JOURNAL OF ENDODONTICS
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Printed in U.S.A.
VOL. 29, NO. 12, DECEMBER 2003

Treatment Outcome in Endodontics: The Toronto Study. Phase 1: Initial Treatment

Shimon Friedman, DMD, Sarah Abitbol, DDS, and Herenia P. Lawrence, DDS, PhD

This study assessed the 4- to 6-yr outcome of initial endodontic treatment during Phase 1 of the "Toronto Study" project. A total of 450 teeth were treated, alternating the "Schilder" technique and step-back with lateral condensation, and examined clinically and radiographically by an independent examiner. Apical periodontitis was recorded as absent (periapical index < 3) or present (periapical index ≥ 3) and outcome dichotomized as "healed" (no apical periodontitis, no signs or symptoms) or "disease." Univariate, bivariate, and multivariate analyses were performed (p = 0.05) on 120 examined teeth. The "healed" rate (81% overall) was significantly higher for teeth treated without apical periodontitis (92%) than with apical periodontitis (74%). Several other factors were associated with healing rate differential of 10% or higher, but no statistical significance. This study confirmed apical periodontitis as the main prognostic factor in initial endodontic treatment. Continuation of the project will allow assessment of other prognostic factors with better power.

The outcome of initial endodontic treatment has been the subject of more than 60 studies published during the past 80 yr, cumulatively including thousands of teeth (1). The reported outcomes have been diverse, reflecting considerable differences among the studies in material composition (tooth type, sample size, case selection), treatment (providers, techniques, bacterial culturing, restoration), and methodology (study design, recall rate, radiographic interpretation, follow-up period, analysis, outcome measures, and criteria) (1). This diversity can be confusing for the conscientious clinician seeking evidence of the benefits of endodontic treatment as a basis for clinical decision-making and prognostication of clinical cases.

In recent years the concepts of assessing and reporting the outcomes of health care, including dentistry, have evolved in the search for evidence base to support treatment procedures (2). A consensus has emerged that the needed evidence base cannot be derived from indiscriminate browsing of all available studies, differing in the level of evidence they provide (2). Consequently, strategies have been suggested for differentiation of clinical studies based on a hierarchy of the levels of evidence (3). Observational cohort studies, such as have been reported on the outcome of endodontic treatment, can be rated as the second-highest or the lowest in the hierarchy, depending on their compliance with criteria of acceptable quality.

The quality of a clinical study is primarily concerned with validity and relevance (3). The quality parameters can be grouped into four categories as follows: (a) Cohort: this should be defined at the inception of the study and clearly described. The pattern of referral and case-selection criteria should be described (4). At the end point of the study, the entire inception cohort should be accounted for (4). The sample size may be required to exceed a certain threshold. (b) Exposure (intervention, treatment): treatment providers and procedures should be clearly described. Procedures considered to be irrelevant or unacceptable may be excluded. (c) Outcome assessment: outcome dimensions (5) should be clearly defined. Measures used to assess these dimensions should be objective and applied consistently by properly calibrated examiners with established reliability. The examiners should be blinded or masked and different from the providers of treatment. Direct visual comparisons of radiographs, e.g. preoperative and at follow-up, should be avoided. The follow-up period should be long enough to capture the completion of the healing process in the majority of the study sample. (d) Data analysis and reporting: potentially confounding prognostic factors should be controlled, or at least observed, and recorded.

Using these criteria, a recent review (1) identified only 11 observational cohort studies of at least mid-range level of evidence (6–16). The select studies are listed in Table 1; the outcomes were construed from those reported by the original authors, as follows: (a) healed: combined clinical and radiographic normalcy; (b) healing: reduced radiolucency combined with clinical normalcy; and (c) functional: clinical normalcy, or the sum of "healed" and "healing." The relatively small number of studies on the outcome of endodontic treatment that meet acceptable quality criteria and at least mid-range level of evidence seems to warrant additional such studies.

The objective of the Toronto Study project, established in 1993, is to prospectively assess the 4- to 6-yr outcome of endodontic treatment performed in a university graduate-clinic environment. The modular project is designed to provide cumulative data with the completion of each successive phase, with the goal of amassing a sufficient sample to study the influence of potential prognostic factors on the outcome of treatment. This article reports Phase 1 of the study, focusing on

TABLE 1. Outcome of initial endodontic therapy of apical periodontitis in observational cohort studies selected on the basis of structured appraisal

Study	Cases Observed	Follow-up (yr)	Appraisal Categories				Outcome (%)		
			Cohort	Exposure	Assessment	Analysis	Healed	Healing	Functional*
Strindberg (6)	60§	0.5–10	y	y	n	y	80		
Engström et al. (7)	147§	4–5	y	y	n	y	73¶		
Kerekes and Tronstad (8)	172§,‖	3–5	y	y	n	y	90¶		
Byström et al. (9)	79‖	2–5	y	y†	y	n	85	9	94
Ørstavik et al. (10)‡	121‖	3	n	y	y	y	82	9	91
Sjögren et al. (11)	204§,‖	8–10	y	y†	y	y	86		
Ørstavik (12)	126§,‖	4	n	y	y	y	75	13	88
Sjögren et al. (13)	53	≤5	y	y	y	y	83		
Trope et al. (14)	76	1	n	y	y	y	80#		
Weiger et al. (15)	67	1–5	y	y	n	y	78	16	94
Peters and Wesselink (16)	38	1–4.5	y	y	y	y	76	21	97

Adapted with permission from (1).
* Asymptomatic, without or with residual radiolucency (reduced or unchanged in size).
† Canals were filled only after negative bacterial culture, undermining universality of results.
‡ Data extracted also from: Eriksen HM, Ørstavik D, Kerekes K. Healing of apical periodontitis after endodontic treatment using three different root canal sealers. *Endod Dent Traumatol* 1988;4:114–7.
§ Data extracted from larger study material that also includes teeth without apical periodontitis.
‖ Roots considered as unit of evaluation, rather than teeth.
¶ Recalculated after exclusion of cases classified as "uncertain."
# Teeth treated in two sessions without intracanal medication excluded.
y = Satisfies criteria of acceptable quality; n = Does not satisfy criteria of acceptable quality.

the outcome of initial endodontic treatment. It was hypothesized that the rate of healing observed in the studied sample would be higher in teeth treated without preoperative apical periodontitis compared with teeth associated with apical periodontitis, and that it would be comparable with that reported in the previous studies that conformed to the quality parameters outlined above (Table 1).

MATERIALS AND METHODS

Inception Cohort

A total of 350 patients received initial endodontic treatment in 405 teeth. All patients had been treated at the Graduate Endodontics Clinic, Faculty of Dentistry, University of Toronto, between September 1993 and September 1995. Informed consent, including participation in research and in the follow-up examinations, was obtained from all patients before commencing treatment.

Treatment

The treatment providers were graduate students supervised by qualified endodontists. An aseptic technique was invariably observed, with rubber-dam isolation and, where needed, copper bands applied to enhance isolation. Canals were invariably cleaned and shaped with stainless-steel hand files and irrigated with 2.5% NaOCl. Any pulp chamber perforation present was sealed with resin-modified, glass-ionomer cement (Vitrebond, 3M, St. Paul, MN). A structured treatment protocol was followed: in approximately half of the teeth, the step-back technique was used, often modified to include extensive apical reaming; the working length was established 1 mm short of the radiographic apex or with the aid of an apex locator (Root ZX, J. Morita, Tokyo, Japan). Canals were filled with laterally condensed gutta-percha and Roth Root Canal Cement type 801 (Roth International Ltd., Chicago, IL), with a small number of teeth root-filled with a single gutta-percha cone and Ketac-Endo sealer (ESPE, Seefeld, Germany). In the remaining teeth, the so-called "Schilder technique" was strictly applied; the working length was established at the radiographic apex. Canals were filled with vertically compacted warm gutta-percha and Kerr Pulp Canal Sealer (Kerr, Romulus, MI), following Schilder's technique except for the occasional use of injectable gutta-percha (Obtura II, Fenton, MO) for back-filling. Tooth allocation to the different treatment protocols followed a predetermined schedule: one protocol was consistently performed on specific days of the week, whereas the other protocol was performed on the other days. The supervising endodontists assigned to the clinic on the different days were formally trained in the respective treatment techniques and have been practicing those techniques.

Recording of Data

Information related to potential prognostic factors, preoperative (gender, age, tooth location, number of roots, clinical signs and symptoms, pulp vitality, radiolucency, periodontal defects) and intraoperative (number of treatment sessions, intracanal medication, canal-preparation technique, apical enlargement, root-filling technique, voids in root filling, sealer extrusion, complications, and temporary seal), was recorded by the treatment providers before and immediately after treatment. A separate structured form was used for each treated tooth, and the information transferred directly to a Microsoft Excel database. A full set of radiographs was attached to each form. All radiographs were exposed using the paralleling technique with the aid of Rinn film holders (Dentsply-Rinn, Elgin, IL). Exposure, developing device (DENT-X, Elmsford, NY), and viewing conditions (view box with 3× magnification) were kept standard. The widest diameter of any preoperative radiolucency was recorded in mm. At the completion of treatment each patient was advised of the importance of the long-term, follow-up examination to assess the outcome.

Before the recall of patients for follow-up, one examiner (S.A.) had been calibrated for radiographic interpretation using the periapical index (PAI) calibration kit of 100 periapical radiographs (17). The same set also was viewed by the co-investigator (S.F.), who is more experienced in conducting research in this area of study. Intra- and interexaminer reliability was then assessed using Cohen's Kappa statistic.

At the follow-up examination, the clinical and radiographic findings were recorded by the calibrated examiner using a structured form for each tooth, and transferred into the database. The radiographs were scored according to the PAI system (17), and then dichotomized for each tooth to reflect absence (scores 1 and 2) or presence (scores 3–5) of apical periodontitis. Multirooted teeth were each given one score: the highest scored for any of the roots.

Recall

Letters and telephone calls, used initially to contact patients, resulted in a recall rate of 20%. To improve the recall rate, two additional letters were sent to nonresponding patients, and the internet-based telephone directory was used to search for new addresses of patients whose letters were returned. Finally, a third letter was mailed to the relocated patients and to those who did not respond to the earlier recall. This time, patients were offered monetary compensation for travel cost and loss of work time. Teeth that were extracted, deceased patients, and those who relocated and could not be reached were recorded in the database with the respective explanation.

Outcome Assessment

Radiographic and clinical criteria were used for a dichotomized outcome. Periapical tissues were classified as "healed" in the absence of (a) radiographic signs of apical periodontitis (PAI score < 3) (17), and (b) clinical signs and symptoms other than tenderness to percussion. Any other condition was classified as "disease." The whole tooth was considered the unit of evaluation. For descriptive purposes, all asymptomatic teeth were considered to be "functional" regardless of the PAI score.

Sample Size Estimation

Two sample size estimations were performed with the Sample Power in SPSS computer software, one for each hypothesis. To compare the rate of healing in teeth treated with or without radiolucency, a differential of 15% in favor of the latter was assumed

TABLE 2. Univariate distribution of prognostic factors in the new sample (N = 277) and the analyzed sample (*n* = 120)

Prognostic Factor		New Sample		Analyzed Sample	
		n	%	*n*	%
Preoperative					
Age	≤45	131	47	39	33
	>45	146	53	81	67
Gender	female	151	55	61	51
	male	126	45	59	49
Tooth location	maxilla	151	55	69	58
	mandible	126	45	51	42
No. of roots	1	93	34	43	36
	≥2	184	66	77	64
Signs and symptoms	absent	153	55	69	58
	present	124	45	51	42
Apical periodontitis	absent	119	43	48	40
	present	158	57	72	60
Pulp vitality	vital	98	35	37	31
	necrotic	179	65	83	69
Intraoperative					
Treatment sessions	1	65	24	23	19
	≥2	212	76	97	81
Root filling	lateral	148	53	64	53
	vertical	118	43	50	42
	other	11	4	6	5
Voids	absent	217	78	98	82
	present	60	22	22	18
Sealer extrusion	absent	125	45	58	48
	present	152	55	62	52
Complications	absent	244	88	108	90
	present	23	12	12	10
Temporary seal	temporary	81	29	33	28
	definitive	195	70	86	72
Postoperative					
Restoration	definitive			111	93
	temporary			9	7
Post	present			62	53
	absent			45	37

TABLE 3. Prognostic factors related to healed rate differential over 10% (N = 120)

Prognostic Factor		n	Healed (%)	p Value
Preoperative				
No. of roots	1	43	88	0.117
	≥2	77	77	
Radiolucency	absent	48	92	**0.014**
	present	72	74	
Pulp vitality	vital	37	95	**0.011**
	necrotic	83	75	
Intraoperative				
Root filling	lateral	64	78	0.379
	vertical	50	86	
	other	6	67	
Temporary seal	temporary	33	70	0.061
	definitive	86	85	

Bold font highlights statistical significance.

TABLE 4. Stepwise logistic regression analysis (N = 120)

Prognostic Factor	Adjusted Odds Ratio	95% CI	p Value
Temporary seal definitive = 0/temporary = 1	2.14	0.81–5.71	0.061
Treatment sessions multiple = 0/single = 1	1.21	0.37–4.01	0.741
Radiolucency absent = 0/present = 1	3.71	1.14–12.0	**0.029**

Bold font highlights statistical significance.
CI = confidence interval.

(13). With a power of 80% and 5% significance (two-tailed test), 80 teeth would be required in each group. To compare the incidence of healing in the present and past studies, the test of proportion was used assuming 80% healing (13). With a power of 80% and 5% significance (two-tailed test), the sample size would have been 170 teeth; however, adjusting for a dropout rate of 30%, the required sample size was 221 teeth.

Analysis

Statistical analysis was performed in three parts: (a) univariate description of the data using percent frequencies; (b) bivariate associations between the treatment outcome and pre-, intra-, and postoperative factors, using contingency tables and Chi-square test of proportions or Fisher's Exact test; and (c) multivariate analysis to evaluate joint associations among various factors, using logistic-regression models. The dependent variable for these analyses was the dichotomous outcome: healed versus disease.

All statistical tests were performed as two-tailed and interpreted at the 5% significance level. The complete material was analyzed first, followed by a stratified analysis according to the preoperative absence or presence of radiolucency.

RESULTS

The Kappa score for interexaminer agreement after the first calibration session was $k = 0.8$. After the second session performed 1 week apart, the Kappa score for intraexaminer agreement was $k = 0.9$. Both scores indicated "good agreement" (18).

Of the 350 patients and 405 teeth treated, 109 patients with 128 teeth (31%) were excluded as "discontinuers": 9 were deceased and 100 relocated and could not be reached. The new sample of 277 teeth is characterized according to pre-, intra-, and postoperative variables in Table 2. Of this sample, 136 teeth (49%) were defined as "dropouts": patients declined the recall (17 teeth) or did not respond (119 teeth). Of the responding sample, comprising the 141 remaining teeth (recall rate = 51%), 21 teeth had been extracted: 11 because of periodontal disease, 6 for restorative considerations, and 4 for unknown reasons. Excluding the extracted teeth, 120 teeth were subjected to statistical analysis; the analyzed sample also is characterized in Table 2. A response bias analysis of the frequency of preoperative radiolucency revealed that the difference between the dropout and the responding populations was not statistically significant ($p > 0.7$).

Ninety-seven teeth (81%) were classified as healed and 23 as having disease: apical periodontitis. Several factors were associated with a healed rate differential of 10% or higher (Table 3). Without preoperative radiolucency, the healing rate was significantly higher than with radiolucency present. The healing rates for teeth with vital and those with necrotic pulps followed the same pattern. A contingency table (not shown) revealed that preoperative pulp vitality and radiolucency were associated variables ($p < 0.001$). The healed rate differential associated with all other pre-, intra-, and postoperative factors was smaller than 10% and not statistically significant.

Stepwise logistic regression (Table 4) revealed that preoperative radiolucency was the only statistically significant factor, with odds ratio of 3.71; the risk for teeth not to heal was almost four times higher when radiolucency was present before treatment than in its absence.

Among the 23 teeth classified as having disease, the radiolucency had decreased in size (13 teeth, 57%), remained stable (4 teeth, 17%), or emerged/increased (6 teeth, 26%). Only 4 teeth (17%) presented clinical signs or symptoms at follow-up; thus 116 teeth (97%) were considered to be functional.

Of the 48 teeth treated without preoperative radiolucency, 44 teeth (92%) remained healed. Stratified analysis of these teeth is presented in Table 5, listing factors associated with a healed rate differential of 10% or higher. None of the differences related to the analyzed factors were statistically significant.

Of the 72 teeth treated with radiolucency, 53 teeth (74%) healed. Stratified analysis of these teeth is presented in Table 6, listing factors associated with a healed rate differential of 10% or higher. The healed rate was significantly higher for single-rooted teeth than for multirooted teeth. None of the differences related to the other factors were statistically significant.

DISCUSSION

This prospective historical cohort study assessed the outcome of initial endodontic treatment. The inception cohort was identified at the outset of the study. All treatment procedures and the recording of the data followed a standardized protocol established before treatment of patients was initiated. The referral pattern included all patients treated at the graduate endodontics clinic in the time period of the study, and no exclusion criteria were applied similarly to a previous study (11). The majority of the patients were referred from the undergraduate clinic while undergoing comprehensive dental care. However, many were referred from the emergency clinic; their dental history frequently revealed lack of regular

TABLE 5. Prognostic factors related to healed rate differential over 10% in teeth treated without radiolucency (N = 48)

Prognostic Factor		n	Healed (%)	p Value
Preoperative				
Age	≤45	13	100	0.562
	>45	35	89	
Signs and symptoms	absent	28	86	0.130
	present	20	100	
Pulp vitality	vital	29	97	0.280
	necrotic	19	84	
Intraoperative				
Treatment sessions	1	11	100	0.560
	≥2	37	89	
Filling technique	lateral	28	93	0.810
	vertical	18	89	
	other	2	100	
Complications	absent	39	95	0.100
	present	7	71	

TABLE 6. Prognostic factors related to healed rate differential over 10% in teeth treated with radiolucency (N = 72)

Prognostic Factor		n	Healed (%)	p Value
Preoperative				
Age	≤45	26	65	0.232
	>45	46	78	
No. of roots	1	31	87	**0.024**
	≥2	41	63	
Pulp vitality	vital	8	88	0.671
	necrotic	64	72	
Intraoperative				
Treatment sessions	1	12	58	0.188
	≥2	60	76	
Filling technique	lateral	36	67	0.139
	vertical	32	84	
	other	4	50	
Sealer extrusion	absent	30	80	0.299
	present	42	69	
Temporary seal	temporary	23	61	0.093
	definitive	49	74	

Bold font highlights statistical significance.

dental care. Only few patients were referred from private practice. Thus the studied cohort might not represent the general population, and the results might not be generalized.

The 4- to 6-yr recall rate of 51% fell short of the guidelines suggested for high level of evidence (3, 4), and of that in the majority of the select previous studies that conformed with the quality parameters outlined earlier (6–8, 10–16). The recall rate could not be improved despite the elaborate efforts to encourage patients to attend the follow-up examination, including a monetary incentive. The large number of discontinuers suggested that in a mega-city such as Toronto, a considerable proportion of the dental school patient population might be transient. The many dropouts either ignored the recall, having no regular relationship with the dental school, or were simply not motivated to attend. Most studies with high recall rates were performed in smaller communities than Toronto (9, 11, 13–15), where the dental school might enjoy a different status and the population might be less mobile. Nevertheless, the extensive dropout population did not vary in prevalence of preoperative apical periodontitis, suggesting the study was not subject to response bias (4).

The treatment procedures (exposure) performed in this study were consistent with the standard of care. Graduate students were closely supervised by experienced endodontists, with ratios of 3:1 (1993–1994) and 6:1 (1994–1995). The most current innovations of that period, nickel-titanium rotary instruments and microscope, were not used; however, there is no evidence to suggest they could have significantly influenced the results. Twelve of the analyzed teeth were referred mid-treatment after different complications had occurred; such complications are normally absent when initial endodontic treatment is performed.

The examiner was calibrated and the outcome assessed blindly and generated by computer according to preset criteria. In this manner, the expectation bias and the diagnostic suspicion bias were controlled in compliance with the quality criteria for clinical research (3, 4), and with most of the select previous studies (7, 9, 11–16).

Strict clinical and radiographic criteria were used for a dichotomous outcome of presence or absence of apical periodontitis. Being frequently related to traumatic occlusion, food impaction, or periodontal disease, tenderness to percussion was allowed if unaccompanied by any other clinical sign or symptom. Significant prognostic factors could not be controlled; however, associations between the outcome and the different factors were observed and analyzed, and the analysis stratified for specific factors when appropriate. The analysis did not consider the number of treated teeth contributed by each patient, because the database was not set to exclude teeth beyond the first one treated in any patient. Nevertheless, the presence of additional endodontically untreated or treated tooth/teeth, even with apical periodontitis, has not been shown to adversely influence the outcome of endodontic treatment in the same patient. Therefore, inclusion of several patients with more than one tooth treated was unlikely to have significantly impacted the results of this study.

According to the strict outcome criteria used, 81% of the teeth had healed. However, if the radiographic criterion used was more lenient, to include decreased lesions, as in several previous studies (1), the healing rate would have been 92%, exceeding that reported in most other studies (1). Clearly then, use of strict, rather than lenient, radiographic criteria in a 4 to 26-year follow-up study reduces the healing rate by approximately 10% (1). By the clinical measure alone, 97% of the teeth were asymptomatic and considered to be functional, consistent with the high end of the range reported in the select previous studies (Table 1). This dimension of outcome is noteworthy: it can provide the patients with an additional perspective when weighing initial endodontic treatment against alternative treatment modalities. The very high functional rate supported the benefit of initial endodontic treatment, and suggested that treatment should be encouraged before tooth extraction and replacement is considered.

The healing rate of 92% for teeth treated without apical periodontitis was in the middle of the previously reported range of 88% (7) to 97% (8, 11), whereas the healing rate of 74% for teeth treated with apical periodontitis was in the lower end of the reported range (Table 1). The latter was significantly lower than the former, confirming the adverse influence on the outcome of preoperative apical periodontitis (6, 7, 9–12). With the high healing rate in the former group, none of the pre-, intra-, and postoperative factors significantly influenced the outcome. In contrast, in the latter group the single-rooted teeth had a significantly better outcome than the multirooted teeth, in agreement with one of the select previous studies (7). It is conceivable that the anatomy of the multirooted teeth presented a greater challenge for elimination of root-canal infection. However, the difference could be attributed to the use of

TABLE 7. Selected studies on the outcome of initial endodontic therapy in teeth with apical periodontitis, performed in one or two sessions

Study	Follow-up (yr)	One Session		Two Sessions	
		n	Healed (%)	*n*	Healed (%)
Sjögren et al. (11)	8–10	—	—	204	86
Sjögren et al. (13)	≤5	53	83	—	—
Trope et al. (14)	1	22*	64	19*	74
Weiger et al. (15)	1–5	36	83	31	71
Peters and Wesselink (16)	1–4.5	21	81	12	71
This study	4–6	12	58	60	76

* Only teeth with extensive apical periodontitis (PAI > 3) included.

the tooth as the unit of evaluation, reflecting the double or triple probability of disease in the multirooted teeth when assessed according to the worst root (1). When roots were used as the unit of evaluation in an earlier study (6), the healing rate for single-rooted teeth was considerably lower than for multirooted teeth.

The dilemma regarding one-session treatment of teeth with apical periodontitis has been the focus of recent debate and at least three select studies (Table 7). In this study a nonsignificant healing rate differential of 18% was observed in favor of the teeth treated in two or more sessions. This finding corroborated one study (14) and differed from the other two (15, 16); however, in the latter the mode of applying calcium hydroxide as the intracanal medication has been questioned (1). Clearly, the sample size in this study, as in the previous ones that addressed this specific research question (14–16), was too small to support statistical significance of the observed healing rate differentials.

Interestingly, 42% of the analyzed teeth were treated in accordance with Schilder's technique, whereas 53% were treated using the step-back technique and lateral condensation. This seems to be the first time that these two technical approaches were compared in a clinical study. Under the conditions of this study, they did not differ significantly with regards to the outcome of treatment.

The treatment outcome achieved in this study was consistent with that achieved by other operators in different settings. This result was disappointing, because the current treatment strategies applied in this study have been commonly perceived to improve the outcome of treatment relative to older techniques. The fact that state-of-the-art treatment did not dramatically improve the outcome once more highlighted the complexity of treating apical periodontitis. Apparently, prevention or treatment of this disease cannot be improved merely by changing treatment techniques. Because apical periodontitis results from interactions between microorganisms, their environment and the host immune system (19), only use of effective modifiers of any of these three factors might significantly improve the outcome of treatment.

Differences in outcome related to most factors examined were fairly small (<10%) and not significant. This finding corroborated the majority of the select previous studies, which reported no influence on the outcome of treatment by the following factors: age and gender (8, 11), tooth location (15), preoperative symptoms (9, 11, 15), size of preoperative radiolucency (9, 11, 13), periodontal condition (11), apical extent of treatment (length) (9, 15), apical enlargement (8), occurrence of flare-up between treatment sessions (8, 9, 11), and type of restoration (13).

Several prognostic factors were associated with large differences (≥10%) in outcome, although not statistically significant. This lack of significance might have been related to the lack of statistical power for some of these factors. Therefore, a power analysis was performed based on the present results, to establish the sample size required to assess the prognostic value of those factors with 80% power and 5% level of significance. As the modular Toronto Study continues, it is expected that pooling the populations of future phases with the one of the present study will eventually meet the required sample size. For example, to better evaluate the influence on the outcome of the number of treatment sessions in teeth with apical periodontitis, at least 110 teeth per group would be required. Considering future recall rates to remain unchanged from this study, this requirement could be fulfilled in 9 yr, when four additional 2-yr phases of the Toronto Study will be analyzed. For other factors, the required sample sizes could be met in shorter time periods. We shall continue to report the findings in successive 2-yr phases, separately and pooled with the previous populations, for the duration of the Toronto Study research project.

Drs. Friedman and Abitbol are affiliated with the Discipline of Endodontics, and Dr. Lawrence is affiliated with the with the Discipline of Community Dentistry, Faculty of Dentistry, University of Toronto, Toronto, Ontario, Canada.

Address requests for reprints to Dr. Shimon Friedman, Professor and Head, Endodontics, Faculty of Dentistry University of Toronto, 124 Edward Street, Toronto, Ontario M5G 1G6, Canada.

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