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

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

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Abstract

AIMS: The European Society of Endodontology (ESE) is in the process of developing S3-level clinical practice guidelines for the treatment of pulpal and apical disease. In order to support robust systematic literature reviews, appropriate outcome measures (OMs) with minimum follow-up times 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 through a standard 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 harmonized to produce 'most critical', 'critical' and 'important' measures. After establishing the final ranked measures, the minimum and maximum length of follow-up related to each OM was defined by the guideline steering group.

RESULTS: The Delphi survey took place over two rounds. The patient-reported outcome measure (PROM) 'tooth survival' was rated the 'most critical measure' in all four WGs, while other PROMs including 'pain' and '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' defined as critical in WG1 and 'increased length and width of the root' defined as 'critical' in WG4. A minimum of 1-year and maximum of 'as long as possible' for all OMs were deemed necessary, except 'pain', 'swelling', 'medication' and 'OHRQoL', where shorter follow-up was accepted.

CONCLUSIONS: The GDG consensus process established the PROM "tooth survival" as the "most-critical". 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.

KEYWORDS

clinical outcome measure, clinician-reported outcomes, Delphi, effectiveness, endodontic treatment, follow-up, guidelines, patient-reported outcomes

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 formalized 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 recognized core outcome set (COS) (Williamson et al., 2012) for endodontics, a list of core outcomes for the treatment of pulpal and apical periodontitis would need to be agreed by consensus as well as recommendations made regarding minimum follow-up times specific to each outcome measure (OM) (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 OMs, 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 OMs 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 OMs was selected from the literature, prior to comment from the 10 members of the ESE S3-level guideline steering group (Duncan et al., 2021b). The aim of the current study was to identify and rank the most important clinician- and patient-reported OMS via several rounds of an online Delphi consensus process which was followed by an online meeting to discuss the outputs. After ranking the OMs, the aim was to select the most critical OM as well as other important and additional measures, before matching the OMs to acceptable minimum and maximum follow-up periods in order to define which outcome studies should be included in the review process.

METHODOLOGY

Protocol

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

Initial steps

A comprehensive literature search was performed to identify potential clinician- and patient-reported OMs 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 OMs 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 OMs was shared with the eight WG

TABLE 1 Rounds 1 and 2 response rates for the four themes

WGs	Themes	Round 1– Response rate (%)	Round 2 – Response rate (%)
1	The treatment of pulpitis	86	100
2	The non-surgical treatment of apical periodontitis	85	100
3	The surgical treatment of apical periodontitis	100	75
4	The regenerative treatment of apical periodontitis	100	100

leads (two leads for each group) in order to acquire their feedback about the completeness of the list and, if necessary, add new OMs. Thereafter, the OMs were sent to the members of each WG within the guideline development group (GDG) via a Google link for further comment relevance of the lists.

Formation of the guideline development group

The GDG was selected from suitable individuals across the globe to participate in the online Delphi process to identify and prioritize the OMs, which will be used by reviewers in systematic literature assessment during the development of the ESE S3-level clinical practice guidelines. The GDG includes members of the 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 overall guideline project. The eligibility criteria to be a member of the GDG were as follows: (i) working within the specialty of Endodontology or a related dental science; (ii) have published articles in the area of evidenced-based dentistry; (iii) have a minimum of 5-year 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 OM 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 and 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 have 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 had an option to add further OMs if they deemed them essential. The Delphi process continued with further rounds until a final set of final OMs were developed and consensus achieved.

Online meeting

The list of OMs finalized during the online Delphi process was presented at an online meeting for further discussion and agreement with the 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 7 days before the online meeting. The online meeting was conducted on 15 April 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 the online meeting, the OMs 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 rates for four themes of rounds 1 and 2 are presented in Table 1. The results of rounds 1 and 2 are presented in Tables S1 and S2 respectively.

Online meeting

The attendees discussed the suitability of the OMs, 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 finalized OMs for the four WGs are presented in Tables 2,3,4and5.

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

Main outcome(s)

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

Additional outcome(s)

Other important outcomes were defined as: '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 OMs, except 'pain, tenderness, swelling, need for medication (analgesics)', which were defined as 'a minimum of 7 days and maximum of 3 months', and OHRQoL, which was defined as '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 were '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 OMs, except 'pain, tenderness, swelling, need for medication (analgesics)', which were defined as 'a minimum of 7 days and maximum of 3 months', and OHRQoL, which was defined as '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 were '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 OMs, except 'pain, tenderness, swelling, need for medication (analgesics)', which were defined as 'a minimum of 14 days and maximum of 3 months', and OHRQoL, which was defined as 'a minimum of 6 months and a maximum of as long as possible'.

TABLE 2 Outcome measures for working group 1: Treatment of pulpitis

Specific outcome measure	Ranked Importance of Outcome Measure from Likert scale	Patient (PROM) or Clinician-Reported (CROM) outcome	Minimum and Maximum Follow-up Period	Tools necessary to measure
Tooth Survival	Most Critical	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history examination
Pain, tenderness, swelling and need for medication (analgesics)	Critical	PROM	Minimum: 7 days Maximum: 3 months	Clinical examination and pain scale
Evidence of emerging apical radiolucency	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph and limited FOV CBCT scan
Response to pulp sensibility test (not full pulpotomy or pulpectomy)	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Thermal and/or electric pulp test
Tooth Function (fracture and restoration longevity)	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Need for further intervention	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Adverse effects (exacerbation, restoration integrity, and allergy)	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
OHRQoL	Important	PROM	Minimum: 6 months Maximum: as long as possible	Validated OHRQoL questionnaire
Sinus tract	Important	CROM	Minimum: 1 year Maximum: as long as possible	Clinical examination
Radiological Evidence of continued root formation	Important	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph, limited FOV CBCT scan

TABLE 3 Outcome measures for working group 2: Non-surgical treatment of apical periodontitis

Specific outcome measure	Ranked Importance of Outcome Measure from Likert scale	Patient (PROM) or Clinician-Reported (CROM) outcome	Minimum and Maximum Follow-up Period	Tools used to measure
Tooth survival	Most critical	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Pain, tenderness, swelling and need for medication (analgesics and antibiotics)	Critical	PROM/CROM	Minimum: 7 days Maximum: 3 months	Clinical examination and pain scale
Radiographic evidence of reduction in apical lesion size (loose criteria)	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph and limited FOV CBCT scan
Radiographic evidence of normal periodontal ligament space (strict criteria)	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph and limited FOV CBCT scan
Tooth Function (fracture and restoration longevity)	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Need for further intervention	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Adverse effects (exacerbation, restoration integrity and allergy)	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
OHRQoL	Important	PROM	Minimum: 6 months Maximum: as long as possible	Validated OHRQoL questionnaire
Sinus tract	Important	CROM	Minimum: 1 year Maximum: as long as possible	Clinical examination

TABLE 4 Outcome measures for working group 3: Surgical treatment of apical periodontitis

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

TABLE 5 Outcome measures for working group 4: Regenerative treatment of apical periodontitis.

Specific outcome measure	Ranked Importance of Outcome Measure from Likert scale	Patient- (PROM) or Clinician-Reported (CROM) outcome	Minimum and Maximum Follow-up Period	Tools necessary to measure
Tooth Survival	Most Critical	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Pain, tenderness, swelling and need for medication	Critical	PROM/CROM	Minimum: 7 days Maximum: 3 months	Clinical examination and pain scale
Radiographic evidence of reduction in apical lesion size (loose criteria)	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph and limited FOV CBCT scan
Radiographic evidence of normal periodontal ligament space (strict criteria)	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph and limited FOV CBCT scan
Radiographic evidence of increased root thickness and length	Critical	CROM	Minimum: 1 year Maximum: as long as possible	Intraoral periapical radiograph, limited FOV CBCT scan and validated quantitative measurement software
Tooth function (fracture and restoration longevity)	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Adverse effects (exacerbation, restoration integrity and discolouration)	Important	PROM/CROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
Need for further intervention	Important	PROM	Minimum: 1 year Maximum: as long as possible	Clinical history and examination
OHRQoL	Important	PROM	Minimum: 6 months Maximum: as long as possible	Validated OHRQoL questionnaire
Sinus tract	Important	CROM	Minimum: 1 year Maximum: as long as possible	Clinical examination
Response to pulp sensibility test	Important	CROM	Minimum: 1 year Maximum: as long as possible	Thermal and/or electric pulp test

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 were '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 OMs, except 'pain, tenderness, swelling, need for medication (analgesics)', which were defined as 'a minimum of 7 days and maximum of 3 months', and OHRQoL which was defined as 'a minimum of 6 months and a maximum of as long as possible'.

DISCUSSION

The treatment outcomes for any medical condition can be ordered using a three-tiered hierarchy: Tier 1: health status achieved or retained; Tier 2: related to recovery process and Tier 3: sustainability of health (Porter, 2010). The value of medical and dental treatment should focus on the patient, with the only way to accurately assess value being to identify outcomes and costs longitudinally, with a follow-up long enough to achieve the best patient care. In general, every medical condition has its own set of bespoke OMs (Porter, 2010). Similarly, endodontic diseases, including pulpitis and apical periodontitis should have their own specific outcomes, creating a need to identify and rank by importance the endodontic OMs for research purposes.

For the benefit of clinicians, the current project was initiated by ESE, with the aim of identifying the OMs that were deemed essential to assess the effectiveness of endodontic treatment for pulpitis and apical periodontitis for use in the developing clinical practice guidelines. A strength of this project is that the outcomes selected from the literature and confirmed by GDG consensus, represented a group of the most important OMs for a range of endodontic treatments, before ranking them in an online Delphi process. This has not been carried out before in endodontics and resulted in the creation of the four outcome tables (Tables 2–5) presented in this document. Another strength is the focus on PROMs, which characterize patients' suffering that constitutes an essential feature of the GRADE framework utilized in clinical guideline development (Sanz et al., 2020).

Finally, in order to reduce potential bias in the selected OMs, the GDG had to declare any potential conflict of interest, which were examined by the guideline steering group. A potential disadvantage in the process is the acknowledgement that the initial literature review used to identify OMs was a narrative rather than a systematic design, which may have limited the scope of the OMs considered. Furthermore, the Core Outcome Set-STAndardised Protocol Items (COS-STAP) statement (Kirkham et al., 2019) highlights that a diverse group of stakeholders, ideally including patients, should also be included in the Delphi process, which was not adhered to in this dentist-only stakeholder group.

FUTURE PLANS

In the next phase of the ESE S3-level guideline process, the consensus OMs and duration of data assessment detailed in this document will be used to form specific PICOTS questions (P=population, I = Intervention, C = Comparison, O = Outcome(s), T = Duration of data collection and S = Included study types) for each of the 14 commissioned systematic reviews, which will thereafter be agreed upon by the S3 steering group. After minor modification and harmonization, 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.

The completed systematic reviews 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). The findings and report may be sent back to

the review authors 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 online 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 organizing a formal moderated consensus conference in order to agree to 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 defined in this process as well as the agreed 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, whilst planning and conducting clinical trials, researchers are encouraged to employ the patient- and clinician-reported outcomes in combination with the long follow-up times identified in this process, which will ultimately standardize the outcomes of clinical trials and improve patient care.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

Study conception and design, and final approval of the manuscript – HD, VN, IEK and PD; material preparation, data collection and analysis, first draft of the manuscript – HD and VN.

ETHICAL STATEMENT

The study did not require ethical approval.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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