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Large-scale Clinical Endodontic Research in The National Dental Practice-Based Research Network: Study Overview and Methods

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Abstract

Introduction—This paper reports on the feasibility of conducting a large-scale endodontic prospective cohort study in The National Dental Practice-Based Research Network. This study was designed to measure pain and burden associated with initial orthograde root canal therapy (RCT) and to explore potential prognostic factors for pain outcomes. The main objectives of this first report in a series are to describe the project's feasibility and methods and the demographics of the sample obtained.

Methods—Sixty-two dentist practitioner-investigators (46 generalists, 16 endodontists) in five geographical areas were certified within the network and trained regarding the standardized study protocol. Enrollment and baseline data collection occurred over 6 months, with post-obturation follow-up for another 6 months. Patients and dentists completed questionnaires before and immediately after treatment visits. Patients also completed questionnaires at 1 week, 3 months, and 6 months after obturation.

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Results—Enrollment exceeded target expectations, with 708 eligible patient-participants. Questionnaire return rates were good, ranging between 90% to 100%. Patient demographics were typical of persons who receive RCT in the United States: mean age 48 years (SD 13 years), with most being female (59%), college-educated (81%), white non-Hispanic (86%), and having dental insurance (81%). The tooth types being treated were also typical: 61% molars, 28% premolars, and 11% anteriors, with maxillary teeth being predominant (59%).

Conclusions—This study demonstrates the feasibility of conducting large-scale endodontic prospective cohort studies in the network. Patients were rapidly recruited, with high levels of compliance in data collection.

INTRODUCTION

Tooth pain is the most common type of orofacial pain (1) and the most common reason for patients to seek dental care (2, 3). Root canal therapy (RCT) is a common, effective treatment for tooth-related pathosis (4-6). Consequently, dental pain and endodontic treatment are of great interest to dentists (5, 7-10) and patients [<http://www.fpa-support.org/about-tna/>].

Ideally, high-impact clinical research applies scientifically rigorous methods to questions of great clinical interest (11, 12). The preferred design for observational studies assessing treatment outcomes is a large, prospective study (13-17). Unfortunately, for questions addressing endodontic pain, few studies meet the standards of evidence-based research methodology (5, 18). The absence of a strong history of endodontic pain research suggests that feasibility challenges may be common. In view of the current level of dental research output (19-21), research-oriented clinicians (22) need to implement such evidence-based recommendations to improve the quality of dental research (23).

The literature on endodontic pain involves predominantly patients from a single clinical practice setting, such as a specific academic center (24), with most data collected by specialists in teaching institutions (25). Because patients who receive medical care in academic institutions may be systematically different from those who present in community-based clinics (26), generalization of findings on dental patients seen in academic environments is questionable. Such assumed differences of patient populations within academic dental institutions is likely dependent on the setting of the institution, regional patient referral practices, type of care being provided, and economic factors; and therefore it is encumbrance of research from such settings to address such issues. Furthermore, while the existent literature is predominantly based on outcomes of patients treated by endodontic specialists (25), most RCTs are performed by general dentists (6). To address these shortcomings, research should enroll patients across a more representative cross-section of care-delivery settings within a reasonable timeframe, to avoid confounding due to differences and changes in clinical practice (27). Practice-based research networks (PBRNs) have provided promising solutions to such challenges. PBRNs typically are composed of a diverse group of clinicians in a variety of practice settings. By engaging such practitioners in subject enrollment, representative patient populations have become accessible for clinical research (28). Recently, dental PBRNs have been developed to address topics of interest to dental clinicians (29). These initiatives can recruit large numbers of dental patients to better reflect the typical U.S. dental patient (30).

This methods paper details the process of implementing in The National Dental PBRN (“network”) a large prospective cohort study to measure the pain, burden, and prognostic factors associated with initial orthograde RCT. The main objectives of this first report in a series are to describe the project’s feasibility and methods, as well as the demographics of the baseline sample obtained.

METHODS

Background

The network is a consortium of practices and dental organizations committed to advancing knowledge about dental practice to improve care (31). At the time of the study, the network mainly comprised five geographical regions: Alabama/Mississippi (AL/MS), Florida/Georgia (FL/GA), Minnesota (MN), Permanente Dental Associates (PDA) in Oregon/Washington, and Denmark and Sweden (SK). Practitioners in Norway were also involved in the network but were not invited to participate in this study. The network's central administrative base and the network-wide Data Coordinating Center were housed at the University of Alabama at Birmingham (UAB). The network has a wide representation of practice types, treatment philosophies, and patient populations, including diversity in race, ethnicity, geography, and rural/urban area of residence of practitioners and their patients. Analysis confirms that network dentists have much in common with other dentists, while offering substantial diversity with regard to these characteristics (32). Details about the network are on its Web site, <http://www.dentalpbrn.org>.

For dentists to be eligible to participate in the protocol, they had to be members of the network, practice in one of its five administrative regions, and indicate interest in participation. Both general dentists and endodontists were eligible. Dentists were recruited through network communications, a notice in the American Association of Endodontics *Communiqué* newsletter, personal invitations from fellow practitioners, and formal study invitation letters distributed to the existing network by regional network staff. Enrolled practitioners represented a wide variety of practice settings, including solo practitioners, private small and large group practices, multispecialty dental practices, larger managed care organizations, and public health/community dental clinics. Because of their role in protocol development, consenting patient subjects, data collection, and the interpretation and presentation of results, network practitioners actively engaged in studies are referred to as practitioner-investigators (p-i).

All enrolled practitioners or their practice organizations completed a memorandum of agreement with UAB and an individual investigator agreement with their regional administrative institution (33), or comparable agreements. The latter document signified that the p-i had undergone human subjects protection training and had received regional institutional review board (IRB) approval. Each p-i agreed to comply with all applicable laws, regulations, and policies, and each signed an informed consent form to participate in this study, if required by their region's IRB.

Study Design

This observational study used a prospective cohort design (16, 34) to estimate the magnitude of post-treatment pain and related pain burden associated with initial orthograde RCT. The primary study endpoints are the report of pain up to 1 week (network Study 17) and 6 months (network Study 18) after obturation. This project was also designed to explore interacting factors that influence the occurrence of perioperative and persistent pain (defined as pain at 6 months). All data were collected using surveys that the collaborating p-i had finalized before enrollment of consenting patients. The study protocol involved no manipulation of the treatment received by participating patients.

IRB Oversight and Human Subjects Protection

IRB requirements in a multisite study of this nature required the collaboration of multiple institutions (33), in addition to the University of Minnesota (principal investigator's home

institution). Informed consent for all human subjects was obtained by each p-i before initiation of the study protocol.

Development, Field-Testing, and Curation of Data-Collection Instruments

Where appropriate, questions used in previous epidemiological research (35, 36) were used as specific items in the study data-collection forms. Additional questions were considered based on their usefulness having been empirically observed and used in the investigators' clinical practices, both academic (University of Minnesota) and a private endodontic specialty practice (The Dental Specialists). Two general dentists and two endodontists in Minnesota field-tested the data-collection forms with two or three patients each. Following pilot testing, data curation was conducted on all questionnaire items. Native speakers with dental expertise translated patient forms into Danish and Swedish languages, without back translation, for the Scandinavian dental practices. Practitioner forms were produced in English for all regions, as Scandinavian practitioners involved in the network were fluent in English. UAB prepared and mailed the study questionnaires to the five regional administrative centers, where staff distributed them to each p-i during the in-person study training sessions described below.

Planned Recruitment Period and Target Enrollment

Enrollment was planned to last 6 months. We anticipated that each general practitioner would recruit one or two patients per month, and each endodontic specialist would recruit four or five patients per month. With a 6-month follow-up after the obturation of each subject's tooth, the total study timeline was 1 year. Enrollment ran from July to December 2010. As the minimum sample size, the projected enrollment target was 600 participants. Table 1 shows that at least 36 general practitioners and 12 endodontic specialists were projected to accomplish the recruitment goal. Over-enrollment of 10% for both dentists and patients was planned *a priori* to compensate for dropout due to unforeseen changes in personal situations, loss of interest, downturn in demand for endodontic treatment, ineligible enrollees, and other possible causes.

Patient Eligibility and Recruitment

Practitioner-investigators enrolled eligible patients seeking dental care at their practices. Inclusion criteria were: i) aged 19 to 70 years; and ii) permanent tooth requiring initial orthograde root canal therapy (RCT). Exclusion criteria were: i) evidence of treatment having been initiated for an iatrogenic pulpal exposure (cases with a carious exposure of the pulp were not excluded); ii) previous enrollment in this study (each patient could contribute only one tooth to the study); iii) previous endodontic treatment that would make it unclear whether pain was associated with the prior treatment or attempt at treatment; iv) obvious cognitive impairments (e.g., previous stroke with communication deficits, dementia, mental disability); v) inability to read, understand, and complete the baseline patient questionnaire in English or one of two Scandinavian languages; and vi) anticipated inability to provide 6-month follow-up information. Participation was strictly voluntary. All participants were informed that they could decline or withdraw from the study at any time without consequence. A consecutive patient log tracked the reason for patient nonparticipation or withdrawal if the patient provided it, but we did not attempt to induce continued participation. For U.S. patients, survey completions were incentivized by means of mailed debit cards or checks: \$10 for each returned 1-week questionnaire, \$10 for the 3-month questionnaire, and \$30 for the 6-month questionnaire. In Scandinavia, patients were incentivized with dental care products at each of the three time points.

Practitioner-Investigator Training Sessions

Before data collection began, DPBRN project staff at each of the five regional administrative centers met face to face with each p-i and his or her office staff. DPBRN staff explained the study protocol and addressed any questions. The study data-collection forms were explained, and printed instructions for completing the forms were provided. Each p-i was invited to seek clarification from their regional coordinator, if needed. Practices were remunerated \$50 for each subject who completed and returned set of baseline questionnaires. For each patient enrolled, one of the practitioner's staff members also was given a \$25 debit card or check for helping manage forms for the office encounter and transmission of the data to the regional coordinator. This staff-centered incentive occurred only in settings in which existing contracts allowed it.

Data-Collection Forms and Procedures

All data-collection forms and procedures for this study can be viewed on the network's public Web site, <http://www.dpbrn.org/users/publications/Supplement.aspx>. These forms pertain to two network studies: Study 17, with the endpoint of pain during the first postoperative week, and Study 18, with its pain endpoint measured at 6 months. Specific study questionnaires are identified in this paper by their form number. We estimated that it would take dentists 15 minutes to obtain consent and complete their questionnaires (Forms 05 and 07), while it would take patients 1 to 5 minutes to complete each of theirs (Forms 04, 09, 11, 12, 13). The Universal Tooth Numbering System was used in the United States to identify tooth type, while the World Dental Federation system was used in Scandinavia. A checklist and script for inviting participation in the study were given to each p-i to help determine a patient's eligibility. We expected each participating practice to tally all consecutive eligible and ineligible patients on a consecutive patient log (Form 03). Following consent, patients completed the first 10 questions of their baseline data form (Form 04) before local anesthetic was administered. Forms 04 and 09, which were completed by patients during their clinic visit, were placed in a sealed envelope, thus maintaining the confidentiality of their responses even with regard to the treating p-i and staff. All patient-sealed packets from each clinical encounter were collected by the office staff, joined to the clinical encounter forms completed by the p-i (Forms 05 and 07), and transmitted to the regional administrative center. Following each RCT-related appointment, patients were given a folder with Form 11 to complete at 1 week and return in a pre-addressed, postage-paid envelope. Patient reminder calls were made 1 day before, on, or up to several days after the deadline for completing the form. If questionnaires were not returned, we tried to collect the data by telephone call. Surveys to be completed at 3 and 6 months were mailed 1 week before their desired completion date and were followed by reminder calls. In FL/GA, all follow-up surveys were conducted via telephone. In MN, subjects who did not respond to telephone calls received a reminder email from the regional coordinator.

Management of Unanticipated and Adverse Events

The p-i, as the care provider, was responsible for attending to all the needs of the patient subjects. Because this was an observational study without any manipulation of the actual treatment rendered, variations of care were tolerated and measured by the data-collection forms. However, any deviations from the specified study protocol also were to be reported by the p-i to the regional coordinator for documentation.

Data Management Procedures and Data Quality Assurance

Regional administrative staff checked for completeness and accuracy of the data. Patient identifiers were maintained only at the regional level for mailing follow-up surveys. Rather

than identifiers, all data-collection forms were labeled with a barcode and unique study identification number to ensure the protection of participant health information. De-identified forms were couriered in batches to the Coordinating Center at UAB. Data management at UAB used standard practices to ensure data accuracy and validity. This included double entry of random 10% of data to screen for errors with re-entry of batches that failed data quality control measures, which was a 0.5% discrepancy in values. All electronic data were stored on a secure network drive with restricted access. Members of the UAB Coordinating Center statistical consulting unit prepared the final dataset and documentation.

Statistical Methods

Frequency tables in the Results section were generated using Proc Freq (SAS® 9.2, SAS Institute, Cary, NC). Multinomial ordinal data were collapsed to binary categories to compare study regions using Pearson's chi-square statistic. Means and standard deviations were computed for the region-specific age distributions as well as for the combined study sample. One-week follow-up data were accepted until study closure. A greater than 80% collection rate of 1-week follow-up questionnaires was considered "adequate," greater than 90% "good," and greater than 95% "excellent" (13, 37).

RESULTS

This paper reports on data collected on Form 03 (Consecutive Eligible Log), Form 04 regarding study sample demographics and socio-economic status, Form 05 for types of teeth obturated, and Form 07 for data on study practitioner capacity for enrollment. We also report on return rates for all data-collection instruments up to and including Form 13, the 6-month post-obturation questionnaire.

Recruitment of Practitioner-Investigators and Study Subjects

Seven-hundred-eight eligible patient subjects participated in this study (Table 1). Sixty-two p-i (46 general practitioners, 16 endodontists) performed an RCT on one or more patients. The recruitment of 708 subjects was 18% higher than the original goal of 600. The 62 collaborating practitioners represented a 29% increase over the projected minimum of 48 dentists necessary to accomplish the study goals.

Figure 1 diagrams the process of enrollment of patients for this study. It shows that 1,044 patients were consecutively screened for this study and logged in the Consecutive Patient Log (Form 03). Eight p-i did not submit a Consecutive Patient Log to their regional coordinator. However, they enrolled an additional 37 patients, thus showing that a minimum of 1,081 patients were invited to participate. Of these, 283 (26%) were not enrolled for the reasons indicated in Figure 1. After completion of informed consent, a total of 59 (7.4% = 57/798) participants did not proceed to obturation (11 withdrew consent, 13 had teeth that were deemed unrestorable, 33 were censored with closure of enrollment). An additional 31 participants were found to be ineligible (3.9% = 31/798) with 13 being identified by the p-i during the treatment process and 18 by study staff at the conclusion of data collection during analysis. Therefore, of the consenting patients, a total of 11.2% (90/798) were excluded thus resulting in 708 eligible participants whose data were analyzed as the baseline study sample.

Table 2 shows the distribution of completed RCT performed by p-i during the 6-month data-collection period. Mean monthly enrollment capacity for endodontic specialists was computed as 413 completed patients per 16 practitioners per 6 months, or 4.3 patients per specialist per month. For general practitioners, we computed 295 completed patients per 46 practitioners per 6 months, or 1.1 patients per generalist per month. Eligible patients

presented as a part of regularly scheduled care in each participating practice. Due to the availability of patients by practice and practitioner, some p-i enrolled throughout the entire enrollment period, while others “timed-out” when they met their enrollment goal.

Return Rates for Study Questionnaires and Usable Responses to Individual Questions

The specific data-collection return rates for baseline information ranged from 87%, for consecutive eligible logs completed by individual practices, to 100% for dentist surveys after treatment (Table 3). Return rates for follow-up questionnaires submitted by patients were 91% for patient 1-week follow-up survey, 90% for patient surveys 3 months after treatment, and 92% for patient surveys 6 months after treatment.

Summary of Patient Characteristics and Study Findings

Table 4 shows the demographic characteristics of the study patients. Mean age over all study regions was 48 years (SD=13). No statistical difference was found for site-specific age distributions ($P=0.06$). Females composed 59% of the study population. The female percentage was higher than that for males in three regions (AL/MS, FL/GA, and MN). In contrast, more males than females were enrolled at PDA and in SK thus resulting in a statistically significant regional difference in gender distributions ($P=0.04$). Ethnic distributions were significantly different ($P<0.001$), with the recruitment of less than or equal to one Hispanic or Latino in three regions (AL/MS, PDA and SK). White patients were the majority in each study region.

Study data indicate that 64% of all study participants had an annual household income greater than \$50,000. An additional 21% were in the \$30,000 to \$50,000 range (Table 4). The regional distributions of the four income categories did not differ significantly ($P=0.43$). A significantly higher proportion of patients in PDA and SK regions had dental insurance ($P<0.001$) and a significantly higher proportion of PDA patients had some college education ($P<0.001$).

Over the five DPBRN regions, 77 maxillary and mandibular anterior teeth, 362 maxillary posterior teeth, and 269 mandibular posterior teeth were obturated, for a total of 708 teeth (Table 5). The proportion of teeth on the left and right sides were equal (50% each).

Frequency of Unanticipated and Adverse Events

One unanticipated data-collection event occurred in the MN region, where a patient included additional health-related information on a follow-up survey in the form of written comments that had not been solicited. No adverse events associated with treatment were observed.

DISCUSSION

Feasibility of Conducting Clinical Endodontic Research in the Network

Project feasibility is typically demonstrated when recruitment goals can be reached, data can be collected regarding the study treatment, and patients can be followed over the specified period of observation. Using these measures, this study showed compellingly that it is feasible to conduct a large, prospective endodontic cohort study in the network.

Practitioner involvement—The pre-study estimate of 48 practitioners needed to accomplish the study goals was exceeded by 29%, with actual recruitment at 62. This enrollment success is greater than the 10% planned over-enrollment, and is a result of the enthusiasm across the network for participation in this research project. These high levels of interest and participation bode well for the feasibility of engaging community-based dentists

to recruit their patients and record data, both key aspects of conducting clinical endodontic research.

Participant enrollment—The projected minimum sample size required was estimated to be 600 participants enrolled over 6 months. After all ineligible subjects had been excluded from the data set, 708 subjects remained, an 18% increase over the pre-study estimate. Pre-study estimates of practitioner productivity were also fulfilled, with the endodontic specialists enrolling 4.3 eligible patients per month and the general practitioners enrolling 1.1 eligible patients per month during the 6-month baseline data collection. Enrollment and training of each p-i was rolling (i.e., most practitioners were not enrolling patients over the entire 6 months). These overall enrollment averages are snapshots in time (weekly and biweekly reporting by the regional coordinators), and do not represent exact “real-time” rates of enrollment in the practices. Therefore, if we subtract the 33 consenting patients who were subsequently determined to be ineligible (18 age-ineligible and 15 for other reasons), 1,048 screened patients yielded 708 eligible study patients completing (Figure 1). This suggests that a p-i had to screen about 1.5 eligible patients to recruit one participant who completed the study enrollment criteria. This is a robust enrollment capacity and demonstrates high levels of feasibility for recruitment of adequate numbers of endodontic patients over a limited timeframe in the network. It also compares well with other large prospective studies (38, 39, 40, 41, 24).

Internal and External Validity

For this prospective observational study, which is the preferred design (42, 43), internal and external validity were addressed by minimization of participant selection bias, unbiased administration of the study questionnaires, and unbiased collection of study questionnaires. In addition, there were ongoing assessments of study implementation and the data quality controls.

Minimizing Selection Bias—The study sample of patients presenting for initial orthograde RCT was not a randomly selected representative sample but rather a convenience sample. To guard against intentional or unintentional p-i bias, consecutive enrollment of patients presenting for RCT was employed. This is the preferred method to minimize the potential for practitioner bias relative to patient selection in prospective cohort studies (26, 44). We note, secondly, that data from the consecutive eligible log suggest that practitioners screened about 1.5 potential patients to enroll one eligible patient who subsequently completed the study. This represents a high acceptance rate of network endodontic patients as research participants, although we were unable to identify any similarly designed studies for comparison. A further indication that selection bias was minimized is noted under the Generalizability heading below: our study patients within the United States were demographically similar to national averages of U.S. patients presenting for initial RCT. This comparison is a recommended method for assessing selection bias (44). Taken together, consecutive patient recruitment, a high percent of enrollment, and the comparability of study patient demographics suggest a low level of selection bias. However, the best guard against such systematic error is to completely document all patients approached for enrollment (16). One possible way to improve the 87% compliance for the consecutive log is to introduce an incentive for capturing appropriate data in this log for all potential patients. Another method would be to increase study oversight with consistent monitoring to ensure compliance.

Appropriate concealment of questionnaires—Study forms were administered in a manner reasonably free from influence by someone other than the person completing the questionnaire. Each p-i and his or her office staff were instructed during protocol training

not to influence their patients' responses on the patients' preoperative or postoperative questionnaires. The dentist providing care was simultaneously the treating clinician (care that would be provided even if the patient did not agree to be a study participants), a study investigator (by enrolling participants, recording data, etc.), and a study subject (because the network is ultimately interested in observing whether the dentist changes how care is provided). These simultaneous roles could theoretically affect the internal validity of the study data. We judge that issues as to internal validity were minimized for these reasons: (1) the treatment was to be provided anyway; (2) the treatment procedures that were done in this study are provided routinely in these offices; (3) data confidentiality was assured to the patients; (4) some patient reports were done via questionnaires or interviews away from the treating dental office. Because the practitioner-investigator was aware that these procedures were being observed and recorded as part of a research study, it is possible that extra attention to care was provided. Patients were not privy to the questionnaires completed by the p-i. The high levels of reporting procedural difficulties by the p-i suggest a good level of their comfort with the confidentiality of the data being collected. In summary, significant bias associated with the data collection process arising from confidentiality concerns was unlikely, supporting a high level of internal validity.

Quality of study data—Study feasibility requires that the study team be able to collect usable questionnaires that are complete and credible. When asked whether those who provided study data are different from those who did not provide data (45), the best defense is to obtain high rates of survey returns (37). The return rates for study questionnaires were “good” to “excellent,” as interpreted from published standards (13, 37) for all forms except the Consecutive Eligible Log, which was “adequate,” at an 87% response rate. These high collection rates, especially for the follow-up questionnaires, indicate a low level of non-responder bias. Several study procedures recommended to promote high levels of data quality were implemented in this study. They include a study manual of operations and procedures, care in designing forms, pre-testing, and curation of data-collection forms, training sessions, and active monitoring (46), as well as enthusiasm of dental personnel and persistence in data-collection efforts by the regional administrative staff. The rigor of the current study design and effort in collecting data likely contributed to the 90+ percentage collection rates of follow-up data, which compares well against similarly designed studies (7, 9, 47).

Generalizability of the Data to the Typical Endodontic Patient

The concept of generalizability pertains to how well the included study sample of participants represents the target population to which the results will be applied. A related consideration is how well the entity or condition being studied is consistent with the spectrum of the condition in clinical practice (37). Recommended strategies to achieve this are sampling from multiple locations, obtaining large numbers, seeking geographic representation, selecting participants early within their care, sampling in a random or consecutive fashion, and selecting participants from different clinical settings. These strategies are considered to enhance inferences of generalizability (11, 37, 44, 48). Because inclusion of every person from the target population with the condition of interest is neither feasible nor necessary, each study must be assessed as to how much it appears to deviate from the ideal so that an assessment of potential errors can be made (44).

The generalizability of this study's findings may be inferred from the fact that study participants were not drawn from a few practices or a single geographical area, but from 62 practices that include both general dentists and endodontic specialists located in four widely separated regions of the United States. In addition, the outcome estimates are based on a large study sample of 708 patients, which compares favorably to other prospective studies

assessing outcome of orthograde RCT (25). In the United States, most patients receive RCT from their general dentists (6, 49) while, in most published research, the care has been provided by endodontists (25). Furthermore, clinical endodontic research data most often are derived from institutions (25, 47), which do not represent the community practice setting where the bulk of such care is provided. These project characteristics all support an improved capacity to generalize results back to the settings from which they were drawn.

Characteristics of the Study Participants

Demographic characteristics—This study was not designed to estimate differences between study regions in study variables. Such a goal would have required a nearly equal number of participants in each region. Data are presented in this report by region to highlight region-specific variability and to demonstrate the potential need for statistical adjustment with respect to region, gender, age, and practice type for the pain prediction models that are to be reported in subsequent papers. The mean age of the American study subjects was 48 years (SD=13), with a range of 19 to 70 years. This is similar to the ages of patients seen by both general dentists and endodontists in the United States, except that the age range, dictated by our design, is more extreme in the U.S. population (6). Females represented 59% and males 41% of the 645 American patients with data, for a 1.44 proportion of female-to-male patients. A similar female-to-male proportion of 1.40 is seen by endodontists for orthograde RCT in U.S. patients, but this ratio is higher than the 1.03 that has been reported in endodontic patients treated by general dentists (6). When we combined the 96% non-Hispanic and 91% White groups, we observed that the White non-Hispanic group constituted 86% of the patients. This means that Hispanic ethnicity and non-White races were underrepresented in the participating study sample compared with the U.S. general population, because non-Hispanic Whites are currently estimated to be 65% of the U.S. population (50).

Socioeconomic characteristics—Annual income greater than \$30,000 was reported by 85% of the U.S. participants, having dental insurance by 80%, and having at least some college education by 84%, which is also different from the general U.S. population (51, 52). These results are not surprising because dental patients in general tend to have these characteristics since we know that dental patients who receive RCT are substantially different from dental patients in general, being predominantly White and female, with higher socioeconomic status (53).

Anatomic characteristics—The teeth treated in this study were predominantly molars (61%) and premolars (28%), with a slight majority in the maxillary arch (59%), but with an equal distribution per side. This is very close to similarly designed studies (24, 38), insurance claims-based research (54), and professional society surveys (6).

CONCLUSIONS

Sufficient numbers of patients can be recruited as participants for a large-scale prospective endodontic study in the context of the network. High levels of patient consent to participation in various community-based practices and high levels of data collection suggest good internal validity. The use of in-office questionnaire-based data collection forms with high levels of acceptance suggests that the burden placed on patients and dentists is acceptable. Overall, we conclude that it is feasible to conduct high-quality clinical endodontic research in the network, a setting that can produce a sample of patients with greater generalizability to the average U.S. dental patient than most previously published endodontic research.

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Figure 1.
Disposition of Consecutive Eligible Patients Reported in Enrollment Logs

Table 1

Target and Actual Enrollment of Practitioners and Patients

Region	Total		AL/MS		FL/GA		MN		PDA		SK		
	Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
	GP	36	46	5	7	5	12	18	19	4	3	4	5
Practitioners	ES	12	16	1	3	2	2	6	7	1	2	2	2
	N	48	62	6	10	7	14	24	26	5	5	6	7
	GP	300	295	42	37	42	72	150	130	33	15	33	41
Patients	ES	300	413	25	61	50	59	150	260	25	21	50	12
	N	600	708	67	98	92	131	300	390	58	36	83	53

GP=General practitioner, ES=Endodontic Specialist

Table 2

Numbers of Patients Recruited, by Practitioner Type and Region

		Region					
		Totals	AL/MS	FL/GA	MN	PDA	SK
General practitioners	< 5 (%)	39	57	42	37	33	20
	5 (%)	61	43	58	63	67	80
	N	46	7	12	19	3	5
Endodontic specialists	< 5 (%)	25	33	0	0	50	100
	5 (%)	75	67	100	100	50	0
	N	16	3	2	7	2	2

Table 3

Questionnaire Return Rates for the 708 Enrolled Patients

Form #	Description	Timing	N (received / expected)	%
03	Consecutive eligible logs	Screening	54 / 62	87
04	Patient surveys before treatment	Baseline	704 / 708	99
05	Dentist surveys before treatment	Baseline	707 / 708	100
07	Dentist surveys after treatment	Baseline – all	863 / 864	100
		1 st appointment	708 / 708	100
		2 nd appointment	149 / 150	100
		3 rd appointment	6 / 6	100
09	Patient surveys immediately after treatment	Baseline – all	856 / 864	99
		1 st appointment	703 / 708	99
		2 nd appointment	147 / 150	98
		3 rd appointment	6 / 6	100
11	Patient 1-week follow-up survey	1 week – all	802 / 864	93
		1 st appointment	655 / 708	93
		2 nd appointment	141 / 150	94
		3 rd appointment	6 / 6	100
12	Patient surveys 3 months after treatment	3 months	640 / 708	90
13	Patient surveys 6 months after treatment	6 months	651 / 708	92

Note: 144 patients had 2 appointments and 6 patients had 3 appointments before tooth obturation occurred

Some percentages were rounded up to equal 100%.

Table 4

Characteristics of Study Subjects by Region

Characteristic		Region					
		Totals	AL/MS	FL/GA	MN	PDA	SK
Age (years)	mean	48	46	48	47	52	51
	SD	13	12	13	13	11	14
	range	19-70	26-69	19-70	19-70	24-68	20-69
	total N	693	97	126	381	36	53
Gender (female)	N (%)	409 (59)	58 (60)	65 (51)	243 (63)	17 (47)	26 (49)
	total N	698	96	127	386	36	53
Ethnicity (not Hispanic)	N (%)	661 (96)	93 (100)	107 (83)	374 (99)	35 (97)	52 (98)
	total N	690	93	129	379	36	53
Race	White	630 (91)	76 (79)	121 (93)	350 (92)	31 (89)	53 (100)
	Black /AA	38 (5.5)	20 (21)	7 (5.4)	10 (2.6)	0 (0)	0 (0)
	Native	9 (1.3)	0 (0)	1 (0.8)	8 (2.1)	0 (0)	0 (0)
	Asian	13 (1.9)	0 (0)	1 (0.8)	8 (2.1)	4 (11)	0 (0)
	Other	6 (0.8)	0 (0)	0 (0)	6 (1.6)	0 (0)	0 (0)
	Total N	696	96	130	382	35	53
Household income (\$30,000)	N (%)	570 (84)	84 (90)	99 (82)	311 (83)	34 (97)	42 (79)
	Total N	675	93	121	373	35	53
Dental insurance (Yes)	N (%)	571 (81)	75 (78)	85 (65)	323 (84)	36 (100)	52 (98)
	Total N	702	96	131	386	36	53
Education obtained (Some college or more)	N (%)	567 (81)	76 (80)	108 (82)	322 (84)	34 (97)	27 (52)
	Total N	698	95	131	385	35	52

Table 5

Types of Teeth Obturated by Dental Arch and Region

Tooth types	Side	Region					
		Totals*	AL/MS	FL/GA	MN	PDA	SK
Maxillary molars (#1-3, 14-16)	right	105	12	17	62	9	5
	left	120	16	21	62	8	13
	N (%)	225 (54)					
Maxillary premolars (#4, 5, 12, 13)	right	70	8	19	34	3	6
	left	67	16	12	32	2	5
	N (%)	137 (33)					
Maxillary anteriors (#6-11)	right	27	5	6	13	2	1
	left	28	5	9	12	2	0
	N (%)	55 (13)					
All maxillary	N (%)	417 (59)	62	84	215	25	30
Mandibular molars (#17-19, 30-32)	right	113	15	18	64	4	11
	left	96	8	11	64	4	9
	N (%)	209 (72)					
Mandibular premolars (#20, 21, 28, 29)	right	34	6	8	19	0	1
	left	26	3	5	17	1	0
	N (%)	60 (21)					
Mandibular anteriors (#22-27)	right	7	3	1	2	0	1
	left	15	1	3	9	1	1
	N (%)	22 (7.6)					
All mandibular	N (%)	291 (41)	36	47	175	10	23
Totals	N (%)	708 (100)	98	131	390	35	53