Outcome measures to assess the effectiveness of endodontic treatment for pulpitis and apical periodontitis for use in the development of European Society of Endodontology (ESE) S3-level clinical practice guidelines: a consensus-based development

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ABSTRACT

Introduction: The European Society of Endodontology (ESE) is in process of developing S3-Level Clinical Practice Guidelines for the treatment of pulpal and apical disease. In order to support robust systematic literature review, appropriate outcome measures (OMs) with minimum follow-up time must first be identified. Hence, the current project aimed to identify the appropriate OMs with minimum/maximum follow-up time to assess the effectiveness of endodontic treatment for pulpitis and apical periodontitis for use in the development of ESE S3-level guidelines by consensus-based methodology.

Methodology: After a literature search, lists of relevant OMs were identified by the Guideline-Development-Group (GDG) for the treatment of pulpitis (working group [WG] 1), the non-surgical treatment of apical periodontitis (WG 2), the surgical treatment of apical periodontitis (WG 3) and the regenerative treatment of apical periodontitis (WG 4). OMs relevant to each WG were ranked by the 43 members of the GDG in their importance to the patient using a 9-point Likert scale. Items with a score of 7-9 (critical-importance) by more than 70% and items with a score of 1-3 (limited-importance) by less than 30% of members were included whereas the items with a score of 1-3 by more than 70% and items with a score of 7-9 by less than 30% were excluded. Several online Delphi meetings established an edited list of only important OMs. The ranked OMs were discussed by the GDG and harmonised to produce ‘most critical’, ‘critical’ and ‘important’ measures. After establishing final ranked measures, the minimum and maximum length of follow-up related to each OM was decided by the Guideline Steering Group.

Results: The Delphi survey was over two rounds. The patient-reported outcome-measure (PROM) ‘tooth survival’ was rated the ‘most critical measure’ in all 4 WGs, while other PROMs including ‘pain’, ‘need for medication’ were considered ‘critical’, alongside the clinician-reported outcome measures (CROM), ‘radiographic assessment’. The PROMs ‘The need for further intervention’ and ‘oral-health-related-quality-of-life’ (OHRQoL) were included, but as ‘important’ not ‘critical’ measures. Differences occurred between WGs with ‘vitality testing’ critical in WG1 and ‘increased length and width of the’ ‘critical’ in WG4. A minimum of 1-year and maximum of as long as possible for all OM was deemed necessary, except ‘pain’, ‘swelling’, ‘medication’ and ‘OHRQoL’ which where shorter follow was accepted.
Conclusions: The GDG consensus process established the patient-reported ‘tooth survival’ as the ‘most-critical’ OM. The identified OMs and length of follow-up will be applied to all the commissioned systematic reviews that will inform the subsequent process when developing the ESE S3-Level Clinical Practice Guidelines.
INTRODUCTION

The European Society of Endodontology (ESE) is currently engaged in a process of developing new practice guidelines for the treatment of pulpitis and apical periodontitis for the benefit of both clinicians and patients (Duncan et al. 2021a). The process will create S3-level guidelines, which represent the highest quality of guideline and includes exhaustive systematic review of the literature and a formalised methodological guideline development procedure (Nothacker et al. 2014). As part of the ESE S3 process, it was previously agreed that in the absence of a recognised core outcome set (COS) for Endodontics (Williamson et al. 2012), a list of core outcomes for the treatment of pulpal and apical would need to be agreed by consensus as well as recommendations made regarding minimum follow-up times specific to each outcome measure (Duncan et al. 2021b). A protocol for this process was previously published (Duncan et al. 2021b), with the focus on patient-reported as well as clinician-reported outcome measures, which is at the core of the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework (Guyatt et al. 2008, Sanz et al. 2020). The agreed outcome measures and associated follow-up periods will be used in subsequent systematic analyses of the literature to investigate the effectiveness of endodontic treatment to alleviate pulpitis and apical periodontitis.

In the previously published protocol a list of clinician and patient reported outcome measures were selected from the literature, prior to comment from the ten members of the ESE S3-Guideline Steering Group (Duncan et al. 2021b). The aim of the current study, was to identify and rank the most important clinician and patient outcome measures via several rounds of an online Delphi consensus process and followed by online meeting. After ranking the outcome measures the aim was to select the most critical outcome measure as well as other important and additional measures, before matching the outcome measures to acceptable minimum and maximum follow-up periods for outcome studies to be included in the review process.
METHODOLOGY

Protocol
An *a priori* protocol with detailed methodology of the current study has previously been published (Duncan *et al.* 2021b).

Initial steps
A comprehensive literature search was performed to identify potential clinician and patient-reported outcome measures, based on primary and secondary-evidence as well as relevant ESE position statements (ESE 2016, ESE 2019) and ESE-treatment guideline documents (ESE 2006). A set of surrogate and real outcome measures were identified and categorized into clinician and patient-reported outcomes for four thematic working groups (WG) (WG1: The treatment of pulpitis, WG2: The non-surgical treatment of apical periodontitis, WG3: The surgical treatment of apical periodontitis and WG4: The regenerative treatment of apical periodontitis). Afterwards, the list of outcome measures was shared with the eight WG leads (two leads for each group), in order to provide their feedback about the completeness of the list and if necessary add new outcome measures. Thereafter, the outcome measures were sent to the members of each WG within the Guideline Development Group (GDG) via a google link.

Formation of Guideline Development Group
The GDG were selected from suitable individuals across the globe to participate in the online Delphi process to identify and prioritise the outcome measures, which will be used by reviewers in systematic literature assessment during the development of the ESE S3 level clinical practice guidelines. The GDG includes ESE S3 level guidelines steering committee (10 members [including 2 project leads and 8 WG leads]) and by all the invited systematic reviewers (34 members) working on the 14 systematic reviews commissioned within the guideline project. The eligibility criteria to be member of the GDG were: i) working within the speciality of Endodontology or a related to dental science; ii) have published articles in the area of evidenced-based dentistry; iii) have a minimum of five-years academic experience post-qualification; and iv) have no conflict of interest in developing ESE S3-level clinical guidelines.
Online Delphi Survey

The project leader (HD) shared the information sheet with GDG which explains the process involved in Delphi process and google survey link. The GDG members, independently and confidentially, were asked to score the items within their own WG based on the suitability and importance of each outcome measure for inclusion in all four thematic WGs. The online survey was conducted using the 9-point Likert scale recommended for assessing the importance of outcomes for GRADE (Guyatt et al. 2011): 1-3 limited importance; 4-6 important; 7-9 critical importance. The items with a score of 7-9 by more than 70% and items with a score of 1-3 by less than 30% of members has been included whereas the items with a score of 1-3 by more than 70% and items with a score of 7-9 by less than 30% were excluded. Additionally, members have an option to add further outcome measures if they deem them important. The Delphi process continued with further rounds until a final set of final outcome measures were developed.

Online meeting

The list of outcome measures finalised in online Delphi process were presented in online meeting for further discussion and agreement with steering group (10 members). The ESE S3-level project leader (HD) shared the results of the online Delphi process, agenda of the meeting and the Zoom meeting link to the steering group seven days before the online meeting. The online meeting was conducted on 29\textsuperscript{th} January 2021 using the Zoom online platform (San Jose, CA, USA), which was chaired by HD and the principle methodologist involved in the guideline process (Ina Kopp). At the end of online meeting the outcome measures and the minimum length of follow-up for four themes were confirmed.

RESULTS

Online Delphi survey

The online Delphi survey was conducted over two rounds. The response rate for four themes of round 1 and 2 were presented in Table 1. The results of round 1 and 2 are presented in Supplementary Table 1 and 2 respectively.

Online meeting
The attendees discussed the suitability of the outcome measures, adjustments to provide consistency between WGs to ensure homogeneity and the minimum length of follow-up for inclusion in the ESE S3 level guidelines project. The finalised outcome measures for four WGs are presented in Tables 2, 3, 4 and 5.

Outcome measures WG1 – The Treatment of Pulpitis (Table 2)

Main outcome(s): The most critical outcome was decided as the patient reported outcome measure ‘tooth survival’, whereas the other critical outcomes were ‘pain, tenderness, swelling, need for medication (analgesics)’, as well as the clinician reported outcome measure ‘evidence of emerging apical radiolucency’ and ‘response to pulp sensibility test (not for full pulpotomy or pulpectomy)’.

Additional outcome(s): Other important outcomes were as follows ‘tooth Function (fracture, restoration longevity), ‘need for further intervention’, ‘adverse effects (including exacerbation, restoration integrity, allergy)’ ,’oral health-related quality of life (OHRQoL)’, ‘presence of sinus tract’ and ‘radiological evidence of continued root formation’.

Duration of data collection: A minimum of 1 year and maximum of as long as possible for all outcome measures, except ‘pain, tenderness, swelling, need for medication (analgesics)’, which will be a minimum of 7 days and maximum of 3 months and OHRQoL which is a minimum of 6 months and a maximum of as long as possible.

Outcome measures WG2- The Non-Surgical Treatment of Apical Periodontitis (Table 3)

Main outcome(s): The most critical outcome was ‘tooth survival’ whereas, other critical outcomes are ‘pain, tenderness, swelling, need for medication (analgesics, antibiotics)’, ‘radiographic evidence of reduction of apical lesion size (loose criteria)’ and ‘radiographic evidence of normal periodontal ligament space (strict criteria)’.

Additional outcome(s): Important outcomes were as follows ‘tooth function (fracture, restoration longevity), ‘need for further intervention’, ‘adverse effects (including
exacerbation, restoration integrity, allergy’), ‘oral health-related quality of life (OHRQoL)’ and ‘presence of sinus tract’.

**Duration of data collection:** A minimum of 1 year and maximum of as long as possible for all outcome measures, except ‘pain, tenderness, swelling, need for medication (analgesics)’, which is a minimum of 7 days and maximum of 3 months and OHRQoL, which is a minimum of 6 months and a maximum of as long as possible.

**Outcome measures WG3 - The Surgical Treatment of Apical Periodontitis (Table 4)**

*Main outcome(s):* The most critical outcome was considered ‘tooth survival’, whereas other critical outcomes are ‘pain, tenderness, swelling, need for medication (analgesics, antibiotics)’, ‘presence of sinus tract, satisfactory soft tissue healing’, ‘radiographic evidence of reduction of apical lesion size (loose criteria)’ and ‘radiographic evidence of normal periodontal ligament space (strict criteria)’.

*Additional outcome(s):* Important outcomes were ‘tooth function (fracture, restoration longevity), ‘need for further intervention’, ‘adverse effects (including exacerbation, restoration integrity, allergy)’, ‘oral health-related quality of life (OHRQoL)’ and ‘mobility’.

**Duration of data collection:** A minimum of 1 year and maximum of as long as possible for all outcome measures, except ‘pain, tenderness, swelling, need for medication (analgesics)’, which is a minimum of 14 days and maximum of 3 months and OHRQoL, which is minimum of 6 months and a maximum of as long as possible.

**Outcome measures WG4 - The Regenerative Treatment of Apical Periodontitis (Table 5)**

*Main outcome(s):* The most critical outcome was ‘tooth survival’, whereas the other critical outcomes are ‘pain, tenderness, swelling, need for medication (analgesics, antibiotics)’, ‘radiographic evidence of reduction of apical lesion size (loose criteria)’, ‘radiographic evidence of normal periodontal ligament space (strict criteria)’ and ‘radiographic evidence of increased root thickness and length’.
**Additional outcome(s):** Important outcomes were considered as 'tooth function (fracture, restoration longevity), ‘need for further intervention’, ‘adverse effects (including exacerbation, restoration integrity, allergy, discolouration)', oral health-related quality of life (OHRQoL), ‘presence of sinus tract’ and ‘response to sensibility testing’.

**Duration of data collection:** Defined as a minimum of 1 year and maximum of as long as possible for all outcome measures, except ‘pain, tenderness, swelling, need for medication (analgesics)’, which is a minimum of 7 days and maximum of 3 months and OHRQoL which is minimum of 6 months and a maximum of as long as possible.

**FUTURE PLANS**
In the next phase of the ESE S3-level guideline process the consensus outcome measures and duration of data assessment detailed in this document will be used to form a specific PICOTS (P=population, I = Intervention, C = Comparison, O = Outcome(s), T = Duration of data collection, S = Included study types) questions for each of the 14 commissioned systematic reviews, which will thereafter be agreed upon by the S3 Steering Group. After minor modification and harmonisation, the final PICOTS will be returned to the reviewers and a review protocol written. The protocol will be checked by the ESE S3-level clinical practice guideline lead (HD) and the respective WG leads, before submission to PROSPERO for *a priori* registration, before starting the review proper.

After completion of the systematic review, they will first be submitted to the Steering Group to check that the PICOTS are adequately covered and the agreed tools have been used, before an assessment of the quality of the systemic review using AMSTAR 2 ([https://amstar.ca/Amstar-2.php](https://amstar.ca/Amstar-2.php)). The paper may be sent back for amendment at this stage, prior to formal submission to the *International Endodontic Journal* and a process of rigorous independent peer review. After the completion of the review process the resulting evidence will be compiled using GRADE and initial evidenced-based clinical recommendations prepared, prior to circulation for comment by the Steering Group during a series of moderated Zoom sessions. At this stage conflict of interest will be analysed and discussed, including issues such as reviewer’s abstention from voting. The Steering Group will discuss the clinical recommendations and reach informal agreement, before organising a formal moderated consensus conference in order to agree the
recommendations. Finally, after guideline text agreement, the guidelines will be approved at the ESE executive board and thereafter disseminated by publication in the International Endodontic Journal, on the ESE website (https://www.e-s-e.eu/) and electronically via local societies and other stakeholders.

CONCLUSION

The identified patient and clinician OMs as well as length of follow-up will be used in all commissioned systematic reviews that will inform the subsequent process when developing the ESE S3-Level Clinical Practice Guidelines. In the future, while planning and conducting clinical trials, researchers can employ the identified patient and clinician-reported outcomes in combination with long follow-up times, which will ultimately standardise the outcomes of trials and improve patient care.
### Table 1: Round 1 and 2 response rate for four themes

<table>
<thead>
<tr>
<th>WGs</th>
<th>Themes</th>
<th>Round 1 - Response rate (%)</th>
<th>Round 2 - Response rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The treatment of pulpitis</td>
<td>86</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>The non-surgical treatment of apical periodontitis</td>
<td>85</td>
<td>100</td>
</tr>
<tr>
<td>3</td>
<td>The surgical treatment of apical periodontitis</td>
<td>100</td>
<td>75</td>
</tr>
<tr>
<td>4</td>
<td>The regenerative treatment of apical periodontitis</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
Table 2: Outcome measures for the working group 1: Treatment of pulpitis

<table>
<thead>
<tr>
<th>Specific outcome measure</th>
<th>Ranked Importance of Outcome Measure from Likert scale</th>
<th>Patient (PROM) or Clinician-Reported (CROM) outcome</th>
<th>Minimum and Maximum Follow-up Period</th>
<th>Tools necessary to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tooth Survival</td>
<td>Most Critical</td>
<td>PROM</td>
<td>Minimum: 1 year</td>
<td>Clinical history examination</td>
</tr>
<tr>
<td>Pain, tenderness, swelling, need for medication (analgesics)</td>
<td>Critical</td>
<td>PROM</td>
<td>Minimum: 7 days Maximum: 3 months</td>
<td>Clinical examination and pain scale</td>
</tr>
<tr>
<td>Evidence of emerging apical radiolucency</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td>Response to pulp sensibility test (not full pulpotomy or pulpectomy)</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Thermal and/or electric pulp test</td>
</tr>
<tr>
<td>Tooth Function (fracture, restoration longevity)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Need for further intervention</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Adverse effects (exacerbation, restoration integrity, allergy)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>OHRQoL</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 6 months Maximum: long as possible</td>
<td>Validated OHRQoL questionnaire</td>
</tr>
<tr>
<td>Sinus tract</td>
<td>Important</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Examination</td>
</tr>
<tr>
<td>Radiological Evidence of continued root formation</td>
<td>Important</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td>Specific outcome measure</td>
<td>Ranked Importance of Outcome Measure from Likert scale</td>
<td>Patient (PROM) or Clinician-Reported (CROM) outcome</td>
<td>Minimum and Maximum Follow-up Period</td>
<td>Tools used to measure</td>
</tr>
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</tr>
<tr>
<td>Tooth Survival</td>
<td>Most Critical</td>
<td>PROM</td>
<td>Minimum: 1 year</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>Pain, tenderness, swelling, need for medication (analgesics, antibiotics)</td>
<td>Critical</td>
<td>PROM/CROM</td>
<td>Minimum: 7 days</td>
<td>Clinical examination and pain scale</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: 3 months</td>
<td></td>
</tr>
<tr>
<td>Radiographic evidence of reduction of apical lesion size (loose criteria)</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>Radiographic evidence of normal periodontal ligament space (strict criteria)</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>Tooth Function (fracture, restoration longevity)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>Need for further intervention</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>Adverse effects (exacerbation, restoration integrity, allergy)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>QHRQoL</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 6 months</td>
<td>Validated OHRQoL questionnaire</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
<tr>
<td>Sinus tract</td>
<td>Important</td>
<td>CROM</td>
<td>Minimum: 1 year</td>
<td>Examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maximum: long as possible</td>
<td></td>
</tr>
</tbody>
</table>
### Table 4: Outcome measures for the working group 3: Surgical treatment of apical periodontitis

<table>
<thead>
<tr>
<th>Specific outcome measure</th>
<th>Ranked Importance of Outcome Measure from Likert scale</th>
<th>Patient (PROM) or Clinician-Reported (CROM) outcome</th>
<th>Minimum and Maximum Follow-up Period</th>
<th>Tools necessary to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tooth Survival</td>
<td>Most Critical</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Pain, tenderness, need for medication (analgesics, antibiotics)</td>
<td>Critical</td>
<td>PROM/CROM</td>
<td>Minimum: 14 days Maximum: 3 months</td>
<td>Clinical examination and pain scale</td>
</tr>
<tr>
<td>Sinus tract, satisfactory soft tissue healing</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Examination</td>
</tr>
<tr>
<td>Radiographic evidence of reduction of apical lesion size (loose criteria)</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td>Radiographic evidence of normal periodontal ligament space (strict criteria)</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td>Tooth Function (fracture, restoration longevity)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Need for further intervention</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Adverse effects (exacerbation discharge, allergy)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Clinical History</td>
</tr>
<tr>
<td>QHRQoL</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 6 months Maximum: long as possible</td>
<td>Validated OHRQoL questionnaire</td>
</tr>
<tr>
<td>Mobility</td>
<td>Important</td>
<td>PROM/CROM</td>
<td>Minimum: 1 year Maximum: long as possible</td>
<td>Examination</td>
</tr>
</tbody>
</table>

### Table 5: Outcome measures for the working group 4: Regenerative treatment of apical periodontitis
<table>
<thead>
<tr>
<th>Specific outcome measure</th>
<th>Ranked Importance of Outcome Measure from Likert scale</th>
<th>Patient (PROM) or Clinician-Reported (CROM) outcome</th>
<th>Minimum and Maximum Follow-up Period</th>
<th>Tools necessary to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tooth Survival</td>
<td>Most Critical</td>
<td>PROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Pain, tenderness, swelling, need for medication</td>
<td>Critical</td>
<td>PROM/CROM</td>
<td>Minimum: 7 days Max: 3 months</td>
<td>Clinical examination and pain scale</td>
</tr>
<tr>
<td>Radiographic evidence of reduction of apical lesion size</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td>Radiographic evidence of normal periodontal ligament space</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan</td>
</tr>
<tr>
<td>Radiographic evidence of increased root thickness and length</td>
<td>Critical</td>
<td>CROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Intraoral periapical radiograph, limited FOV CBCT scan, validated quantitative measurement software</td>
</tr>
<tr>
<td>Tooth Function (fracture, restoration longevity)</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Adverse effects (exacerbation, restoration integrity, discoloration)</td>
<td>Important</td>
<td>PROM/CROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>Need for further intervention</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Clinical history and examination</td>
</tr>
<tr>
<td>QHRQoL</td>
<td>Important</td>
<td>PROM</td>
<td>Minimum: 6 months Max: long as possible</td>
<td>Validated OHRQoL questionnaire</td>
</tr>
<tr>
<td>Sinus tract</td>
<td>Important</td>
<td>CROM</td>
<td>Minimum: 1 year Max: long as possible</td>
<td>Examination</td>
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REFERENCES


### Supplementary Table 1 - Results of Round 1 Delphi survey

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<td>Radiographic evidence of apical lesion size (loose criteria)</td>
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Supplementary Table 2 - Results of Round 2 Delphi survey
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