american association of endodontists

Guidelines for the Methodology of Cracked Tooth Studies

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Introduction

The guidelines for the methodology of cracked tooth epidemiologic studies are intended to allow institutions, practice-based research networks, large group practices and even individual private practitioners to collect and publish important data with regard to the incidence and/or prevalence of root cracks or fractures (RC/F) in teeth.

While they are not fixed protocols, the guidelines will standardize methodology and data collected across studies, facilitating future meta-analysis of the data from the studies that use this protocol. It should be noted that this methodology would not include cracks that result from acute dental trauma, such as a horizontal root fracture, but the increasingly common type that is perhaps a repetitive stress injury.

Special thanks to the Special Committee on Methodology of Cracked Tooth Studies for their work in developing these guidelines:

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Methodology for Assessment of Prevalence of RC/F in Root-Filled Teeth

Eligible Study Designs

- Cross-sectional longitudinal study — follow STROBE guidelines

Methodology and Reporting Requirements

- Confirm approval of study protocol by relevant Institutional Review Board and compliance with informed-consent protocol for subject recruitment for the study.
- Estimate required sample size including reference data/assumptions.
- Define the study population of interest and describe methods of recruiting subjects.
- Specify eligibility criteria for subjects, if applied.
- Specify how root-filled teeth are identified, e.g., inspection of panoramic radiographic records, review of cone beam computed tomography volumes.
- Describe data collection process used to assess root-filled teeth, e.g., exposure of periapical radiographs, face-to-face interview, clinical examination, or combination of the above.
- Define inclusion/exclusion criteria for root-filled teeth, if applied. For example, to assess RC/F, time lapse of ≥ 2 years after endodontic treatment may be considered as threshold for inclusion.
- Define how missing teeth were considered, specifically how any root-filled teeth among them were identified.
- For root-filled missing teeth, describe how the study determined whether RC/F was the cause of extraction, e.g., by asking the patient, by examining treatment records, or by asking the dentist who last examined the tooth before extraction.
- Define outcome assessment/diagnostic (clinical, radiographic) measures of periapical health/disease and RC/F. Include specific features suggestive of/consistent with RC/F.*
- Specify outcome assessment criteria used, with specific mention of criteria for assessment as RC/F.*
- Define assessment (clinical, radiographic) measures and criteria for assessment of root-filling quality. Optional in study focused on RC/F.
- Define assessment (clinical, radiographic) measures and criteria for assessment of restoration type and quality. Optional in study focused on RC/F.
- Define interval period(s) between successive examinations of the same population. For assessment of RC/F, intervals of 5 to 10 years may be considered.

* See page 12 for list of specific diagnostic criteria for RC/F

Statistical Methods

- Define the approach to longitudinal data analysis and reporting, in regards to root-filled teeth captured at the inception of the study.
- Define method for univariate reporting of frequencies within the study sample.
- Define method for bivariate analysis of variables associated with the outcome(s) of interest, including prevalence of RC/F.
- Define method for multivariate analysis of outcome-associated variables.
- Define the level of significance.

Reporting of Results

- Report the study sample captured (N) at the outset of the study. Identify numbers of subjects, teeth, root-filled teeth, missing teeth.
- Characterize the study sample with regards to radiographic (and clinical, if assessed) findings.
- Report the numbers/frequencies of periapical health/disease and other variables of interest, i.e., root-filling quality, restoration type and quality.
- Report specifically on RC/F in captured teeth and, if construed, in missing teeth. Identify numbers/frequencies of the following:
  - teeth with obvious root fractures with separated fragments
  - teeth with fracture lines evident in radiographs or cone beam computed tomography images
  - teeth with radiographic findings suggestive of RC/F
  - teeth with clinical findings suggestive of RC/F
  - teeth with RC/F evident by direct inspection (observation of root surface, exploratory surgery, orthograde access, post-extraction)
- Report on the study sample captured (n) at each subsequent examination juncture, in regards to subjects, teeth, root-filled teeth, missing teeth, RC/F.
- Report specifically on changes observed within the subset of root-filled teeth, with regard to periapical health/disease, e.g., improvement, deterioration, no change, more missing teeth, RC/F.
- Where possible, in reporting of teeth diagnosed as having RC/F, differentiate between roots with and without posts.
- Report the bivariate analysis to identify variables associated with outcomes of interest, including RC/F.
- Report the multivariate analysis to identify predictive variables including those related to RC/F.

Methodology for Assessment of Incidence of RC/F in Root-Filled Teeth

Eligible Study Designs

- Prospective cohort study – follow STROBE guidelines
- Randomized controlled trial – follow CONSORT guidelines
- Retrospective cohort study – follow STROBE guidelines

Preoperative Data Collection and Reporting Requirements

- Confirm approval of study protocol by relevant Institutional Review Board and compliance with informed-consent protocol for subject recruitment for the study.
- Define inception cohort/study population/study groups.
- Define preoperative assessment/diagnostic (clinical and radiographic) measures and criteria.
- Specify inclusion/exclusion criteria, with specific mention of diagnostic features suggestive of/consistent with root crack/fracture.
- Define included study sample (N).
- Characterize the study sample in regards to demographic and pre-operative clinical and radiographic features.
- For randomized controlled trials, describe method of randomization for primary variable of interest and how secondary variables are controlled.
- Estimate required sample size including reference data/assumptions and projected attrition of the sample.

Intraoperative Data Collection and Reporting Requirements

- Describe all intervention steps/techniques/instruments/materials in detail, in a manner that will support duplication of the interventions by others. Include pertinent data regarding temporary and definitive restorations, including time elapsed between root filling and restoration.
- Describe intraoperative complications that occurred, if any.
- Outline the observation (follow-up) schedule and methods used to ascertain attendance, including incentives offered to subjects. The observation period(s) must be sufficient to express the outcome(s) of interest. For RC/F, this period could be 4-7 years or even longer.

Postoperative Data Collection and Reporting Requirements

- Define outcome assessment/diagnostic (clinical and radiographic) measures. Include specific features suggestive of/consistent with RC/F.*
- Differentiate RC/F from other types of tooth cracks and fractures (because the main dilemma about RC/F in root-filled teeth concerns roots that have no posts).
- Specify outcome assessment criteria, with specific mention of criteria for assessment as RC/F.*
- Describe methods used to characterize subjects lost-to-follow-up into categories of "dropouts" and "discontinuers."
- Describe methods used to account for any teeth that have been lost or further treated (nonsurgically or surgically) during the observation period, including specific reasons that led to such occurrences.

* See page 12 for list of specific diagnostic criteria for RC/F.

Statistical Methods

- Define the approach(es) to data analysis and reporting, i.e., as one-point data, longitudinal data, incidence/frequency of health/disease or survival.
- Define method for univariate reporting of frequencies within the study cohort and sample.
- Define method for bivariate analysis of variables associated with the outcome(s) of interest.
- Define method for multivariate analysis of outcome-associated variables to identify outcome predictors.
- Define the level of significance.

Reporting of Results

- Define the final study sample (n) attending the end-point(s) of the study and characterize it in regards to variables of interest.
- Account for "dropouts" and "discontinuers" (whose absence is not assumed to be related to the interventions or outcomes of interest) and report the recall rate (%N).
- Characterize the final sample (n) in comparison to the original sample (N) and identify differences between the two samples, with regard to outcome predictors, to explore potential bias related to loss-to-follow-up.
- Report the number of teeth lost or further treated during the observation period and the reasons for these occurrences.
- Report the breakdown of results, including RC/F, in relation to specific outcome measures or the outcome criteria or both. Report specifically on teeth diagnosed as having RC/F while differentiating between roots with and without posts.
- Report the bivariate analysis to identify potential outcome predictors, including potential predictors of RC/F.
- Report the multivariate analysis to identify outcome predictors, including predictors of RC/F.

Template for Data Collection

Type of Data	Possible Entries					
Demographic Data						
Sex	☐ Female	☐ Male				
Age (years)	☐ 15-24	☐ 25-34	☐ 35-44	☐ 45-54	☐ 55-64	☐ ≥65
Treated tooth	(enter number 1-32) _____					
Preoperative Clinical Symptoms and Signs						
Spontaneous pain	☐ Absent	☐ Present				
Triggered pain	☐ Biting	☐ Touch	☐ Cold	☐ Hot	☐ Sweet	
Swelling	☐ Absent	☐ Buccal	☐ Lingual/palatal			
Sinus tract	☐ Absent	☐ Buccal	☐ Lingual/palatal			
Preoperative Diagnostic Data – Clinical						
Cold test	☐ Positive	☐ Non-lingering		☐ Lingering	☐ Negative	
Heat test	☐ No pain elicited		☐ Pain elicited			
Percussion	☐ Not tender	☐ Tender	☐ Very tender			
Palpation	☐ Not tender	☐ Tender				
Mobility	☐ Physiological	☐ 1	☐ 2	☐ 3		
Probing depth	☐ ≤ 3 mm	☐ 4-5 mm	☐ ≥ 6 mm			
Probed defect location	☐ Mesial	☐ Distal	☐ Buccal	☐ Lingual	☐ None	
Tooth Slooth	☐ No pain	☐ Pain at one cusp		☐ Pain at ≥2 cusps		
Coronal crack	☐ Not evident	☐ Buccal	☐ Lingual/palatal			
Root crack (with gingiva reflected)	☐ Not evident	☐ Buccal	☐ Lingual/palatal			
Fractured/dislodged restoration	☐ Not evident	☐ Evident				
Preoperative Radiographic Findings						
Periapical area of radiolucency (low attenuation)	☐ Absent	☐ Widened PDL space	☐ 2-4 mm (widest dimension)	☐ 5-7 mm (widest dimension)	☐ ≥ 8 mm (widest dimension)	
Lateral area of radiolucency (enter applicable roots)	☐ Absent	☐ Widened PDL space	☐ Apical 1/3	☐ Middle 1/3	☐ Coronal 1/3	☐ Entire root length
Furcal area of radiolucency	☐ Absent	☐ Level of coronal 1/3	☐ Level of middle 1/3	☐ Level of apical 1/3	☐ Entire root length	
Root fracture	☐ Not evident	☐ Evident				

Type of Data	Possible Entries					
Preoperative Diagnosis						
Pulp	☐ Normal	☐ Reversible pulpitis	☐ Asymptomatic irreversible pulpitis	☐ Symptomatic irreversible pulpitis	☐ Necrosis	☐ Previously treated
Apical	☐ Normal	☐ Asymptomatic apical periodontitis	☐ Symptomatic apical periodontitis	☐ Chronic apical abscess	☐ Acute apical abscess	
Root	☐ Intact	☐ Vertical crack suspected	☐ Vertical crack/ fracture	☐ Horizontal fracture suspected	☐ Horizontal fracture	
Intraoperative (intervention) Data						
Preflaring	☐ Gates-Glidden drills	☐ Orifice Shapers	☐ Other: _____		☐ None	
Instrumentation	☐ Hand instruments only	☐ Rotary used	☐ Reciprocation used	☐ Other (specify) _____		
Irrigation (check all that apply)	NaOCl ☐ 1% ☐ 2.5% ☐ 5%	EDTA ☐ 17% ☐ Other ____ %	Chlorhexidine ☐ 0.12% ☐ 2%	☐ MTAD	☐ QMix	☐ Other (specify) _____ _____
Intracanal medication	☐ Calcium hydroxide	☐ Other (specify) _____			☐ None	
Medication period	☐ < 7 days	☐ 7-10 days	☐ 11-14 days	☐ > 14 days	☐ None	
MAF sizes (enter for each canal)	☐ Distal/palatal	☐ Mesio-buccal/ buccal	☐ Mesio-lingual/ lingual/MB2	☐ Disto-buccal	☐ Single	☐ Other (specify) _____ _____
Root filling technique	☐ Cold lateral	☐ Warm lateral	☐ Warm vertical	☐ Carrier based	☐ Single cone	☐ Other (specify) _____ _____
Temporary access restoration	☐ Composite resin	☐ Glass-ionomer cement	☐ IRM	☐ Cavit	Cotton pellet placed: ☐ Yes ☐ No	
Final restoration	☐ Glass-ionomer cement	☐ Composite resin	☐ Amalgam	☐ Onlay	☐ Crown	
Timing of final restoration	☐ Immediate	☐ ≤ 2 weeks	☐ ≤ 2 – 4 weeks	☐ > 4 weeks		

(Continued on next page)

Template for Data Collection

Type of Data	Possible Entries
Intraoperative (intervention) Data (continued)	
Post	☐ Absent ☐ Cast ☐ Prefabricated metallic ☐ Prefabricated fiber ☐ Prefabricated ceramic
Post extent (relative to crestal bone)	☐ 1-2 mm ☐ 3-4 mm ☐ 5-6 mm ☐ > 6 mm
Post width	☐ ≤ 1/3 of root width ☐ 1/2 of root width ☐ ≥ 3/4 of root width
Post luting cement	☐ Dentin-bonded ☐ Non-bonded
Procedural complication	Perforation: ☐ chamber ☐ coronal 1/3 ☐ middle 1/3 ☐ apical 1/3 Instrument fracture: ☐ coronal 1/3 ☐ middle 1/3 ☐ apical 1/3 Crack extending into canal: ☐ distal/palatal ☐ mesio-buccal/buccal ☐ mesio-lingual/lingual ☐ disto-buccal ☐ other
Postoperative (follow-up) Clinical Diagnostic Data	
Observation period	☐ < 1 year ☐ 1-2 years ☐ > 2-3 years ☐ > 3-4 years ☐ > 4-5 years ☐ > 5 years
Further treatment	☐ Nonsurgical ☐ Apical surgery ☐ Root amputation ☐ Hemisection ☐ Intentional replantation ☐ Extraction
Spontaneous pain	☐ Absent ☐ Present
Triggered pain on biting	☐ Absent ☐ Present
Swelling	☐ Absent ☐ Present
Sinus tract	☐ Absent ☐ Buccal ☐ Lingual/palatal
Percussion	☐ Negative ☐ Positive
Palpation	☐ Negative ☐ Positive
Mobility	☐ Physiological ☐ 1 ☐ 2 ☐ 3
Probing depth	☐ ≤ 3 mm ☐ 4-5 mm ☐ ≥ 6 mm
Probed defect location	☐ Mesial ☐ Distal ☐ Buccal ☐ Lingual ☐ None
Root crack (with gingiva reflected)	☐ Not evident ☐ Buccal ☐ Lingual/palatal
Fractured/ dislodged restoration	☐ Not evident ☐ Evident

Type of Data	Possible Entries					
Postoperative Radiographic Findings						
Periapical area of radiolucency (low attenuation)	☐ Absent	☐ Widened PDL space	☐ 2-4 mm (widest dimension)	☐ 5-7 mm (widest dimension)	☐ ≥ 8 mm (widest dimension)	
Lateral area of radiolucency (enter applicable roots)	☐ Absent	☐ Widened PDL space	☐ Apical 1/3	☐ Middle 1/3	☐ Coronal 1/3	☐ Entire root length
Furcal area of radiolucency	☐ Absent	☐ Level of coronal 1/3	☐ Level of middle 1/3	☐ Level of apical 1/3	☐ Entire root length	
Root fracture	☐ Not evident	☐ Evident				
Postoperative CBCT Findings						
Root fracture/ separation	☐ Not evident	☐ Mesial	☐ Distal	☐ Buccal	☐ Lingual/palatal	
Bone defect pattern	☐ Lateral – narrow	☐ Partial root length	☐ Total root length	☐ Bone plate eroded		
Postoperative Diagnosis – Treatment Outcome						
Apical	☐ Normal	☐ Asymptomatic apical periodontitis	☐ Symptomatic apical periodontitis	☐ Chronic apical abscess	☐ Acute apical abscess	
Root	☐ Intact	☐ Vertical crack suspected	☐ Vertical crack/ fracture	☐ Horizontal fracture suspected	☐ Horizontal fracture	
Cracked/ fractured root	☐ Without post	☐ With post	☐ Mesial/ mesio-buccal	☐ Distal/ disto-buccal	☐ Palatal/lingual	☐ Buccal ☐ Single

Diagnostic Criteria for Application in Epidemiological Studies on RC/F in Root-Filled Teeth

Listed features may be used to diagnose or differentially diagnose RC/F.

Diagnosed as RC/F	Differentially Diagnosed as RC/F	Comments
Observed Features – Clinical		
Spontaneous pain	Spontaneous pain	
Pain on biting	Pain on biting	
Swelling	Swelling	
Single sinus tract	Single sinus tract	
Buccal + lingual/palatal sinus tracts*		
Percussion tenderness	Percussion tenderness	
Palpation tenderness	Palpation tenderness	
Increased mobility	Increased mobility	Mobility 2 or 3
Narrow isolated probing ≥ 6 mm	Narrow isolated probing ≥ 6 mm	Without periodontal disease
Buccal + lingual narrow probing ≥ 6 mm*		Without periodontal disease
Root crack evident*		With gingiva reflected, staining, transillumination, magnification
Observed Features – Radiographic		
Root fracture/separation evident*		
"J" shape defect	"J" shape defect	Without periodontal disease
Extensive radiolucency	Extensive radiolucency	≥ 5 mm
Lateral radiolucency	Lateral radiolucency	• Apical 1/3, middle 1/3, coronal 1/3, entire root length • Without periodontal disease
Lateral widened PDL space*		
Furcal radiolucency	Furcal radiolucency	• Extends to middle 1/3 or entire root length • Without periodontal disease

* Typical feature of RC/F

Diagnosed as RC/F	Differentially Diagnosed as RC/F	Comments
Observed Features – Limited Field of View CBCT		
Root fracture/separation evident*		
Single lateral narrow radiolucency	Lateral narrow radiolucency	• Apical 1/3, middle 1/3, coronal 1/3, entire root length • Without periodontal disease
Buccal + lingual lateral narrow radiolucency*		• Apical 1/3, middle 1/3, coronal 1/3, entire root length • Without periodontal disease
Furcal radiolucency	Furcal radiolucency	Without periodontal disease
Loss of cortical plate	Loss of cortical plate	Full length of root
Radiolucency surrounding entire root		
Observed Features – Exploratory		
Crack line detected upon exploration*		Extraction, surgical exposure or endodontic access

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