitbol S, Lawrence HP. Treatment outcome in endodontics: the Toronto Study: phase I—initial treatment. *J Endod* 2003;29:787–93.
19. Farzaneh M, Abitbol S, Lawrence HP, Friedman S. Treatment outcome in endodontics: the Toronto Study—phase II: initial treatment. *J Endod* 2004;30:302–9.
20. Marquis VL, Dao T, Farzaneh M, Abitbol S, Friedman S. Treatment outcome in endodontics: the Toronto Study—phase III: initial treatment. *J Endod* 2006;32:299–306.

21. Sjogren U, Hagglund B, Sundqvist G, Wing K. Factors affecting the long-term results of endodontic treatment. *J Endod* 1990;16:498–504.
22. Seltzer S, Bender IB, Turkenkopf S. Factors affecting successful repair after root canal therapy. *J Am Dent Assoc* 1963;67:651–62.
23. Orstavik D, Qvist V, Stoltze K. A multivariate analysis of the outcome of endodontic treatment. *Eur J Oral Sci* 2004;112:224–30.
24. Orstavik D. Time-course and risk analyses of the development and healing of chronic apical periodontitis in man. *Int Endod J* 1996;29:150–5.
25. Reit C. Decision strategies in endodontics: on the design of a recall program. *Endod Dent Traumatol* 1987;3:233–9.
26. Field JW, Gutmann JL, Solomon ES, Rakusin H. A clinical radiographic retrospective assessment of the success rate of single-visit root canal treatment. *Int Endod J* 2004;37:70–82.
27. Sathorn C, Parashos P, Messer HH. Effectiveness of single- versus multiple-visit endodontic treatment of teeth with apical periodontitis: a systematic review and meta-analysis. *Int Endod J* 2005;38:347–55.
28. Orstavik D, Kerekes K, Eriksen HM. The periapical index: a scoring system for radiographic assessment of apical periodontitis. *Endod Dent Traumatol* 1986;2:20–34.
29. Lazarski M, Walker W, Flores C, Schindler W, Hargreaves K. Epidemiological evaluation of the outcomes of nonsurgical root canal treatment in a large cohort of insured dental patients. *J Endod* 2001;27:791–6.
30. Delano EO, Ludlow JB, Orstavik D, Tyndall D, Trope M. Comparison between PAI and quantitative digital radiographic assessment of apical healing after endodontic treatment. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2001;92:108–15.
31. Peters OA, Barbakow F, Peters CI. An analysis of endodontic treatment with three nickel-titanium rotary root canal preparation techniques. *Int Endod J* 2004;37:849–59.
32. Landis JR, Koch GG. An application of hierarchical kappa-type statistics in the assessment of majority agreement among multiple observers. *Biometrics* 1977;33:363–74.
33. Friedman S, Mor C. The success of endodontic therapy: healing and functionality. *J Calif Dent Assoc* 2004;32:493–503.
34. Mikrogeorgis G, Lyroudia K, Molyvdas L, Kikolaidis N, Pitas L. Digital radiographic registration and subtraction: a useful tool for the evaluation of the progress of a chronic apical periodontitis. *J Endod* 2004;30:513–7.
35. Farzaneh M, Abitbol S, Friedman S. Treatment outcome in endodontics: the Toronto Study—phases I and II: orthograde retreatment. *J Endod* 2004;30:627–33.