Long-term Clinical Outcome of Teeth Obturated with Resilon

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Abstract

Introduction: Although Resilon has been in clinical use as an endodontic obturation material for more than a decade, there is a lack of long-term clinical outcome studies. The purpose of this retrospective case-control study was to compare long-term clinical outcomes in teeth obturated with Resilon/RealSeal SE (RS) and GP/AH Plus (GP). **Methods:** One hundred teeth treated at Texas A&M University College of Dentistry between 2007 and 2012 were included; 50 teeth were obturated with RS and 50 with GP. All cases were initial treatments without preoperative periapical radiolucencies. Success and failure were assessed on the basis of clinical signs and symptoms and/or the presence of periapical radiolucency. Chi-square test and odds ratio were used to determine the association between the obturation material and outcome. Potential prognostic factors were evaluated including age, sex, tooth location, preoperative diagnosis, and one versus multiple visits. **Results:** The average recall time for RS was 5.8 years and 6.6 years for GP. Fifty-six percent of RS-obturated teeth were classified as successful at recall compared with 88% of GP-obturated teeth. RS had 5.7 times greater odds of failure compared with GP ($P < .001$). When periapical radiolucencies were present, they tended to be larger and involve multiple roots in the RS group compared with GP group. None of the prognostic factors examined were found to have any significant effect on outcome. **Conclusions:** Within the limitations of this study, teeth obturated with RS had 5.7 times greater chance of failure compared with teeth obturated with GP. *(J Endod 2017;43:556–560)*

Key Words

Clinical outcome, gutta-percha, obturation, Resilon, root canal treatment

Significance

This was a retrospective case-control study with a follow-up time longer than 4 years. Teeth obturated with Resilon were found to have 5.7 times greater chance of failure compared with teeth obturated with GP.

The primary objective of root canal treatment is to eliminate the etiology of pulpal or periapical diseases and to promote tissue healing (1). This objective is accomplished through root canal disinfection and obturation. Obturation is an important link of root canal treatment. Ideal obturation should create a fluid-tight seal to prevent bacterial and tissue fluid from reentering the root canal space and to entomb any potential remaining microorganisms/irritants (2, 3). The obturation material should possess excellent sealing ability and be dimensionally stable and biocompatible (4). Gutta-percha (GP) has been the most widely used root canal obturation material for more than a century. Although excellent clinical results have been achieved by using GP (5), it does not possess all the desired properties of an ideal obturation material. One of the most critical drawbacks of GP is its poor sealing ability and lack of bonding to sealer and root canal walls (6–8).

In 2004, Resilon emerged as a promising alternative to GP. It is a polycaprolactone polymer that contains bioactive glass and radiopaque fillers. It is described as a thermoplastic, synthetic polymer-based, bonded root canal filling material. Resilon was purported to bond to the adhesive sealer, which in turn bonds to dentin, therefore creating a monoblock and a better seal. The majority of early research on Resilon showed superior or equal sealing ability compared with GP (9, 10). Literature also suggested improved fracture resistance in teeth obturated with Resilon (11–13). Good biocompatibility and low cytotoxicity were demonstrated in *in vitro* and animal studies (14–17). Contrarily, the *in vivo* stability of Resilon and its ability to form a monoblock were challenged in a number of studies (18–20).

The ultimate evidence to support the use of an obturation material should come from clinical studies. Unfortunately, very few patient-based studies can be found to date that address the clinical outcome of this material. In a case series, Conner et al (21) showed an overall success rate of 89.4% with Resilon, which was "within the range of success rates for studies with uniform treatment techniques mostly in university settings with gutta-percha root filling." A retrospective study reported "statistically indistinguishable differences in clinical outcome" between Resilon and GP groups after 12–25 months (22). Finally, a case series of 21 patients treated with Resilon obturation showed treatment was clinically and radiographically successful in all cases at 6 and 12 months (23).

Although it was withdrawn from the commercial market in 2014, Resilon was in clinical use for more than a decade. In that time, several compatible sealers were mar-

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TABLE 1. Demographic Information on the Study Population

Demographics	RS, % (n/total)	GP, % (n/total)
Gender		
Male	52 (26/50)	40 (20/50)
Female	48 (24/50)	60 (30/50)
Age (y, mean ± standard deviation)	53.9 (±13.8)	55.5 (±15.3)
Follow-up time (y, mean ± standard deviation)	5.8 (±1.1)	6.6 (±1.6)
Tooth type		
Maxillary anterior	12 (6/50)	14 (7/50)
Maxillary posterior	46 (23/50)	50 (25/50)
Mandibular posterior	42 (21/50)	36 (18/50)

keted including Epiphany (Pentron, Wallingford, CT) and later RealSeal (Sybron, Orange, CA) among others. The earlier Resilon compatible sealers used a separate self-etching primer. All-in-one self-etching sealers were later introduced including Ephiphany SE (Pentron) and RealSeal SE (Sybron), which eliminated the separate priming step, allowing for more efficient obturation.

In recent years, anecdotal reports began to emerge suggesting higher failure rates in teeth obturated with Resilon, particularly when a one-step SE sealer was used. Discolored, partially disintegrated Resilon material was discovered during retreatment or apical surgery of these failed cases. These reports raised the question of long-term stability of the material and long-term success in teeth obturated with Resilon.

The purpose of this retrospective case-control study was to compare the long-term clinical outcomes of teeth obturated with RealSeal/SE and teeth obturated with GP/AH Plus. The null hypothesis is that the long-term success of teeth obturated with Resilon is not significantly different from that obtained with GP.

Materials and Methods

This study was approved by the Institutional Review Board of Texas A&M University College of Dentistry. An electronic records search identified patients who received root canal treatment at Texas A&M University College of Dentistry. Patients were selected on the basis of the following inclusion criteria:

1. Initial root canal treatment completed between 2007 and 2012
2. One of the following obturation materials was used:
   a. Resilon and Real-Seal SE sealer (RS)
   b. Gutta-percha and AH Plus sealer (GP)
3. Preoperative radiographs showing no periapical radiolucency (PARL)
4. Postoperative radiographs showing adequate obturation with no gross procedural errors

Patients' medical history was reviewed to ensure that all included patients had an American Society of Anesthesiologists classification of I or II. Patients with uncontrolled diabetes, acquired immunodeficiency syndrome, or other immunocompromised conditions were excluded. During the recall processes if a tooth met the inclusion criteria and it was discovered that a clinical and radiographic recall examination had been performed with adequate documentation, the case was considered for inclusion in the study. Patients were excluded from final analysis if a satisfactory permanent restoration was absent, or if there was evidence of vertical root fracture at the time of recall. The GP cases in the control group were identified to match the age, gender, and tooth type of the cases in the RS group.

All RS and the majority of GP treatment procedures were performed by endodontic residents who used semi-standardized protocols under surgical microscopes. Irrigation protocols included the use of 6% NaOCl during cleaning and shaping, followed by 17% EDTA before obturation. RS cases received a final 2% chlorhexidine rinse per the manufacturer's recommendations. Several GP cases were performed by dental students under the supervision of endodontic faculty. Patient age at recall, preoperative diagnosis, tooth location, and number of visits to complete root canal therapy were recorded. During patient recall a clinical exam and periapical radiographs were taken to assess clinical signs and symptoms of the treated tooth.

Three calibrated examiners (2 board-certified endodontists and 1 second-year endodontic resident) independently reviewed preoperative, postoperative, and recall periapical radiographs side-by-side for the included cases. In cases where there was disagreement among the evaluators, a discussion was carried out until a consensus was reached. The outcome assessment was categorized as follows:

1. Success: absence of any clinical signs or symptoms, normal periapical tissue with intact periodontal space and lamina dura or slightly widened periodontal ligament less than 2× normal periodontal width
2. Failure: clinical signs or symptoms and/or the presence of PARL

Recall periapical radiographs that exhibited PARLs were analyzed by using ImageJ (National Institutes of Health, Bethesda, MD) software to quantify the PARL area of the failed cases. Independent samples *t* test was used to determine any significant differences in PARL size between groups. Chi-square and odds ratio with associated 95% confidence intervals were calculated to determine the magnitude of association between the obturation material and outcome of root canal treatment. Chi-square was used to identify any significant prognostic factors including age, tooth location, preoperative diagnosis, and one versus multiple visits. A *P* value less than .05 was considered statistically significant.

TABLE 2. Areas of PARL in the RS and GP Groups (mm^2)

Material	n	PARL area (mean ± standard deviation)	*P* value
RS	22	19.1 ± 15.9	.988
GP	6	19.0 ± 26.0	

Results

One hundred study subjects were included in the final analysis. Fifty cases were obturated with RS and 50 with GP. The demographic information on the study subjects is summarized in Table 1. Average recall times for RS was 5.8 years and 6.6 years for the GP group. Average subject age at time of recall was 53.9 years for RS and 55.5 years for GP. Fifty-six percent of RS cases were classified as successful compared with 88% for GP cases. Six RS subjects had clinical signs and symptoms at recall compared with 1 subject from the GP group. Statistical analysis showed odds ratio of 5.7, indicating 5.7 times greater likelihood for failure for RS when compared with GP ($P < .001$).

The areas of PARL associated with RS-obturated teeth were not found to be significantly different from those associated with GP (Table 2). However, the PARLs in the failed RS cases tended to be associated with evidence of root resorption and involved more than 1 root (Fig. 1).

When potential prognostic factors were analyzed, no association was found between outcome and patient age, gender, preoperative diagnosis, or one versus multiple visits (Table 3).