LONG TERM OUTCOMES OF ENDODONTIC TREATMENT PERFORMED WITH RESILON/EPIPHANY SYSTEM

PART 1: RADIOGRAPHIC OUTCOME ASSESSMENT OF ENDODONTIC TREATMENT WITH RESILON/EPIPHANY SYSTEM

PART 2: POST OPERATIVE FACTORS EFFECT ON OUTCOMES OF ENDODONTIC TREATMENT WITH RESILON/EPIPHANY SYSTEM

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ABSTRACT

Krista Andersen Strange: Long Term Outcomes of Endodontic Treatment Performed with Resilon/Epiphany System
Part 1: Radiographic Outcome Assessment of Endodontic Treatment Performed with Resilon/Epiphany System
Part 2: Post-Operative Factors Effect on Outcomes of Endodontic Treatment performed with Resilon/Epiphany System
(Under the direction of Peter Z. Tawil)

The purpose of this retrospective cohort study was to evaluate the radiographic and clinical outcome of the Resilon/Epiphany ™ obturation system and to determine if Resilon differed in healing. In part 1, 125 teeth were radiographically evaluated using Orstavik's PAI; 80 treated with Resilon and 45 with gutta percha. Age, gender, tooth position and number of months to follow up were documented and a multivariate analysis was performed. Resilon treated teeth were more likely to have a lesion at follow up when compared to gutta percha (p=0.009). Teeth presenting with pre-operative lesions, regardless of material used, were also more likely to present with a lesion at follow up (p=0.04). In part 2, 38 subjects were clinically evaluated. Bivariate analysis showed no difference in any clinical signs between Resilon and gutta percha and placement of a final restoration within 3 months of root canal completion, regardless of material, was beneficial (p=0.047).

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LIST OF ABBREVIATIONS

Ant	Anterior
CBCT	Cone beam computed tomography
GP	Gutta percha
PA	Periapical
PAI	Periapical Index
PCL	Polycaprolactone
Post	Posterior
R	Resilon
RCT	Root canal treatment
UNC-CH-SOD	University of North Carolina at Chapel Hill, School of Dentistry

THESIS INTRODUCITON

Endodontics is the field of dentistry specifically designed to prevent and treat injuries and diseases to the dental pulp and periapical region (1). A proper chemomechanical preparation of the root canal with antibacterial irrigation and mechanical instrumentation is critical to properly disinfect the canal space. Placement of a root canal filling and coronal restoration are equally as important steps in treatment to ensure a proper barrier from a secondary bacterial infection (2). The root canal filling should be biocompatible, dimensionally stable, able to seal both apically and coronally, insoluble to tissue fluids, bacteriostatic, radiopaque, and removable from the canal if a re-treatment is needed (1).

Gutta percha is one of the most widely used obturation material in practice today (3). It is composed of 20% gutta percha, 66% zinc oxide, 11% radiopacifier, and 3% plasticizer (4). It has multiple beneficial properties, such as biocompatibility, thermoplasticity, and ease of removal (5). Several methods of obturation with gutta percha have been used. Effective root canal obturation can be achieved with the injection-molded, thermoplasticized gutta percha method (6) and also cold lateral method (7). In an in vitro study using injection-molded, thermoplasticized gutta percha, radiographs showed uniformed density, close adaptation to the walls, a detailed replication of the canal system, and a good apical seal (6). Although its benefits are great, there is a critical element that gutta percha lacks: direct adhesion to the canal wall (8)(9).

Different obturation materials have been introduced into the market that claim to have superior if not equivocal results to gutta percha. Resilon (Resilon Research LLC, Madison, CT) was introduced in 2004 as a thermoplastic synthetic polymer alternative to gutta percha. It is composed primarily of a parent polymer polycaprolactone (25-40%), which is a biodegradable aliphatic polyester. The remaining fillers are bioactive glass, bismuth oxychloride and barium sulfate (10). Both Sodium and Calcium ions are released upon setting. The sealer, Epiphany™ Sealer (Pentron Clinical Technologies, Wallingford, CT), is a dual curable dentin resin composite sealer (11). Its bond occurs under chemical reaction, a halogen curing light, and with the Primer, which prepares the canal wall to get in contact with Resilon and the sealer (12). When Epiphany ™ sealer is used with Resilon, a bond is said to be created to both the canal wall and the core canal filling material. This type of obturation system is considered a single entity which forms a "Monoblock"(13). This "monoblock" is due to Resilon containing 3-10% dimethacrylates, which enables it to bond to methacrylate-based resin sealers to create a continuous chemical union (14). This method claimed to have less leakage than the traditional gutta-percha with sealer (11).

Although this obturation system had received much support after its introduction, there are several undesirable properties that have been discovered over time including its degradation, lack of a true monoblock, shrinkage of the sealer, and lack of antibacterial properties. Resilon consists of 25-40% polycaprolactone (PCL), which is itself biodegradable in nature and susceptible to enzymatic hydrolysis by endodontic bacteria and fungi (15)(16). Gutta percha was found to be inert against the activities of these enzymes and did not degrade when exposed to them (17). Through scanning electron microscopy, Tay et al. showed that gaps were present

between AH Plus sealer and gutta-percha as well as gaps present between Resilon and the Epiphany™ sealer. This indicated that a hermetic apical seal, which Resilon based its superiority on, was not occurring. The finding was likely due to rapid polymerization contraction of the Epiphany™ sealer (18). When bonding to the narrow root canal the configuration factor (C-factor) imposes many challenges including great polymerization shrinkage. C-factor is the ratio of bonded surface area to the unbonded surface area in a cavity. In a long narrow root canal, the unbonded surface area becomes smaller and has insufficient stress relief creating a high probability that multiple bonded areas will debond. The C-factor in a canal has been shown to be extremely high (over 1000) when compared to indirect intracoronal restorations (19). It is doubtful that the Resilon sealer bonds can resist this shrinkage stress (20). The presence of sodium hypochlorite, the primary irrigant used in almost every endodontic procedure, has also been shown to significantly reduce the bond strength of resin to dentin. The technique of riding the canal of sodium hypochlorite for better bonding of Resilon presents as another challenge. It is not only difficult to fully visualize the canal space but hard to fully rid the canal of moisture, since the narrow canals can hold water by surface tension (21). In addition to studies on the bonding effectiveness of Resilon, its antibacterial properties have also been reviewed. An in vitro study showed that Resilon did not display any antibacterial properties, whereas gutta percha inhibited *F. nucleatum* and *A. naeslundii* (22). It seems the properties that attracted many clinicians to use Resilon are not being supported by recent findings and their claims of its superiority to gutta percha are weak.

Even with a favorable prognosis and proper techniques re-infection of the canal space can still occur, resulting in an unfavorable procedure. Bacteria from the oral environment can invade

the canal system through exposed dentin at the gaps of restorations, which can result in periapical inflammation (23). The root canal system can also be re-infected during or after treatment in several ways. Delaying the placement of the coronal restoration, leakage of the temporary filling, tooth fracture and recurrent decay can all subject the tooth to re-infection.

Radiographs can be used to assist in determining the treatment outcome. When root resorption is observed, when a new periapical lesion is found or when an existing periapical lesion has grown, the prognosis of the tooth changes and can be considered unfavorable (1). In studies evaluating primary endodontic treatment success, teeth with pre-operative radiographic lesions consistently have lower success rates than those without any periapical pathosis (24). When taking into account studies without bias and with high levels of evidence the proportion of completely healed root canal treated tooth after initial treatment ranges from 75% to 86% (25). Rates of failure of traditional gutta-percha obturation techniques is dependent on whether an apical radiolucency is present pre-operatively. In cases with no lesion, success ranges from 89.5-95.4% In teeth with apical radiolucencies the success ranges from 75.5-82.7% (26)(27). The healing rate of Resilon vs gutta percha in an in vivo 12-month minimum follow up was found to have no significant difference (28). Another retrospective study with 12-25 month follow-ups also found indistinguishable differences in clinical outcome between the two obturation methods (29). Resilon's outcome is clearly not superior to gutta percha, as many have tried to show. It is apparent that this material has no short-term benefit to the traditionally used gutta percha.

A recent study out of Texas A&M found that Resilon obturated teeth had 5.7 times greater chance of failure when compared to gutta percha (30). This material was used at Texas A&M for a 5-year span and the average follow up for Resilon was 5.8 years. Not only was

Resilon used for a 9-year span at UNC but it was first introduced in an academic setting at UNC-SOD. Its precise technique was taught to faculty and students by the pioneers behind this material. By examining the outcome of Resilon treated cases at its primarily used University, and through a longer 9-year period, this study will establish a stronger level of evidence to assess the healing ability of this material when compared to gutta percha. The objective of study is to determine if the long-term outcome of Resilon differs from classic gutta percha.

Healing following non-surgical root canal treatment is dependent on multiple factors. These factors can occur before any treatment is rendered, during root canal shaping and filling, and after completion of root canal therapy. Although we know many prognostic factors of healing and failure, it would be beneficial to the clinician to know whether a particular obturation system's mode of failure was the same or different from another. This would aid that practitioner in better choosing treatment options if the primary non-surgical root canal treatment was unsuccessful and further treatment needed to be rendered.

In 1979 Crump created the mnemonic POOR PAST to assist clinicians in their differential diagnosis in endodontic failure. P-perforation; O-obturation; O-overfill; R-root canal missed; P-periodontal disease; A-another tooth; S-split tooth; T-trauma (31). Although these are not the only causes of root canal failure it is a wonderful basis to begin ones thought process on the etiology of failure.

Radiographs are commonly used to evaluate the health of the periapical structure. When a periapical lesion is present pre-operatively there is a negative impact on treatment outcome (32)(33)(34). In a prospective study the treatment outcome was most affected by pre-operative periapical pathosis(33). In addition to radiographic signs of health or disease, patient

demographics have also been shown to affect the outcome of root canal treatment. In a 2 year follow up of over 100,000 teeth treated with primary endodontic treatment the incidence of subsequent extraction increased with patient age (35). An epidemiological study also suggested that increasing age can contribute to decreased retention of endodontically treated teeth (36). The tooth position has also been evaluated in regards to effect on treatment outcome. In a prospective study, tooth type was shown to have a strong effect on healing, maxillary and mandibular molars being the location with higher success (37). After root canal treatment is completed the presence and quality of coronal restoration has been found to be even more important than the quality of the root canal fill (38). In a prospective study of factors affecting outcomes of non-surgical root canal treatment good-quality coronal restoration significantly increased the odds success by 11-fold (37). Leakage into the coronal restoration can be due to delay in a final restoration, fracture of the existing restoration or if less than 5mm of gutta percha remains apical to a post space (39). If the coronal seal is compromised the literature states a range of time in which exposure to the oral environment can contaminate the canal(s). In vitro studies show in as early as 3 days (40), 30 days (41) or up to 3 months (42) of exposure, the root canal system can be irreversibly contaminated. In addition to the coronal seal, the apical seal is also of concern if leakage occurs, leading to treatment failure (43)(44). If there are voids present, especially more apically, failure is more common than if no voids existed (45). Azim et. al in a prospective outcome study evaluated over 400 teeth for 2 years and determined the density of root fillings significantly affected the treatment outcome (46). It is clear that a quality coronal restoration completed quickly after root canal treatment is also necessary for healing as well as a shaping and

obturation technique that mimic's the original canal and exhibits proper length and density of fill.

By comparing the modes of failure of Resilon and gutta percha cases, this study will determine if one material has a less favorable outcome. Having this knowledge can assist in deciding the best treatment option for non-healing Resilon filled root canals and how to secure better outcomes. By having a greater understanding of the etiology of the failure, the decision between non-surgical retreatment or apical microsurgery with root end filling could be aided.

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MANUSCRIPT 1: RADIOGRAPHIC OUTCOME ASSESSMENT OF ENDODONTIC TREATMENT PERFORMED WITH RESILON/EPIPHANY SYSTEM

Introduction

Resilon with Epiphany™ Sealer was brought to market in 2004 as a new method of root canal obturation and was introduced at the University of North Carolina – Chapel Hill (UNC) in that same year. Both predoctoral and graduate endodontic students were taught the bonding technique required for its use. This material, as well as the traditionally used gutta percha (Diadent Group International Burnaby, BC Canada) with AH Plus© sealer (Dentsply, De-Trey GmbH, Konstanz, Germany), was in use over a 9-year span in the UNC endodontic clinics. While Resilon was initially thought to create a "monoblock" seal between the material and the canal(1), in vitro studies later suggested this concept to be flawed (2). Potential drawbacks of Resilon have been reported in several publications. Degradation to oral enzymes, shrinkage of its sealer, and lack of antibacterial properties compared to gutta percha were all reported (3)(4)(5). The long-term outcome of Resilon in comparison to gutta percha using a proven radiographic index has not been assessed. The purpose of this study was to radiographically evaluate the outcome of Resilon treated root canals to traditional gutta percha.

Materials and Methods

Institutional Review Board approval for this retrospective clinical study was obtained from the Biomedical Review Board at the University of North Carolina at Chapel Hill (16-1069).

Patients who were 18 years or older, had completed root canal treatment (dental codes D3310, D3320, D3330) during the time period of 08/2004 – 08/2013, and had been treated in the predoctoral or graduate Endodontic clinic were identified through a search of the electronic patient records. Patients whose dental records did not include a radiograph immediately after the original root canal treatment or specify which material was used for obturation (Resilon or gutta percha) were excluded.

Patient record review indicated that 7,376 patients were seen for primary root canal treatment during the specified time period in either the predoctoral or graduate Endodontic clinic. Five hundred eighty patients that met the inclusion and exclusion criteria were randomly selected and telephone calls were made to the primary number on file. If there was no answer, a scripted voice message was left and the secondary number on file was then called. One hundred twenty-five (21.6%) patients agreed to come into the Endodontic clinic for a follow up visit and signed a consent form.

Sample Size Estimation

After a preliminary sample of 50 teeth, using NQuery ®, a sample size estimation indicated that a two-group chi square test with a 0.05 two-sided significance level would have greater than 80% power to detect a 25% difference in healing between Resilon and gutta percha using an unequal sample size ratio of 1.5. An unequal sample size was used as Resilon treated cases were more numerous during the time frame studied.

Treatment

The follow up examination was performed under supervision of board certified endodontists. Patient age, gender, tooth type (Ant vs Post) and the obturation material used (R or

GP) were recorded and the presence or absence of a pre-operative periapical lesion was also documented. Two digital periapical images of each tooth were collected for evaluation using Photostimulable Phosphor Plates (Gendex: DenOptix QST PSP #2 Plates) with Rinn XCP precision instrument (Rinn Corp., Elgin, IL). The plates were scanned into the company recommended scanning device (Gendex: DenOptix QST Class 1 Laser Scanner). The first image was taken immediately after root canal treatment, and the second at the most recent follow up. The time from initial root canal treatment to the most recent follow up was recorded to the nearest month. At the recall visit, diagnostic tests were performed on the treated tooth and patient symptoms were recorded.

Recording of Data

The information gathered at the follow up examination was recorded during the appointment on an assessment form specific for each patient. This information was then transferred to a Microsoft Excel database (© 2017 Microsoft). Before the periapical images were evaluated, two board certified endodontists (P.T.) (H.W.) were calibrated to interpret the images using Orstavik's PAI calibration kit of 100 periapical radiographs. Intra- and interexaminer reliability was done using the calibration kit with study radiographs and assessed using Cohen's Kappa statistic. The inter-examiner reliability was found to be in nearly perfect agreement (k=0.87). The intra-examiner reliability was also excellent (k=0.90).

The post-treatment and follow up images were viewed and assessed under similar lighting and monitor screens. The index was scored from 1 to 5 with the following descriptions 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

The examiners (P.T.) (H.W.) were masked to the material used for obturation. They evaluated and ranked the radiograph immediately following root canal treatment and the follow up radiograph of each tooth according to the PAI criteria. Multi-rooted teeth were given one score: the highest score of any of the roots. If there was disagreement greater than 1 rank, the two examiners met at a later time to discuss the images until consensus agreement was reached.

Outcome Assessment

The radiographic data was dichotomized into no lesion present (PAI scores of 1 and 2) and lesion present (PAI scores of 3,4 and 5).

Statistical Analysis

Bivariate analysis to compare the obturation materials was performed using chi-square for nominal variables and Wilcoxon rank-sum for continuous variables. Proc-Genmod (SAS ® Vers 9.3), as a conditional logistic regression analysis, was used to assess the effect of material, months to follow up, presence of a pre-operative lesion, age, gender and tooth position on the presence of a follow up lesion. The level of significance was established as $p < 0.5$.

Results

The majority of the 125 subjects were female and had a root canal of a posterior tooth (Table 1). Forty-three percent of the subjects had presented with a pre-op lesion and 36% had a follow up lesion. Eighty subjects had Resilon used as the obturation material and 45 gutta

percha. There were no statistically significant differences between the two obturation materials with respect to gender, tooth position, or age (Table 1). The two materials were statistically significantly different with respect to presence of a pre-operative lesion, presence of a follow up lesion and months to follow up (Table 1). Subjects with Resilon had a higher percentage of pre-operative lesions, a higher percentage of follow up lesions, and a longer time to follow up. Follow up periapical radiographs of Resilon and gutta percha treated teeth showed varying levels of healing (Figure 1).

In the multivariate analysis, age, gender, tooth position, and months to follow up were not statistically significantly associated with the presence of a follow up lesion when the presence of an initial lesion and material were controlled for (Table 2). The presence of a pre-operative lesion and the type of material used for obturation were statistically significant when controlling for the age, gender, tooth position, and months to follow up (Table 2). Both the lack of an initial lesion and having gutta percha were protective i.e. individuals with an initial lesion and those receiving Resilon were more likely to have a follow up lesion.

Table 1: Characteristics for All Subjects and a Comparison of the Two Obturation Materials

	ALL N, %	**Resilon** N, %	**Gutta Percha** N, %	**P value**
Gender				0.73
Male	53, 42.4%	33, 41.3%	20, 44.4%	
Female	72, 57.6%	47, 58.7%	25, 55.6	
Tooth Position				0.77
Ant	26, 20.8%	16, 20%	10, 22.2%	
Post	99, 79.2%	64, 80%	35, 77.8%	
Pre-Op Lesion				0.015
Yes	54, 43.2%	41, 51.3%	13, 28.9%	

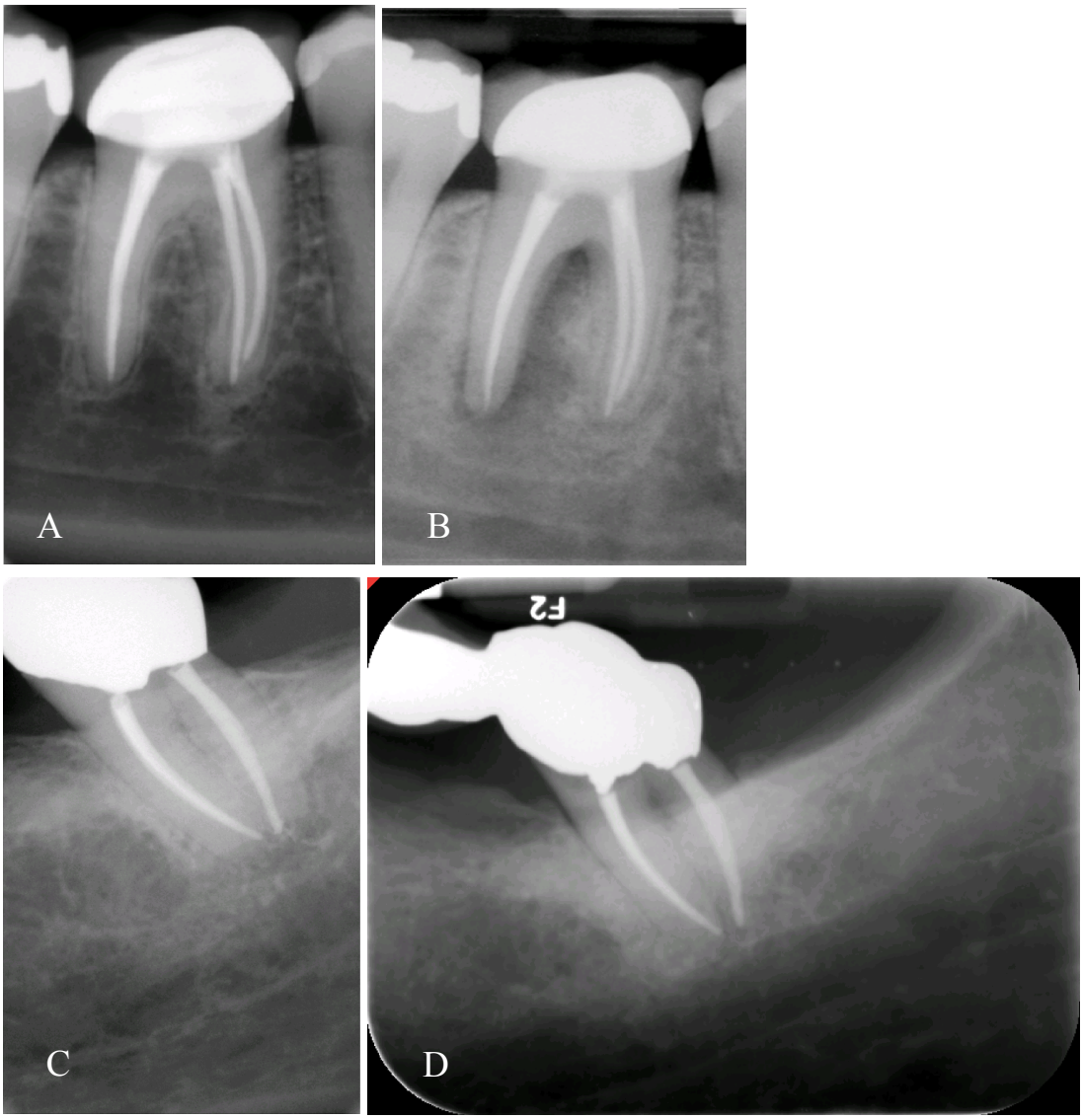
No	71, 56.8%	39, 48.7%	32, 71.1%			
Follow Up Lesion						0.0004
Yes	45, 36%	38, 47.5%	7, 15.6%			
No	80, 64%	42, 52.5%	38, 84.4%			

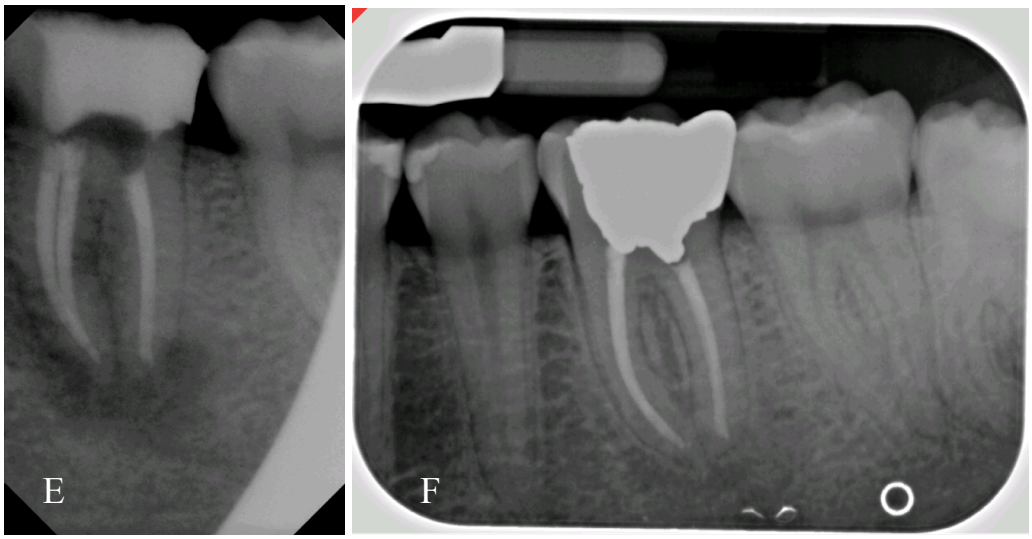
	ALL			**Resilon**			**Gutta Percha**			**P value**
	N	Median	IQR	N	Median	IQR	N	Median	IQR	
Age	125	56	19	80	57.5	19.5	45	54	20	0.70
Months to Follow Up	125	49	63	80	62.5	62	45	26	19	<0.0001

Table 2: Odds Ratio from the Multivariate Analysis of the Presence of a Follow Up Lesion. A negative estimate indicates a protection factor.

Variable	**Estimate**	**Error**	**95% CI**	**P value**
Pre-Op Lesion	-0.87	0.42	-1.7 – (-0.05)	0.04
Material	-1.67	0.64	-2.9 – (-0.42)	0.009
Months to FU	-0.16	0.24	-0.6 – 0.3	0.49
Age	-0.02	0.02	-0.05 – 0.02	0.34
Gender	-0.56	0.49	-1.5 – 0.39	0.25
Tooth Position	-0.10	0.48	-1.04 – 0.84	0.84

Figure 1: Post treatment (A,C,E) and follow up (B,D,F) radiographs of (A) Resilon treated #30 with PAI score of 1 (B) 3.5 year follow up of #30 with PAI score of 5 (C) Resilon treated #18 with PAI score of 3 (D) 11.9 year follow up of #18 with PAI score of 1 (E) Gutta percha treated #19 with PAI score of 4 (F) 1.3 year follow up of #19 with PAI score of 1





DISCUSSION

This study represents the longest outcome data available for a comparison of Resilon and gutta percha materials. The use of Resilon was introduced at UNC by those who pioneered this product and its use was continued for almost a decade. Fortunately, this meant that the sensitive technique of the bonded material was taught to both the faculty and students at UNC at the introduction of the material into clinical practice. This puts this data set in a unique advantage in providing a good level of evidence in the long-term outcome of Resilon.

All subjects treated at UNC were treated under standard protocol, one for Resilon, and one for gutta percha, that was taught to predoctoral and graduate students by instructors that were familiar with both obturation techniques. From the 580 subjects that fit our inclusion and exclusion criteria, 125 subjects had a follow up visit for a follow up rate of 21.6%, which is comparable to other long-term outcome studies (6). The minimum follow up for both materials was 12 months, as it has been shown that initiated healing can be observed in 89% of cases in as early as 1 year (7). The maximum follow up of Resilon and gutta percha was 12.4 years and 12.1

years respectively. While both Resilon and gutta percha were in use from 2004-2013, gutta perhca was more common clinically in the later years. Resilon patients were recalled primarily from the beginning of Resilon's implementation as well as the last year of its use which explains why the follow up for gutta percha was on average less than Resilon.

The primary outcome for this study was radiographic healing. This was established by using Orstavik's proven PAI to evaluate the periapical structure of the treated teeth. We chose to dichotomize the data into either a lesion not being present (PAI 1,2) or a lesion being present (PAI 3,4,5). By dichotomizing our data these ranks could be sorted into two distinctive and radiographically separate groups. The multivariate analysis, shown in Table 2, controlled for all other explanatory variables. We found that Resilon treated teeth were more likely to have a periapical lesion at follow up than the control material, which was found to be statistically significant ($p=0.009$). We also determined that a tooth with a pre-operative lesion, regardless of material used, was more likely to have a follow up lesion ($p=0.04$). This agrees with many classic and current studies that pre-operative pathosis has a negative effect on treatment success (8)(9).

Regardless of the positive findings reported in in-vitro studies of Resilon (10)(11) clinical studies should influence the materials used in the clinic setting. Resilon and gutta percha showed an indistinguishable difference in healing outcome in a 12-25 month retrospective follow-up (12). This study evaluated 103 teeth, 68 of which were evaluated between 18 and 25 months. The other 35 were evaluated less than 18 months. The only other long-term outcome study on Resilon was a 5.6 month follow up recently published in 2017 by Barborka et al (13). There were similarities in the study design between these two papers and ours. Both our paper and Cotton et

al. used Orstavik's PAI to score the periapical images of teeth at time of treatment and at follow up. Gutta percha was used as a control for comparison with Resilon in the Cotton et al, Barborka et al, and our paper. A large difference between Barborka et al. and our paper was how they radiographically assessed healing. Instead of using a proven periapical index they chose to evaluate the images side by side with a study derived definition of success. They also did not actively recruit patients with phone calls or use a power analysis to determine the amount of cases needed in each group.

There are potentially several reasons for the decreased outcome of Resilon. The first being the composition of the material. Polycaprolactone, the biodegradable polyester compromising a majority of Resilon, was suggested to result in severe surface pitting and erosion (3). The adhesive property of Resilon was also shown to not be as predictable in the long narrow canal even with aid from a surgical microscope. The effectiveness of the bond was also a concern as it is difficult to avoid over-thinning of the adhesive (14). In an in vitro study, the presence of gaps along the core/sealer/dentin interface was shown to potentially create an environment for leakage and re-infection (2). A retrospective study used data from PA radiographs and CBCT scans to examine various factors affecting the outcome of root canal treatment. The density of the root filling was identified in both PA and CBCT as a predictor that significantly influenced the treatment outcome (15). Figure 1 shows several periapical radiographs of Resilon and gutta percha treated teeth. While recalling patients we noticed that despite the highly dense and radiopaque appearance of Resilon treated teeth (A), large periapical lesions were seen upon follow up (B). Resilon was advertised as more radiopaque than gutta percha (16), so it is possible that the extreme radio-opacity was masking areas of voids during obturation. However, not every

Resilon treated case developed a periapical lesion. Resolution of periapical lesions were noted as well (D).

Although Resilon is no longer on the market there are countless patients that still retain Resilon treated teeth. As this study has shown that Resilon treated teeth present with more lesions at follow up we must ask the question if a "recall" of all Resilon treated cases is indicated. It may be necessary to advise these patients that their treatment may be compromised

CONCLUSION

Within the limitations of the study, the results demonstrate that teeth presenting with pre-operative lesions are more likely to have a lesion at follow up regardless of obturation material. Teeth that are obturated with Resilon present with more lesions at follow-up compared to gutta percha obturated teeth suggesting that there is no long-term benefit to this material as the healing capability of Resilon is inferior to gutta percha. It may be indicated to share these findings with patients that still retain Resilon treated teeth so that the appropriate follow ups can be scheduled.

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MANUSCRIPT 2: POST OPERATIVE FACTORS EFFECT ON OUTCOMES OF ENDODONTIC TREATMENT WITH RESILON/EPIPHANY SYSTEM

Introduction

The outcome of root canal treatment is influenced by many factors once the procedure is completed. Presence and quality of a final restoration has shown to be of equal importance to the quality of obturation (1). A full coverage crown after root canal treatment has been shown to increase fracture resistance (2) and the tooth survival rate against fracture when compared to teeth restored with resin composite (3). The timing of restoration placement is also a factor that has shown to have an effect of healing. Long-term survival rates of initial root canal treatment were adversely affected when the placement of the final restoration was delayed according to a national insurance database (4).

A thorough follow up clinical exam is an ideal way to determine the presence and type of final restoration and evaluate other sign and symptoms of disease. The objective of this study was to assess whether the difference in healing of Resilon and gutta percha treated root canals was related to the clinical signs of disease (swelling, sinus tract, mobility, percussion, and probing) or the presence, the type, and the timing of final restoration.

Materials and Methods

Institutional Review Board approval for this retrospective cohort clinical study was obtained from the Biomedical Review Board at the University of North Carolina at Chapel Hill

(16-1069). Patients who were 18 years or older, had completed root canal treatment (dental codes D3310, D3320, D3330) during the time period of 08/2004 – 08/2013, had been treated in the predoctoral or graduate Endodontic clinic, and had a full comprehensive clinical evaluation with an endodontic resident were identified through a search of the electronic patient records. Patients whose dental records did not include a radiograph immediately after the original root canal treatment or specify which material was used for obturation (Resilon or gutta percha) were excluded.

Patient record review indicated that 7,376 patients had primary endodontic treatment in either the predoctoral or graduate Endodontic clinic during the specified time period. Five hundred eighty patients were randomly selected and telephone calls were made to the primary number on file. If there was no answer, a scripted voice message was left and the secondary number on file was then called. One hundred twenty-five (21.6%) patients agreed to come into the Endodontic clinic for a follow up visit and signed a consent form. Of these, thirty-eight (30.4%) patient received a comprehensive intra- and extra-oral exam.

Treatment

Two endodontic residents performed all of the clinical exams under supervision of a board-certified endodontist. In addition to the data gained from the radiographic interpretation, other post-operative factors were collected to evaluate for potential prognostic factors. Presence of mobility, sensitivity to percussion, and probing depths greater than 3mm obtained with standard periodontal probe were noted. Presence of a final restoration and whether or not that restoration was a crown was recorded. The time from completion of the root canal to placement of the final restoration was documented to the nearest month. The restoration time was

considered to be ideal if placed within 3 months of root canal treatment completion. If the tooth being evaluated showed signs of re-infection the proper referrals were provided to the patient.

Recording of Data

The post-operative factors and patient information gathered at the follow up examination was recorded during the appointment on an assessment form specific for each patient. This information was then transferred to a Microsoft Excel database (©Microsoft 2017).

Statistical Analysis

Bivariate analysis was performed using Fisher's exact test for nominal variables and Wilcoxon rank-sum for continuous variables. The level of significance was established as $p < 0.5$. The power was established at 80.

Results

The majority of the 38 patients were male and had a root canal of a posterior tooth (Table 3). Fifty percent of the subjects had presented with a pre-op lesion and forty-five percent had follow up lesion. Thirty-one subjects had Resilon used as the obturation material and seven gutta percha. There were no statistically significant differences between the two obturation materials with respect to gender, tooth position, or age (Table 3). The majority of the 38 patients had a final restoration, and one that was a full coverage crown placed in the ideal amount of time. There were not statistically significant differences between the two obturation materials with respect to presence of percussion sensitivity, mobility, or deep probing depths (Table 3). Time to placement of restoration was dichotomized into within 0 to 3 months of root canal completion (ideal time) or longer. There were no statistically significant differences between the two

obturation materials with respect to placement of the final restoration in an ideal time. When evaluating the effect of time to restoration on follow up lesion, teeth presenting without a lesion had a median time to restoration of 2 months and teeth presenting with a lesion had a median time to restoration of 4 months. A shorter time to placement of final restoration (within 3 months) was found to be beneficial (p=0.047), regardless of the material used to obturate.

Table 3: Characteristics for All Clinically Evaluated Subjects and a Comparison of the Two Obturation Materials

	ALL	**Resilon**	**Gutta Percha**	**P value**
	N, %	N, %	N, %	
Gender				0.43
Male	21, 55.2%	16, 51.6%	5, 71.4%	
Female	17, 44.7%	15, 48.4%	2, 28.6%	
Tooth Position				0.62
Ant	8, 21%	6, 19.4%	2, 28.6%	
Post	30, 79%	25, 80.6%	5, 71.4%	
Pre-Op Lesion				1.00
Yes	19, 50%	15, 48.4%	4, 57.1%	
Follow Up Lesion				1.00
Yes	17, 44.7%	14, 45.1%	3, 42.9%	
Restoration				1.00
Yes	36, 94.7%	29, 93.5%	7, 100%	
Crown				1.00
Yes	29, 76.3%	24, 77.4%	5, 71.4%	
Ideal time				0.68
Yes	22, 57.9%	17, 54.8%	5, 71.4%	
Percussion				0.4
Yes	12, 31.6%	11, 35.5%	1, 14.3%	
Mobility				1.00
Yes	1, 2.6%	1, 3.2%	-	
Probing				1.00
Yes	5, 13.2%	4, 12.9%	1, 14.3%	

	ALL			**Resilon**			**Gutta Percha**			**P value**
	N	Median	IQR	N	Median	IQR	N	Median	IQR	

Age	38	57.5	19	31	57	20	7	60	17	0.88
Months to Follow Up	38	95	72	31	102	54	7	49	92	0.07

Discussion

In order to truly determine healing following non-surgical root canal treatment, an extra-oral and intra-oral clinical exam is indicated. Clinical findings along with updated radiographs give the practitioner everything needed to properly diagnose the tooth and assess the treatment's outcome. From our initial 125 subjects, 38 received a full comprehensive clinical exam. The majority of subjects evaluated clinically were Resilon (31/38). Since 80/125 of the initial subjects were Resilon, it would be expected that more Resilon treated subjects were able to have a full clinical exam. The presence of a restoration and the type of restoration, filing or crown, was documented. This was important, as endodontically treated teeth that have not been crowned after obturation have been shown to be lost at a 6.0 times greater rate than those crowned (5). Only 2 teeth total did not present with a final restoration, both Resilon treated. The first of the two teeth still contained the temporary. The second tooth's restoration was completely missing. If the root canal treatment was performed through a crown, and a core filling was placed afterwards, the tooth was considered to have a crown as its final restoration. The majority of Resilon and gutta percha treated teeth that had final restorations were full coverage crowns (77.4%, 71.4%). No statistical significance was found between the two materials and presence or type of restoration. The ideal time to restoration was an important factor to consider, as a delay in restoration can adversely affect a tooth's survival rate (4). A recent study showed teeth that received a crown 4 months after RCT were almost 3 times more likely to get extracted(6). We chose 3 months as the cutoff for a restoration to be considered placed in an ideal time as it is also

recommended at UNC dental school to place the final restoration on a root canal treated tooth within 3 months.

In the clinical exam, none of the 38 subjects had any signs of extra-oral/intra-oral swelling or presented with a sinus tract. Only 1 subject treated with Resilon presented with tooth mobility which was determined to be anything greater than Class 1 mobility. It was important to test percussion sensitivity as this can indicate inflammation of the periodontal ligament. A greater number of Resilon treated teeth exhibited sensitivity on percussion, however, this was not statistically significant ($p=0.4$). Using the biological width measurements of Gargiulo, any isolated probing depth greater than 3mm was considered to be positive for a periodontal probing. There was no statistically significant difference between the two materials and the number of teeth with probing defects ($p=1.00$). When our primary outcome was evaluated, regardless of the material used, we found teeth that had a final restoration placed within 3 months of root canal completion were less likely to have a PA lesion at follow up ($p=0.047$). When there was no lesion, the median time for placement of the restoration was 2 months. When a lesion was present the median time for placement of the restoration was 4 months.

Conclusion

Within the limited scope of this study there were no statistically significant differences in the clinical presentation of teeth obturated with Resilon or gutta percha. There were no statistically significant differences between the two obturation materials with respect to presence of a restoration, type of restoration, or placement of the final restoration in an ideal time. When all 38 teeth were evaluated, placement of the final restoration within 3 months of root canal completion, regardless of obturation material, was found to be beneficial. These teeth were less

likely to have a periapical lesion at follow up. This finding stresses the importance and benefit of a faster placement of the final restoration after root canal treatment has been completed. None of the other explanatory variables showed a statistical significance between the two materials. It appears that future studies with a higher subject number would allow for greater power to potentially find other significant factors and/or differences in prognostic factors between Resilon and gutta percha.

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THESIS SUMMARY

Resilon was brought to market in the dental community with its support mainly being from in vitro leakage and structural strength studies (1)(2). In vitro studies are very helpful from a proof of concept perspective and to aid the manufacturers in finding weaknesses and strengths of a material. It is however, critical to base the use of newly introduced clinical materials from clinical in vivo research so that the effectiveness and safety can be properly determined.

Our retrospective study evaluated the radiographic outcome of 125 subjects, and the clinical outcome of 38. When controlling for all explanatory variables, teeth treated with the Resilon/Epiphany ™ system were more likely to have periapical lesions at follow up when compared to gutta percha ($p=0.009$). This finding implies that Resilon treated teeth are not healing at a similar rate to the control material and its use is not warranted as there is no long-term treatment benefit. Although this material is no longer on the market, its use in the country spanned over a decade. There are countless patients that still have Resilon treated teeth. It may be necessary to advise patients of the new clinical findings and urge them to have a follow up examination. These patients may not be having any signs of infection or re-infection. In a recently published 20-year cohort study, of the teeth that presented with re-infection of the root canal system, 62% were asymptomatic (3). Our clinical evaluation did not show any significant difference in presence of percussion sensitivity, deep probing pockets, or tooth mobility between Resilon and the control.

Teeth that presented with apical lesions at the time of initial root canal treatment were also more likely to have a periapical lesion at their follow up, regardless of material used for obturation ($p=0.047$). The presence of a pre-operative lesion has been shown by many studies to be a major prognostic factor in treatment success(4)(5)(6), which this study also confirmed.

At UNC, the patient is advised to receive their final restoration within 3 months of the root canal treatment completion. At times the restoration can be placed immediately following RCT, other times a separate appointment is needed with the restorative provider. The data collected was dichotomized into teeth receiving final restoration within 0 to 3 months and those receiving the final restoration after 3 months. The clinical evaluation was able to show that the presence of a final restoration placed within 3 months after completion of root canal treatment was beneficial to the tooth's outcome, regardless of obturation material ($p=0.047$). Teeth without a lesion at follow up had a median time to restoration of 2 months, whereas teeth with a lesion at follow up had a median time to restoration of 4 months. A proper coronal seal placed in an appropriate amount of time is critical to root canal treatment healing.

These results should add to the current knowledge of Resilon and help aid practitioners who are following up with Resilon treated root canals. It appears that Resilon treated teeth present with decreased long-term healing when compared to gutta percha. Future studies to evaluate the reasons behind the greater presence of lesions in Resilon cases would be beneficial.

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APPENDIX A: PATIENT CONSENT FORM

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 07/22/2016
IRB Study # 16-1069
Title of Study: Long-term outcome assessment and treatment of Resilon obturation system compared to gutta percha.
Principal Investigator: Peter Tawil
Principal Investigator Department: Endodontics
Principal Investigator Phone number: 919-537-3403
Principal Investigator Email Address: pzt@unc.edu
Co-Investigators: Steven Card, Lesleigh Payne, Krista Andersen

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What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this study is to evaluate the long-term outcome of root canal therapy at the UNC graduate and undergraduate endodontic clinics. The materials used for treatment will be evaluated as well as other factors that could affect the success of treatment. Teeth that need retreatment will be examined for canal filling break down, flare-ups or other post-operative complications.

You are being asked to be in the study because you have had root canal therapy completed at UNC school of dentistry at a time where different materials were in use.

Are there any reasons you should not be in this study?

You should not be in this study if you are under the age of 18.

How many people will take part in this study?
There will be approximately 6,855 people in this research study.

How long will your part in this study last?
Your visits may range from one to four appointments over a maximum of three months with the investigators throughout the research study. The first interaction will be the standard of care follow up evaluation and introduction of the research study. It will last no more than 30 minutes. If re-treatment of the tooth/teeth in question is needed and deemed appropriate a questionnaire will be given for you to answer in between appointments. The completion of the questionnaire will take no more than 5 minutes and will be given to the investigator at the final appointment.

What will happen if you take part in the study?
As part of this research study, the researchers will also examine your dental records involving your treatment.

After your initial follow-up appointment, blinded and calibrated dental examiners who are apart of the research team will review your dental radiographs.

Following any treatment rendered, a questionnaire will be given to you between appointments, which should be returned to your investigator at the final appointment. This questionnaire will ask you to record any post-operative pain or swelling that occurred after the initial visit. You may choose not to answer a question for any reason.

The clinician who the patient is assigned to will be responsible for the patients welfare during the study.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
There are no foreseen immediate or long-term physical, psychological, or social risks/discomforts.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Every effort will be made to protect your privacy. All information collected in this study will remain confidential and only those directly involved in the study will have access to this information. All participants will be assigned numbers and all electronic data collected will be password protected on a secure UNC server. Paper documents will be stored in a locked filing cabinet in a locked office where only research participants will have access.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not receive any personal or financial benefit from being in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

APPENDIX B: HIPPA CONSENT FORM

University of North Carolina at Chapel Hill

HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study # 16-1069

Title of Study: Longterm outcome assessment and treatment of Resilon obturation system compared to Gutta Percha,
Principal Investigator: Peter Tawil
Mailing Address for UNC-Chapel Hill Department: CB:

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

---

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System and its members and affiliates (collectively, "UNCHCS"), health insurance plans, and government health agencies.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates to your participation in this research. This information may include medical and dental health history, clinic notes, radiographs, and clinic visit schedule.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the University of North Carolina at Chapel Hill or other affiliated entities conducting the research, or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

APPENDIX C: IRB APPROVAL LETTER

To: Peter Tawil
Endodontics

From: Biomedical IRB

Approval Date: 9/20/2016
Expiration Date of Approval: 9/19/2017
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Initial
Expedited Category: 5.Existing or non-research data,7.Surveys/interviews/focus groups
Study #: 16-1069

Study Title: Long-term outcome assessment and treatment of Resilon obturation system compared to gutta percha.

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

Study Description:

Purposes: To assess the long-term outcome and treatment of Resilon/Epiphany filled root canals compared to gutta percha filled root canals

Participants: Patients from the University of North Carolina School of Dentistry who received root canal therapy (dental codes D3310, D3320, D3330, D3999, D3346, D3347, D3348) that was completed using Resilon/Epiphany obturation system or gutta percha from August 1, 2004 - August 31, 2013.

Procedures: Electronic patient records will be reviewed, the standard of care radiographs will be scored, and a written survey will be conducted of a subset of the participants.

Regulatory and other findings:
The IRB has determined that the study-specific rationale provided by the investigator is sufficient to justify a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA authorization will be sought when applicable. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal

Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=16-1069.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

Please be aware that additional approvals may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Krista Andersen, Endodontics
Elisa Arnarsdottir, Endodontics
Steven Card, Endodontics
Ashraf Fouad, Endodontics
Michael Mittelsteadt, Endodontics
Lesleigh Payne, Endodontics
Nicholas Pettit, Endodontics
Ceib Phillips, Orthodontics
Eric Rivera, Endodontics
Pooja Saha, Biostatistics Operations
Mark Shallal-Ayzin, Endodontics
Tam Trinh, Endodontics
William Yeung, EndodonticsIRB

APPENDIX D: FIGURES

Figure 1: PAI Diagram & Radiograph 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.)

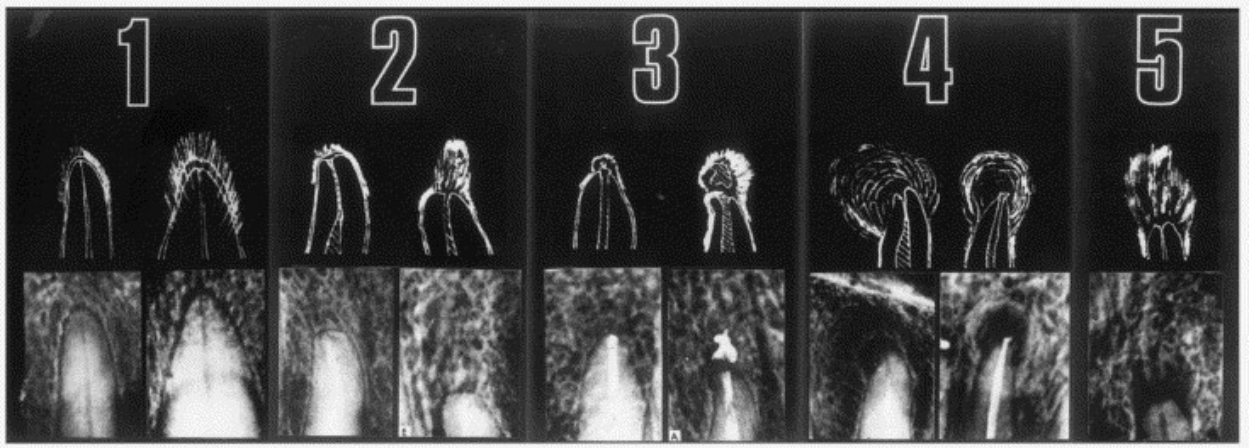
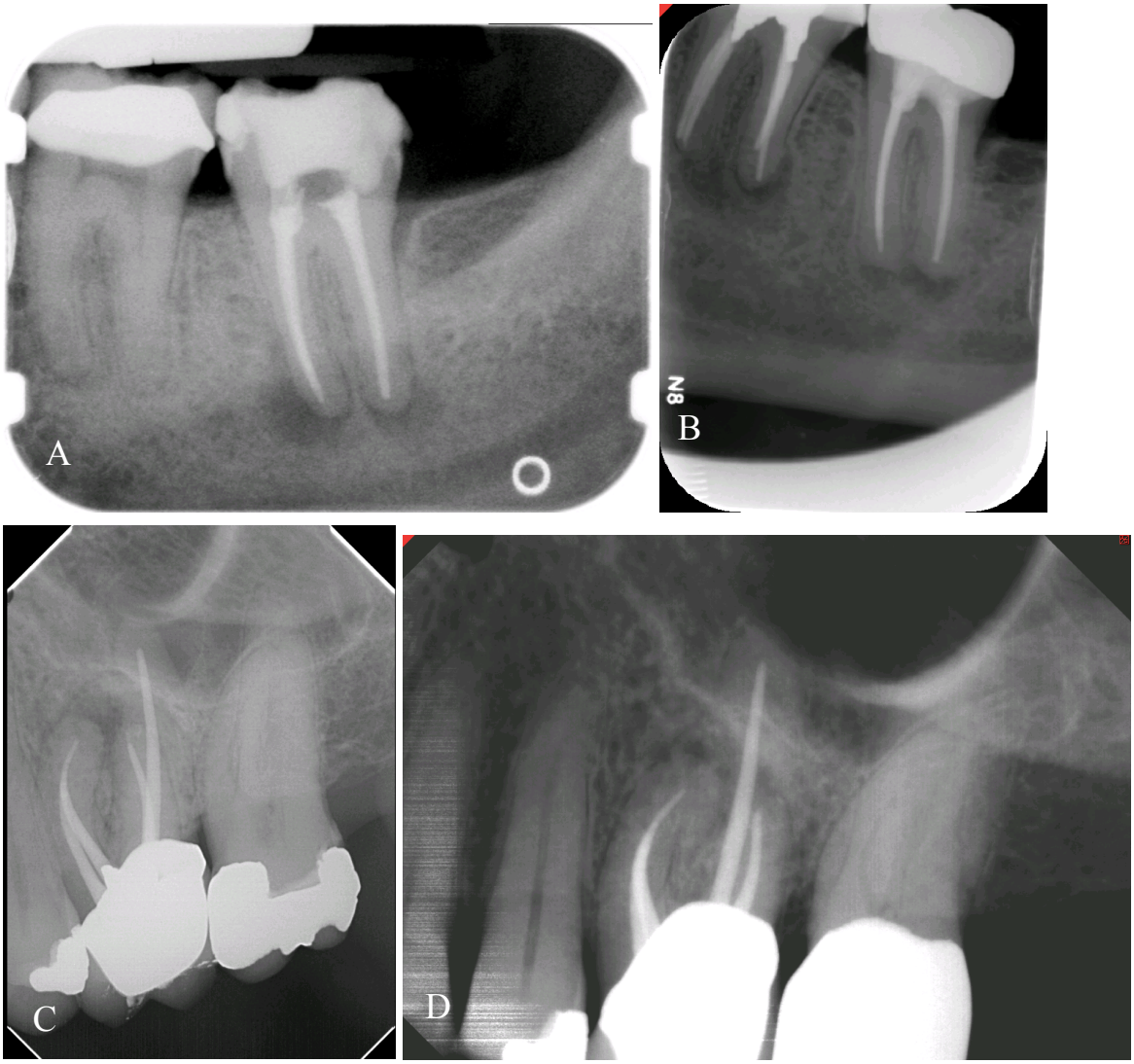


Figure 2: Post treatment (A,C,E,G) and follow up (B,D,F,H) radiographs of (A) Resilon treated #18 with PAI score of 4 (B) 9.5 year follow up of #18 with PAI score of 4 (C) Resilon treated #14 with PAI score of 4 (D) 3.5 year follow up of #14 with PAI score of 4 (E) Gutta percha treated #6 with PAI score of 5 (F) 1.4 year follow up of #6 with PAI score of 1(G) Gutta percha treated #13 with PAI score of 3 (H) 3.8 year follow up of #13 with PAI score of 1



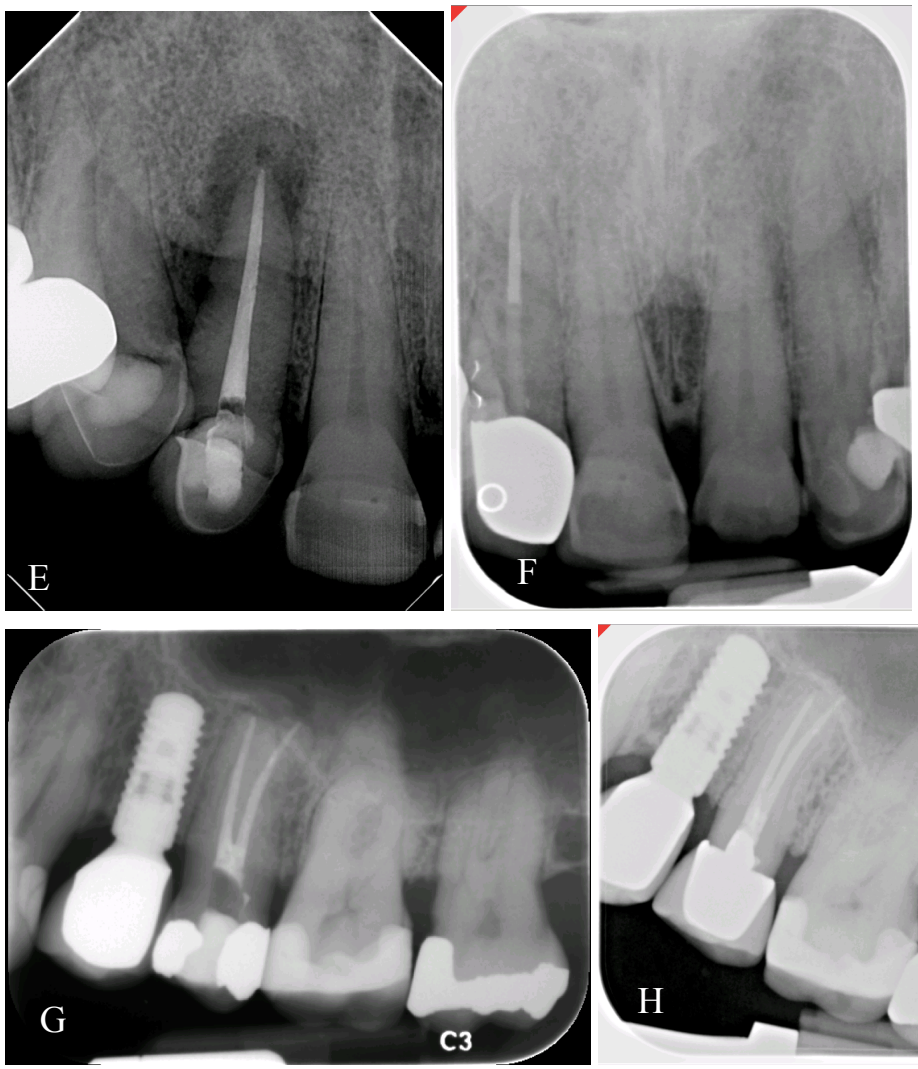

E
F
G
C3
H

Figure 3 – Subject Assessment Form: Clinical Examination

Long-term outcome assessment of Resilon compared to gutta percha – Dr. Strange

Initial Evaluation	Patient ID:		Date:
Age:	Gender:	Tooth #:	R or GP:
Date RCT completed:		Time to follow up (mo.)	

		Y	N
Head & Neck	Swelling Trismus TMJD LAD		
Intra Oral Eval	Swelling S.T. Mobile		

Pre-op Dx of original tx: Restoration present (Y/N): Type of Restoration: Time from RCT to Placement of restoration:

Diagnostic Testing
Endo Ice: EPT: Percussion: Probing: Palpation:
DX today:

Needs referral for further tx:
NO YES Clinic: