
**ABSTRACT**

**Introduction:** Despite initiatives to standardize and improve reporting of rapidly growing endodontic outcome research studies, issues related to missing and ambiguous information are still of great concern. In this article, we propose a framework for standardized data collection and a compiled checklist for reporting of various study designs on endodontic outcome. **Methods:** A comprehensive search was carried out to locate randomized controlled trials, cohorts, case-control studies, or case series of >100 patients that reported on endodontic outcomes. We reviewed these articles to develop a Data Collection Template and compiled a checklist for reporting of future endodontic outcome research. **Results:** Out of 354 eligible articles previously reported in our scoping review on endodontic outcome studies, 109 articles were selected and screened for study variables or levels of categorization. Our compiled Data Collection Template was developed in 19 domains to highlight important demographic, preoperative, intraoperative, and postoperative variables. Because of the specific needs for endodontic outcome literature, we also proposed a compiled checklist (consisting of 4 main domains) to facilitate the reporting of various study designs on endodontic outcome studies. This checklist included simple descriptions of the required items and examples on reporting from published endodontic studies. **Conclusions:** By facilitating the collection and reporting of relevant research data by investigators in private practice and academia, we hope that the proposed Data Collection Template and reporting guideline can highlight the importance of standardization among clinicians and researchers while producing valid scientific information that will support evidence-based treatment decisions. (J Endod 2022;48:40–44.)

**KEY WORDS**

Data collection template; dental pulp diseases; endodontics; outcome studies; reporting guideline; standardization
There is a growing demand for endodontic therapies such as nonsurgical root canal treatment (NS-RCT) and nonsurgical retreatment (NS-ReTx). An assessment of clinical outcomes will be key indicators to determine effectiveness and safety of such treatments. Despite the increased number of published studies on endodontic therapies over the past 4 decades, most of these publications still have significant disparities in their outcome assessment methods and reporting the results. This variance in reporting the outcome reporting creates a problem when conclusive evidence regarding therapies needs to be made.

In the first phase of the current study, we carried out a scoping review of 354 randomized controlled trials, cohort, case-control studies, and case series. These articles were published after 1980 and included ≥10 patients, aged ≥10 years, with any preoperative pulpal and periapical diagnoses in permanent teeth requiring NS-RCT, NS-ReTx, and apicectomy procedures. Despite the implementation of guidelines for conducting and reporting research, our scoping review identified 2 overarching limitations that are the product of significant heterogeneity and variance in study methods and results of endodontic outcome studies: missing information and misreporting of data. Missing information included timeframe direction (particularly in cohort and case series), outcome assessor and treatment provider, reason, or timeframe for loss of follow-up and masking. Second, misreporting was noted for units of sample size, as a function of the number of teeth, patients, roots, or not specified; outcome measures, because of use of tooth, root, or both as the unit of outcome analysis that overestimated outcome measure in multi-rooted teeth; dropouts and excluded teeth, because of dual exposure as a unified variable without segregating the individual variables, obfuscating the actual loss to follow-up value; and terminologies of pulpal and periapical diagnoses.

Despite a subtle improvement in adherence to well-established guidelines and checklists in more recent studies, there still exists an overall lack of adherence to terminology and quality of reporting. Owing to these inconsistencies, we planned to develop a framework for standardized data collection and reporting of endodontic outcome studies. The aim is to facilitate researchers in private practice and academia to collect and publish important data in a standardized manner and to help to overcome inconsistencies.

**METHODS**

**Preparation of Data Collection Template**

The Data Collection Template was initially prepared by using the American Association of Endodontics Guidelines for the Methodology of Cracked Tooth Studies, cross checked against the available systematic reviews. A panel of 3 endodontists (HJ, GM, AA) prepared the initial draft and modified the categories in consensus.

From the list of our database in the scoping review, 109 prospective studies (i.e., randomized controlled trials, cohorts, or case series) and mixed cohort studies with a sample size >100 were selected. These studies represent 33% of randomized clinical trials (n = 22), 58% of prospective cohorts (n = 38), 25% of prospective case series (n = 5), and 79% of mixed cohort studies (n = 44) included in our recently reported scoping review (Fig. 1). These 109 articles (Supplement 1 is available online at www.jendodon.com) were screened for additional variables or levels of categorization for incorporation to our data collection template.

**Preparation of a Complied Checklist to Report Endodontic Outcome Studies**

Two reviewers (SK, AA) prepared a compiled checklist for methodology and reporting of endodontic outcome studies following the Clinical Study (Observational) Protocol of the National Institute of Dental and Craniofacial Research, Fletcher textbook of Essentials Clinical Epidemiology, Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), Consolidated Standards of Reporting Trials (CONSORT), and Appropriate Use and Reporting of Uncontrolled Case Series in the Medical Literature. To ensure high-quality reporting, both Newcastle-Ottawa Scale for assessing the quality of nonrandomized studies and Cochrane Risk of Bias assessment tool were also considered. For each item on the reporting checklist, a short description and an example of published endodontic study were added.

**RESULTS**

**Data Collection Template**

Upon updating to variable names, classification, and simplification, the Data Collection Template was prepared in 19 domains per the following:

1. Demographic data
2. Preoperative patient-related data (medical history)
3. Preoperative clinical signs and symptoms
4. Preoperative clinical findings (intraoral and extrarctal examination)
5. Preoperative diagnostic data (clinical)
6. Preoperative radiographic techniques and findings
7. Preoperative diagnosis
8. Estimated prognosis
9. Intraoperative (intervention) data
10. Treatment visits
11. Additional intraoperative (intervention) data for retreatment and previously initiated therapy cases
12. Additional intraoperative (intervention) data for apicectomy cases
13. Post-endodontic restoration
14. Postoperative (follow-up) diagnostic data
15. Postoperative (follow-up) clinical findings
16. Postoperative radiographic (follow-up) techniques and findings
17. Postoperative (follow-up) cone-beam computed tomography findings
18. Postoperative diagnosis–treatment outcome
19. Operators, data collectors, and outcome assessors

The Data Collection Template is presented in Figure 2. The Microsoft Excel version (Microsoft, Redmond, WA) has been prepared for the convenience of modification and for the actual data collection and is accessible in Supplement 2 (available online at www.jendodon.com).

**Complied Checklist for the Reporting of Endodontic Outcome Studies**

To enhance the quality of reporting of important elements of future endodontic outcome studies, the following checklist was compiled to guide authors in writing their study’s introduction, methodology, and results. For each item, a short description and examples from previous published endodontic outcome studies are provided.

1. Introduction: Background Information and Scientific Rationale
   This section should address the health problem related to endodontics and provide background information on the study subject. The text should be informative. In addition, discussion of important relevant research (clinical, epidemiologic, or public health background) is helpful to establish the state and gap of knowledge.
2. Methodology

2.1 Objectives
A detailed description of primary and any secondary objective(s).

eg, “The objectives of this part of trial were to assess the intermediate- and long-term (6- and 12-month) radiographic and clinical success rates of vital pulp therapy with calcium-enriched mixture cement and root canal therapy”.

2.2 Research question
Define components of the research question based on Population, Intervention/Exposure, Comparison/Unexposed, Outcome, and Follow-Up Time (PICOT).

eg, “… that necrotic teeth with chronic apical periodontitis (P) treated with Er,Cr:YSGG laser and radial firing tips (I) would demonstrate similar outcomes using the periapical index (O), when compared with teeth treated with 3% NaOCl and calcium hydroxide dressing (C)”.

2.3 Study design

2.3.1 Ethics statement
Confirm that the study protocol and the informed consent for subject recruitment compliance have received ethics approval. Study registration number or public profile link of ethics approval should be mentioned.

eg, “The study protocol was approved by the Human Ethical Committee of Ege University, School of Medicine (No:14-12/2, 09. January. 2015), and the trial was registered on clinicaltrials.gov with ID: NCT03855501”.

2.3.2 Describe study type/design
- For a cross-sectional study follow STROBE guidelines. Outline eligibility criteria, sources and methods of participant recruitment. Describe methods of follow-up, and define matching criteria and number of exposed and unexposed subjects for matched studies.

eg, Ng et al designed a cohort study to investigate the probability of and factors influencing periapical status of teeth following primary (1RCTx) or secondary (2RCTx) root canal treatment as follows: “The sample population included all patients undergoing 1RCTx or 2RCTx, commencing from the 1st October 1997 until the end of June 2005 in the Unit of...”
Endodontology (part of Department of Conservative Dentistry prior to 2004), UCL Eastman Dental Hospital, London, UK. The patients were referred from general dental practice, secondary dental or maxillo-facial referral centres and other Clinical Units of the dental hospital. All

| Proposed guidelines for the standardization of study variables for endodontic outcome studies |

**Demographics**
- Gender: Male, Female
- Marital status: Single, Married, Divorced, Widowed
- Occupation: Professional, Student, Retired, Housewife, Other

**Medical History**
- Allergies: None, Food, Medication, Other
- Previous surgery: None, Head, Neck, Other
- Previous irradiation: None, Partial, Full

**Prognostic factors**
- Root canal treatment: Primary, Secondary
- Root canal filled: Yes, No
- Root canal filled with: Gutta Percha, Composite, Other

**Endodontic treatment**
- Type: Non-surgical, Surgical
- Technique: EndoSequence, Protaper, Other

**Radiographic examination**
- Type: Bitewing, Periapical, Panoramic

**Prognostic clinical signs and symptoms**
- Presence of pain: Yes, No
- Absence of pain: Yes, No
- Sensitivity to percussion: Yes, No
- Sensitivity to cold: Yes, No
- Radiopacity: Yes, No

**Proposed diagnostic tests**
- Radiographic examination: Yes, No
- Endodontic surgery: Yes, No
- Endodontic retreatment: Yes, No

**Proposed treatment modalities**
- Techniques: NR, SR, Other
- Materials: NR, SR, Other

**Proposed outcomes**
- Success: Yes, No
- Failure: Yes, No

**Proposed reporting guideline**
- Data: NR, SR, Other

**Proposed data collection template**
- FIGURE 2 – A framework for Data Collection Template.

JOE • Volume 48, Number 1, January 2022

Proposed Data Collection Template and Reporting Guideline for Endodontic Outcome Studies
patients were over 15 years of age when treatment commenced and had either 1RCTx or 2RCTx completed and had at least a semi-permanent restoration placed. Teeth were excluded from this study if they had preoperative periodontal disease or prior surgical-endodontic treatment, or if...
the apex/apices under investigation was/were not discernible on any of the periapical radiographs. The teeth were excluded from the analysis of ‘periapical status following treatment’ if: (i) they were not followed-up for at least 2 years, (ii) they were extracted for reasons not related to endodontic problems, (iii) information on the periapical status at the time of the extraction was not available and (iv) a completed pre- and intraoperative data collection form was not available for each tooth.*

- For a case-control study follow STROBE guidelines11

Outline eligibility criteria, and sources and methods of case ascertainment and control selection. Define rationale for choice of cases and controls. Define matching criteria and number of controls per case for matched studies.

eg, “A clinic database was used to identify all patients treated with single-tooth implant restorations within the 10-year period between January 1993 and December 2002. From a total of approximately 2,000 charts of patients receiving implant therapy, 405 implant restorations fit the preliminary inclusion criteria. From this group, a subset of patient charts was collected, consisting of restored implants with at least 1-year recall or those that had an untoward event prior to restoration. Each restored implant that met inclusion criteria had a matched endodontically treated tooth chosen as follows. For an implant restoring tooth number X (using the universal system 1-32), three potential matches were randomly chosen by using the clinic database, according to ADA codes, from among charts where tooth X was endodontically treated. These three endodontic charts were consecutively evaluated until a subject met inclusion criteria; this subject was included as the match and information from the chart was recorded. A total of 196 single-tooth implants in 171 patients and 196 endodontic restorations in 196 patients were evaluated*20.

- For case series follow the guideline on Appropriate Use and Reporting of Uncontrolled Case Series in the Medical Literature13

Data of these studies should include specific information about a group or series of patients that includes demographic, diagnosis, treatment, response to treatment, and follow-up information.

eg, “The target population included all patients receiving root filling by general dental practitioners in the City of Helsinki in 2010–2011. Equal numbers of each tooth type (antennas, premolars, molars) by jaw were included, resulting in 426 teeth. Pre- and postoperative periapical
radiographs were assessed to evaluate periapical status and quality of root filling\(^{23}\). Patients’ demographic information was presented in well-structured tables.

- For a randomized controlled trial follow CONSORT guidelines\(^{12}\).

Report all related CONSORT checklist items such as ethical approval, protocol registration, trial design, settings, location of data collection, recruitment, eligibility criteria, sample size calculation, random sequence generation, allocation concealment, study interventions, calibration of evaluators/evaluations, and statistical analysis.

eg, “The study protocol was approved by the institutional review board of the Faculty of Dentistry, Alexandria University, Alexandria, Egypt, under the institutional review board number 00010556-IORG 0008839 and dated January 2017 and registered in ClinicalTrials.gov (ID: NCT03804450). Oral and written informed consent were obtained from all the study participants after explaining the study methodology. The study conducted was a prospective, parallel-design randomized controlled clinical trial performed following the Consolidated Standards of Reporting Trials guidelines. Eighteen participants were recruited from the outpatient clinic, Conservative Dentistry Department, Faculty of Dentistry, Alexandria University where the study was performed from July 2017 until December 2018. The eligibility criteria ... Participants complying with the eligibility criteria were randomly divided based on the apical diameter size during ProTaper Next (Dentsply Sirona, York, PA) rotary instrumentation into 2 groups: the test group (n = 9 teeth) and the control group (n = 9 teeth) until size X3 and X5, respectively. The allocation ratio between the test and the control groups was 1:1. Each case was represented by a code and a group name. These were then sealed in a sequentially numbered opaque envelope. Upon enrollment of a new case, the in-line envelope was chosen and then opened to start the intervention. The participants, the radiographic specialists, and the statistician were blinded to the treatment group\(^{12}\).

2.3.3 Identify whether it is a multicenter study

Report each center’s detailed information. Include date of enrollment, endpoint of study, sample size, and number of assigned investigators, if applicable, for each center.

2.3.4 State study timeframe

Specify whether the study was retrospective, prospective, or ambispective:

- Prospective: studies are prospective when participants who met the inclusion criteria were enrolled into study before development of disease or any specific outcome and were followed longitudinally\(^{10}\). For example, Chybowski et al studied the outcomes of nonsurgical root canal treatment using a single-cone and EndoSequence bioceramic sealer to determine factors related to success or failure. Inclusion criteria were set on teeth with signs and symptoms of post-treatment endodontic disease. Patients who met inclusion criteria at the commencement of study underwent root canal retreatment and were followed up 12 months to assess the outcome of interest\(^{23}\).

- Retrospective: studies are retrospective when existing dental databases or patients’ charts were evaluated to investigate exposure and outcome. There is no need to consider individuals during the follow-up period since information is already available\(^{10}\). For example, Caplan et al used an available database to identify all permanent teeth receiving root fillings between July 1985 until 31 December 1987. Samples were limited to the patients who had at least one visit in each year that resulted in 1089 teeth from 734 patients. Then, all patient records including radiographs and computerized databases were evaluated to elicit variables in association to their outcome of interest, which was survival\(^{14}\).

- Ambispective: sometimes cohort studies can integrate both prospective and retrospective components in which there is a mixed timeframe (retrospective/prospective). For example, a cohort study of endodontic outcomes could have recruited participants who had received treatment in the past (hence, the retrospective component). The investigators then recalled these patients to recruit them for prospective evaluation of outcomes\(^{25-27}\). For example, Monte et al designed cohort to investigate healing of teeth with open apices. Teeth that were treated between 2000 and 2006 with enlarged apical constriction because of over instrumentation were considered. Patients were contacted for follow-up 12 to 68 months after treatment to assess the clinical and radiographic criteria as outcome\(^{25}\).

2.3.5 Provide additional protocol-specific details, such as a reading center for clinical image or evaluations.

eg, “Cone-beam computed tomography examinations from 1160 patients, 497 males and 663 females with an average age of 48.4 years, were collected from databases in eight health centres. The metropolitan areas of Lisbon, Oporto, Espinho, Moita and Maia, were selected in order to include the main population regions throughout Portugal. All the CBCT examinations available on those centres were analysed. Each scan was evaluated on-site using the same step-by-step screening protocol by one of five
2.4 Study enrollment and withdrawal

4.1.4 Report target sample size (patients and teeth)
Identify anticipated numbers screened in order to reach target enrollment.

eg, “From a pool of 688 consecutively patients enrolled from June 2017 to April 2018, sixty volunteers fit the inclusion criteria and exclusion criteria”.32

2.5 Eligibility criteria

2.5.1 State that in order to be eligible to participate in the study, individuals must meet all the inclusion criteria and list each criterion. Report detailed information regarding a specific condition or systemic disease in studies that aim to evaluate endodontic outcomes in such groups.

eg, “All patients fulfilling the inclusion criteria were invited to attend the first follow-up appointment between 6 and 12 months following completion of root canal treatment. Patients who failed to attend the first review appointment, those who were less than sixteen years old by the first review appointment, or were unable to complete the relevant questionnaires, were excluded.”

Teeth associated with preoperative advanced periodontal bone loss to the apical third were also excluded.33

2.5.2 Provide a statement that all individuals meeting any of the exclusion criteria at baseline were excluded from study participation. Note that the same criterion should not be listed as both an inclusion and exclusion criterion.

eg, “Patients were excluded if they were younger than 12 years old, pregnant, had a positive history of antibiotic use within the past month, needed antibiotic premedication for dental treatment (for infective endocarditis or immunocompromising disorders), suffering from uncontrolled hypertension, uncontrolled diabetes mellitus, chronic renal failure, hematologic diseases, HIV, osteoporosis treated with bisphosphonates, steroid therapy in excess of 5 mg/day of prednisolone, or head and neck irradiation therapy. No compulsion was allowed (e.g., terminal stages, prisoners). Teeth with abnormal root canal anatomy, longer than 26 mm in length, non restorable teeth, and teeth with advanced periodontal disease were not included in the study. Once eligibility was confirmed, the study was explained to the patient by one endodontic resident, and the
patient was invited to participate. Treatments were not subsidized, and no financial incentive was offered (i.e., patients were responsible for the usual root canal treatment fee). It was advised that root canal treatment would be performed regardless of participation in the study. **Azarpazhooh et al.**

### 2.6 Strategies for recruitment and retention

#### 2.6.1 Identify all applied strategies for participant recruitment and retention.

eg, “Subjects were recalled 4–6 years after treatment. They were contacted by letter and telephone, encouraged to attend a follow-up examination, and offered compensation for time lost and travel expenses. Attempts were made to locate and contact subjects whose letters were returned. If the subject reported the tooth had been extracted, the subject’s chart at the Faculty of Dentistry was examined to establish the reason for extraction, or for externally referred subjects, the subject was questioned about the reason for extraction.”

#### 2.6.2 Report all information regarding voluntarily subject withdrawal from the study or if investigator terminated a subject’s participation.

Report if an investigator terminates their participation due to occurrence of a medical condition, or if the participant terminates due to any specific reasons.

eg, “Because of the irritating nature of the 1% diphenhydramine solution (Tables 1 and 2) and the lack of anesthetic success (Table 3), this solution administration was discontinued after 10 subjects.”

Any replacements of study participants who withdrew or discontinued should be reported.

eg, “The patient was questioned every minute for 15 minutes to determine if his or her lip was numb after completion of the IAN block injections. If profound lip numbness was not recorded at 15 minutes, the block was considered missed. The patient was dismissed from the study, and they received appropriate emergency care for their tooth.”

Three patients were dismissed from the study because of missed blocks (1 in the buffered group and 2 in the nonbuffered group), making the final number 100.”

### 2.7 Study schedule and follow-up

#### 2.7.1 Provide a schedule of all study visits or follow-up.

Provide details on participants for each visit. All information regarding contacts with participants should be reported (eg, telephone or email contacts). Report sequence of events that occurred during screening or follow-up. Outline the steps that must occur when screening participants, including inclusion criteria, and the period within which screening and enrollment assessments occur. For each visit, identify the purpose of obtained data.

eg, “At visit 1 after the screening exam, the inclusion/exclusion criteria were checked for each potential subject. Oral soft and hard tissues were examined for any abnormal conditions. Visit 2: Interim Recall Visit: Four weeks after the baseline, participants were asked to return to the Research Clinic at the University of Toronto’s Faculty of Dentistry. The oral soft and hard tissue examinations, as well as the baseline examinations, were conducted on the study teeth. Tactile and thermal simulations were carried out, and the levels of pain were recorded by using new VAS sheets after each stimulus. Then the same treatment as baseline was carried out for 40 seconds, and the measurements were recorded and entered in data entry software. All subjects were asked to call the researchers in case of any health complaint for an immediate appointment. Visit 3: Final Visit: Tactile and thermal simulations were carried out, and the levels of pain were recorded by using new VAS sheets after each stimulus. Also, plaque on the surface of the study teeth was disclosed, and the pictures of the selected study teeth were taken with the same camera.”

#### 2.7.2 Observation period must be sufficient to express the outcome of interest.

Due to the slow dynamic rate of periapical tissue healing, long-term follow-up periods are needed in endodontic outcome studies to report a stable healing process of apical periodontitis. Some studies have suggested a 3–4-year follow-up, whereas others suggest that 5 years results in less biased studies.

#### 2.7.3 For follow-up visits

Report visit number and visit window.

eg, “All patients fulfilling the inclusion criteria were invited to attend the first follow-up appointment between 6- and 12-months following completion of root canal treatment. Patients who failed to attend the first review appointment, those who were less than sixteen years old by the first review appointment, or were unable to complete the relevant questionnaires, were excluded.”

Report list of evaluations/procedures/specimen collections.

eg, “Follow-up assessments of patients were performed by two authors, consisting of updating medical history, routine history-taking and clinical plus periapical radiographic examination of the studied teeth. Extra-oral examination included clinical examination of the face, head and neck (asymmetry, tender points, auscultation and palpation of the temporomandibular joints and assessment of mandibular movements). Intra-oral examination included an assessment of the patients’ occlusion and any interferences on the root filled teeth. Clinical details recorded included tenderness of the adjacent soft tissues, the presence/absence of a swelling, sinus tract, periodontal probing depths, tenderness to pressure or percussion of the tooth and integrity of the restoration margin. Any signs or symptoms originating from adjacent teeth were assessed and accounted for.”

Describe methods used to account for any teeth with untoward events (eg, further treated nonsurgically or surgically or extracted) during the observation period. Explain how the reasons for untoward events were identified (eg, asking the patient, reviewing the examining treatment.
records, consulting with the last provider) and whether endodontic treatment was the cause. eg, “If the subject reported the tooth had been extracted, the subject’s chart at the Faculty of Dentistry was examined to establish the reason for extraction, or for externally referred subjects, the subject was questioned about the reason for extraction”.

2.8 Study outcome measure

Report and clearly define how relevant endodontic outcome measures (eg, success, survival, and radiographic healing) were assessed. Patient centred outcomes (eg, Chewing ability, Aesthetic evaluation, Quality of life measures, Number of visits needed, Pain assessment, Patient’s satisfaction, Treatment time, Treatment cost, as applicable) should ideally be included. Describe clinical, diagnostic, radiographic measures as applicable. As applicable, define criteria for assessment of root-filling quality and assessment of restoration type and quality.

eg, “Successful treatment based on strict criteria was defined as absence of pain, clinical evidence of inflammation or swelling and conventional radiographic measures of complete healing/presence of a normal periodontal ligament space. Successful treatment based on loose criteria was defined as absence of pain, clinical evidence of inflammation or swelling and conventional radiographic measures of complete healing/presence of a normal periodontal ligament space or incomplete healing (if there was reduction in size of the lesion without return to normal periodontal ligament space width). If a tooth had been extracted because of endodontic problems (persistent pain, swelling, sinus or periapical radiolucient lesion), the treatment was considered failed. Tooth extraction without any exit data on postoperative periapical status excluded it from further ‘periapical healing’ analysis”.

2.9 Study procedures/evaluations

2.9.1 Describe all performed procedures and assessments. Provide details on outcome assessment methods, treatment provider, and outcome assessors (eg, endodontist, undergraduate student, etc).

eg, “the present follow-up group, 112 roots in 70 individuals, retreated by undergraduate students in a teaching Clinic”.

2.9.2 Report endodontic procedures, anesthesia, cleaning and shaping of root canals, intracanal medicament and obturating materials and restorative procedures temporary and definitive restorations in details. Provide required details to facilitate duplication of interventions by other clinicians.

eg, “the root canal was instrumented to a No: 25 file and copiously irrigated with 5.2.5% sodium hypochlorite. After drying with sterile paper points, calcium hydroxide paste (Calcium hydroxide and barium sulfate powder in a ratio of 8:1 mixed with glycerin as a medium) was applied to the canal and packed with an absorbent paper point. The access cavity was sealed with zinc oxide-eugenol cement (Austenal, Harrow, UK)”.

2.9.3 If the main aim was evaluating endodontic outcome with regards to specific materials (eg, sealers or calcium silicate based cements), detailed information of composition, handling, and application should be reported.

eg, “After drying the canals by paper points (Dentsply Maillefer; China), one of the two materials, i.e. MTA or Ca(OH)2 was introduced into the canal space depending upon the group to which the tooth had been allotted. Ca(OH)2 paste (Diapaste™, Daedent Co Ltd; Korea) (Ca(OH)2, methyl cellulose [base], barium sulfate [radio-opacifier]) was inserted and condensed into the canal space with hand pluggers, while the MTA (ProRoot™, Dentsply, Tulsa Dental; USA) powder was mixed with distilled water in the ratio of 3:1 and gently inserted at the apical one third of the root canal of teeth with the help of but end of a large sized gutta-percha (GP) point and incrementally pushed up to the apex and slowly compacted (to avoid over insertion into periapical area) by repeated insertion of material”.

2.9.4 If the aim of study was evaluating the endodontic outcome of specific individuals (eg, with related gene polymorphisms or salivary/serologic markers), describe the collection procedures, handling, storage, and processing in detail.

eg, “During the follow-up visit, after the radiographic examination, saliva samples were collected from all included patients. The genotyping analysis was performed from genomic DNA extracted from buccal cells isolated from saliva as previously described. A spectrophotometer (NanoDrop 1000, Thermo Scientific, Wilmington, DE, USA) determined the quantity and purity of the DNA. Two genetic polymorphisms in HIF1A genes were selected. Real-time polymerase chain reaction (PCR) using the TaqMan assay was used to perform genotyping. Water was used as a non-model control (negative control) to ensure the quality control of genotyping reactions”.

2.9.5 Describe data collection process for evaluation. Provide details on outcome assessment methods, eg, details on patient interview, clinical findings, and/or radiographic assessment.

2.10 Statistical considerations

2.10.1 Estimate required sample size/power.

Report all information needed to validate your calculations and to judge the feasibility of enrolling and following the necessary number of subjects. Consider applicable items from the following list when describing sample size determination:

- Statistical method used to calculate sample size
- Outcome measure used for calculations (almost always the primary variable)
- Test statistics and assumed Type I and II error rates
- Method for adjusting calculations for planned interim analyses, if any
- Provide reference data and define assumptions used in calculations, for example, the assumed event rate for
dichotomous outcome (or mean or variance of continuous outcome), justified and referenced by historical data, assumed dropout rates, withdrawal, missing data, etc. Explain the approach to handle withdrawals and protocol violations.

eg, “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. 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. 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 teeth45.

3.2 Report numbers of individuals/teeth at each stage of study.

Report numbers of potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed.

eg, “The inception cohort and study sample are compared in Table 1. Characteristics of the lost-to-follow-up population and the study sample were compared to identify possible response bias. The analysis (not shown) revealed that the study sample was significantly older (mean age, 52 vs 44 years) and had a significantly lower proportion of teeth root-filled with VC (71% vs 81%), compared with the lost-to-follow-up population including dropouts and discontinuers”44.

Report that analyses were based on number of teeth or patients. Do not use roots as unit of analysis.

eg, “The inception cohort of 371 patients and 442 teeth was distributed into the following categories: (a) discontinuers (excluded), 126 teeth from 4 deceased and 105 relocated patients who could not be contacted; (b) dropouts, 163 teeth from 11 patients who declined recall and 121 patients who did not respond; and (c) attending, 153 teeth (48% recall rate) from 130 patients, including 122 teeth examined for outcome (study sample) and 31 extracted teeth (3 for advanced periodontal disease, 12 for restorative considerations, 16 for unknown reasons)45.

3.3 Report number of untoward events and reasons for these occurrences.

eg, “Of all treated teeth, 1019 (0.33%) underwent nonsurgical retreatment and 3767 (1.2%) underwent apical surgery (Table 2). Most untoward events occurred during the first 3 yr. During this period, 870 teeth were retreated (85%), 3607 teeth underwent apical surgery (96%), and 6723 teeth were extracted (84%) (Fig. 1)”45.

3.4 Report numbers of dropouts and reasons at each visit (individuals and teeth) and present the recall and dropout rates, accounting for discontinuers.

Dropout rates should be calculated in prospective or ambispective studies for patient or teeth samples (as applicable to the study). The formula is \( \frac{\text{Baseline} - \text{Final analyzed}}{\text{Baseline}} \). If needed, this rate can be adjusted for “Discontinuer Subjects”; ie, those whose withdrawal was likely unrelated to the study (ie, deceased, relocated, or with wrong phone numbers and addresses45). Such missing data are generally described as missing completely at random45 and can be treated as potential “Discontinuer subjects”. The adjusted formula is \( \frac{\text{Baseline} - \text{Discontinuers} - \text{Final analyzed}}{\text{Baseline} - \text{Discontinuers}} \). eg, “The inception cohort of 371 patients and 442 teeth was distributed into the following categories: (a) discontinuers (excluded), 126 teeth from 4 deceased and 105 relocated patients who could not be contacted; (b) dropouts, 163 teeth from 11 patients who declined recall and 121 patients who did not respond; and (c) attending, 153 teeth (48% recall rate) from 130 patients, including 122 teeth examined for outcome (study sample) and 31 extracted teeth (3 for advanced periodontal disease, 12 for restorative considerations, 16 for unknown reasons)45.

3.5 Explore potential bias related to loss to follow-up.

Compare the final analyzed versus baseline samples with regard to outcome predictor.

eg, “The analysis (not shown) revealed that the study sample was significantly older (mean age, 52 vs 44 years) and had a significantly lower proportion of teeth root-filled...
with VC (71% vs 81%), compared with the lost-to-follow-up population including dropouts and discontinuance.

3.6 Report characteristics of study participants.

Report demographic, preoperative, intraoperative, and postoperative clinical and radiographic features—eg, “Ninety teeth were included in the study; however, nine patients were not available for recall, five patients could not be contacted, and three patients refused to participate in the recall examination. Eighty-one per cent (73/90) of the teeth were available for recall (87% for MTA and 76% for CH) (Fig. 1). Trauma was evaluated as the most common aetiologic factor in pulp death and the development of periapical lesions (62 teeth), followed by either caries (7 teeth) or defective restorations (2 teeth) and dens invaginatus (2 teeth). Sixty-two maxillary incisors had crown fractures that had been present for a prolonged period approximately ranging between 8 and 30 years. The patient sample consisted of 40 males and 33 females, and the age of the patients at the time of apexification treatment was between 18 and 40 years with a mean of 23.34 (5.98) years.”

3.7 Describe if any intraoperative complications or unanticipated problems occurred.

Report on any complications or serious adverse events on participants regarding all endodontic procedures, materials, and medications—eg, “Discomfort ratings for patients experiencing anesthetic failure upon access showed that 46% of the patients in each group experienced moderate to severe pain in dentin.” eg, “In the acetaminophen/hydrocodone group, 76% of the patients reported side effects from the medication (Table 1). The majority of the patients reported euphoria, a few reported sleepiness and a few nausea. Because the patients were blinded to which medication they were receiving, the placebo group also had a 33% incidence of effects (mostly euphoria, some sleepiness, and a few with nausea).”

3.8 Report results of unadjusted and adjusted estimates.

Identify outcome predictors in reporting bivariate and multivariate adjusted estimates, accounting for confounder- and outcome-associated variables, and their precision (eg, 95% confidence intervals). eg, “The overall healed rate of teeth after apexification with MTA (92%) was similar to that of apexification with CH (91%) (hazard ratio [HR] = 1.2, 95% confidence interval [CI] = 0.2–7.1, P > .05). Of the tested clinical factors, none had a significant impact on the outcome of apexification with MTA and CH (P > .05). The evaluated clinical variables had no significant effect on the outcome of apexification with MTA (P > .05; Table 2), and none of the investigated clinical variables had a significant effect on the outcome of apexification with CH (P > .05; Table 3). The survival rate of apexification with MTA (90%) was similar to the survival rate observed with CH (91%)”.

4. Quality Control and Quality Assurance

To enhance the quality of the final manuscript, consider self-assessment of critical appraisal for the study:

- For case series studies, use Appropriate Use and Reporting of Uncontrolled Case Series in the Medical Literature. Make sure that you have reported information related to all four domains (ie, eligibility criteria and selection, treatment procedure and potential risk, comparability and outcome).
- For cross-sectional studies, cohort studies, and case control studies, use Newcastle-Ottawa Quality Assessment. Make sure that you have reported information related to all four domains (ie, selection, comparability, and outcome).
- For randomized controlled trial, use Cochrane Risk of Bias Assessment Tool. Make sure that you have reported information related to all six domains (ie, random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting.

DISCUSSION

In the last 4 decades, there has been a rapid growth of endodontic outcome literature. However, an increase in reporting consistency was not observed. Despite the introduction of initiatives to standardize and improve reporting of research studies, issues related to missing and ambiguous information are still of great concern.

Because of the specific needs for endodontic outcome literature, in this article we proposed a compiled checklist for reporting of various study designs on endodontic outcome studies that would decrease presumptive errors while highlighting important demographic, preoperative, intraoperative, and postoperative variables.

Standardized reporting guidelines have multiple benefits, including facilitating the dissemination of evidence, encouraging reference to the published articles, easier replication of methods, and allowing for proper synthesis of literature for future development of systematic reviews and meta-analyses, as well as recommendations and guidelines. Integration of such compiled checklists to common practice in outcome studies reporting would allow for increased public transparency in quality of research for journal editors and readers. Journal editors will be more able to precisely and systematically assess manuscripts, and readers benefit by being able to differentiate between high-quality studies that utilized the standardized approach versus lower-quality reports that did not. In fact, if journal publishers were to integrate the checklist as a publication requirement, similarly to the way many publishers require adherence to the CONSORT checklist and flowchart for manuscript publication, then initial reporting quality can be expected to substantially increase. This may in turn reduce the time to publication and increase the percentage of accepted manuscripts.

By facilitating the collection and reporting of relevant research data by investigators in private practice and academia, we hope that the proposed Data Collection Template and reporting guideline can highlight the importance of standardization among clinicians and researchers while producing valid scientific information that will support evidence-based treatment decisions.

CONCLUSION

This article developed a comprehensive data collection form to assist clinicians in evaluating the outcome of their treatment. The Data Collection Template will enhance the quality of reporting on endodontic outcome studies. The proposed compiled checklist for reporting is also presented to...
further enhance standardization. We hope that the use of the proposed framework for standardized data collection and reporting is encouraged among researchers and clinicians from institutions, practice-based research networks, or large group practices, as well as individual private practitioners. It can potentially advance endodontic research by yielding relevant data in a uniform and consistent manner over time, which will greatly facilitate future knowledge synthesis development.

ACKNOWLEDGMENTS

The authors thank the American Association of Endodontists and the American Association of Endodontists Foundation for Endodontics for supporting this project.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found in the online version at www.jendodon.com (https://doi.org/10.1016/j.joen.2021.09.017).


