Clinical and Radiographical Evaluation of a Resin-based Root Canal Sealer: A 5-Year Follow-up

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Abstract

A retrospective clinical and radiographical analysis of 5-year postendodontic treatment with a resin-based sealer (EndoRez; Ultradent Products Inc, South Jordan, UT) and gutta-percha was conducted. The results after 14 to 24 months were reported previously. Of 180 patients, 120 responded to the 5-year recall. Success of root canal treatments was based on absence of clinical symptoms, a normal or slightly widened periodontal ligament, and absence or reduction of periapical radiolucencies in patients who had preexisting lesions. Root canals had been adequately filled to the working length in 92 teeth (76.66%) and short in 13 (10.83%). Fifteen cases (12.50%), filled flush at the initiation of the experiment, showed slight resorption of the filling material at the apex within the lumen of the root canal. Of the 10 roots with extrusion, none had radiographic evidence of sealer in the periradicular tissues after 5 years. All patients were free of clinical symptoms. Four cases (3.3%) showed partial healing, whereas 8 cases (6.66%) were judged failures. A life table analysis revealed a cumulative probability of success of 86.3% at the 5-year recall with a 95% confidence interval of 79.7 to 91.0. The clinical and radiographical data suggest that the tested resin-based sealer used in conjunction with gutta-percha performed very well as a root canal sealer over a period of up to 5 years. *(J Endod 2007; 33:676–679)*

Key Words

Endodontic therapy, EndoRez, resin-based sealer, root canal filling

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Numerous studies have been published evaluating endodontic success and failure using a clinical and radiographical examination (1–5). Predefined criteria offer a reliable method to evaluate the long-term results of endodontic therapy (4).

It is generally accepted that after complete debridement and disinfection, total obliteration of the root canal system with biocompatible materials constitutes one of the principal prerequisites for successful endodontic therapy (6). In this respect, the choice of a sealer will influence the outcome of endodontic therapy (7). In a preliminary short-term retrospective study on 180 patients (8), the results of endodontic treatment of root canals filled with laterally condensed gutta-percha cones in conjunction with EndoRez (ER; Ultradent Products Inc, South Jordan, UT) were evaluated. ER is a hydrophilic, 2-component dimethacrylate- based material that meets the essential requirements of an endodontic sealer (9). When retreatment is indicated, it can easily be removed by mechanical instrumentation (9). After 14 to 24 months, 145 patients were available for a follow-up examination. The results showed an overall success rate of 91% and indicated that the use of ER as a sealer constituted a potential promising alternative to conventional sealers. Because the favorable outcome of the preliminary evaluation (8) was not considered a long-term success, the present retrospective study was undertaken to obtain 5-year posttreatment data on the same patient pool that was previously evaluated.

Materials and Methods

Patients responding to a 5-year follow-up examination were clinically and radiographically evaluated for the outcome of endodontic treatment. In the original 180 patients (age range 12–75 years, 41.67% male and 58.33% female), 295 root canals were filled with gutta percha and ER. At the time of initial endodontic therapy, an informed consent was obtained, preoperative radiographs were made, and the condition of the pulp and a periradicular tissue diagnosis was recorded. All root canal treatment procedures were completed in one visit by one operator in a private practice limited to endodontics. After administration of local anesthesia, a rubber dam was placed and the pulp chamber accessed. In all cases, canals were prepared and filled according to a standardized procedure. Canals were hand instrumented by using a crown-down technique for radicular access combined with a step-back technique for apical preparation. After the coronal two thirds of the canals were flared with #1 to 3 Gates Glidden burs (Dentsply/Maillefer, Ballaigues, Switzerland), the working length was established with a #15 file, approximately 1-mm short of the radiographic apex. Finally, the canals were prepared with K-type and Hedström files (Dentsply/Maillefer) at the apical third to a master apical # 30 to 40 file and coronally to a #60 file, each size 1-mm short of the preceding instrument. On occasion, the instrumentation sequence had to be modified because of difficulty in negotiating root canals with complex anatomy. The patency of the apical foramen was confirmed with a #10 K-file. During instrumentation, the canals were irrigated with 2.0 mL of 2.5% NaOCl followed by rinsing with 2.0 mL of sterile saline after every instrument change. The irrigants were delivered from plastic syringes and through 30-G endodontic irrigation needles. Excess irrigation solution was removed with sterile paper points. For obturation, a master cone fitted with tug-back at the working length was selected. ER was obtained directly from the TwoSpense2 mixing and delivery syringe (Ultradent Products Inc), and the moist canal walls were coated with the sealer by using a size 20 K-file. The master cone was coated with the sealer and placed to length followed by lateral condensation by using fine-fine or fine-medium accessory cones dipped in sealer. The access cavities were temporarily

TABLE 1. Tooth Number and Location in the Maxillary or Mandibular Arch Evaluated 4.5 to 5 Years Postoperatively

	Maxillary	Mandibular	Total
Central incisor	20	2	22
Lateral incisor	10	1	11
Canine	12	5	17
First premolar	5	10	15
Second premolar	9	10	19
First molar	8	11	19
Second molar	4	8	12
Third molar	1	4	5
Total	69	51	120

sealed with IRM (Dentsply/LD Caulk Division, Milford, DE), and the patients were instructed to see their referring dentists for definitive restorative care.

Postoperative and recall radiographs were made immediately and 5 years after endodontic treatment by using the same X-ray unit with a film holder attached to a beam-guiding XCP instrument (Rinn Corp, Elgin, IL) and Kodak 32 × 43 mm ultraspeed films (Eastman Kodak Company, Rochester, NY). When needed, additional radiographs were made at different horizontal angles to enhance visualization and evaluation. To minimize subjectivity during evaluation, the following precautions were taken. Postoperative radiographs were compared with the 5-year recall radiograph by using a viewer with a magnifying glass. All radiographs were analyzed by two independent endodontists with more than 25 years of clinical experience. Before evaluating the radiographs, both endodontists were calibrated by having them analyze twice a standard set of 100 individual pairs of postoperative and recall radiographs of endodontic treatments that were selected at random from the files of two private endodontic services. The radiographs were of high quality and exhibited findings such as normal periapical tissues, widened or thickened periodontal ligament space, loss of cortical bone, changes in trabecular patterns, and radiographically discernible periapical radiolucencies. If there was a disagreement between the evaluators; the X-rays were reassessed jointly until a consensus was reached. The level of the root fillings in relation to the working length was recorded, and the quality of the fillings were judged to be adequate when they were placed to the full working length and no voids or empty spaces were observed, especially in the apical third. Canals that did not meet these conditions were categorized as short fill or inadequate obturation. In multirooted teeth, one or more canals showing similar conditions resulted in a designation of inadequate obturation for the entire tooth. In cases with apical radiolucencies, the size of each lesion was estimated on the radiograph as being <2 mm or >2 mm. The success and failure of the endodontic therapy was determined on the basis of radiographic findings and clinical signs and symptoms. The following criteria were used. Treatment was considered successful when at recall the contours and width of the periodontal space were normal or sligthly widened around an overfill and the patient was free of symptoms. Slight tenderness to percussion for a brief postoperative period was acceptable. The treatment was considered a failure when periapical radiolucencies were observed in the preoperative radiograph and remained unchanged or increased over time. If the radiolucency decreased in size by at least 50% and the patient was comfortable and the contours and width of the periodontal space had returned to normal, the treatment was considered successful. The treatment was also considered successful in the absence of periapical radiolucency in the preoperative radiographs and with an appearance that remained unchanged. Vice versa, a root that developed a radiolucency was considered a failure. Failure of one canal in multirooted teeth was considered a complete failure; thus, multirooted teeth were evaluated as single-rooted ones, regardless of the number of canals. The relation of the treatment outcome with respect to age, sex, and specific preoperative and postoperative data were analyzed by using the Fisher exact test with a significance factor of $p < 0.05$. Taking into consideration the number of patients who did not respond to the 14- to 24-month recall (35 patients, censored data), a life table survival analysis was used to determine the cumulative probability of success at the 5-year recall. A corresponding 95% confidence interval was determined.

TABLE 2. Analysis of Success and Failure by Sex and Age in Root Canals Filled with Gutta-Percha and ER

Factor	# of cases %	Success %	Failure %
Sex			
Male	52 (43.33)	49 (94.23)	3 (5.76)
Female	68 (56.66)	63 (92.64)	5 (7.35)
Age			
12–30	21 (17.5)	19 (90.47)	2 (9.52)
31–55	62 (51.66)	59 (95.16)	3 (4.83)
56–75	37 (30.83)	34 (91.89)	3 (8.10)

TABLE 3. Relation of Preoperative Factors to Treatment Results in Root Canals Filled with Gutta-Percha and ER

Factor	# of teeth %	Success %	Failure %
Pulp diagnosis			
Vital	51 (42.50)	48 (94.11)	3 (5.88)
Non vital	69 (57.50)	64 (92.75)	5 (7.24)
Periapical radiolucency			
Present	48 (40.00)	44 (91.66)	4 (8.33)
Absent	72 (60.00)	68 (94.44)	4 (5.55)
Lesion size			
<2 mm	37 (77.08)	33 (89.18)	4 (10.81)
>2 mm	11 (22.91)	7 (63.63)	4 (36.36)

Results

The calibration exercise established that the interexaminer agreement ratio was 93%. Because this constituted a strong interobserver agreement, the radiographic interpretation was considered reliable. The posttreatment time ranged from 4.5 to 5 years. The recall rate after 5 years was 66.66%. A total of 120 patients with 218 treated root canals presented for follow-up evaluation. All data that were collected from the 120 patients who presented at the 5-year recall were entered in a computer program. Table 1 presents the number and location of teeth that were evaluated. Distribution of patients by age and sex is presented in Table 2. Distribution by significant preoperative factors and postoperative factors related to treatment results are presented in Tables 3 and 4, respectively.

Ninety-two teeth (76.66%) were rated to be adequately filled to the working length. Thirteen cases (10.83%) were obturated short; 15 (12.50%), although filled flush at the initiation of the evaluation, showed a slight resorption of the filling material (probably sealer) within the lumen of the root canal. In these cases, the end of the root fill

TABLE 4. Relation of Final Restoration to Treatment Results in Root Canals Filled with Gutta-Percha and ER

Restoration	# of teeth %	Success %	Failure %
None	4 (3.3)		4 (100.0)
Post (with or without crown)	50 (41.66)	48 (96.00)	2 (4.00)
Coronal filling (amalgam, composite glass ionomer, etc)	66 (55.00)	64 (96.96)	2 (3.03)