DENTAL PATIENT-REPORTED OUTCOMES IN ENDODONTICS - A NARRATIVE REVIEW

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Highlights

The main dPROs following endodontic treatment include pain, tenderness, tooth function, need for further intervention, adverse effects and Oral Health–Related Quality of Life.

dPROs are essential for endodontic treatment as they enable dentists and patients to discuss and identify the most appropriate management options, whilst providing the opportunity for researchers to improve the methodology and design of future clinical trials to ensure the patient's interests are at the center of the study.

Clinicians and researchers working in Endodontology should focus on patient wellbeing and routinely use dPROs

ABSTRACT

Recently in oral healthcare settings, the focus of assessing treatment outcomes has shifted from the perspective of the clinician towards that of the patient. Endodontology is a specialty of dentistry concerned with the prevention and treatment of pulp and periapical diseases. Research in endodontology and its associated treatment outcomes have focused mainly on clinician-reported outcomes (CROs) and not patient-reported outcomes (PROs). As a result, there is a need to emphasize the importance and relevance of dPROs to researchers and clinicians. The aim of this review is to present an overview of dPROs and dPROMs within clinical endodontics in an attempt to create a better understanding of the patient experience, highlight the need to place the patient at the center of treatment, enhance patient care and encourage more research into dPROs. The key dPROs following endodontic treatment include pain, tenderness, tooth function, need for further intervention, adverse effects (exacerbation of symptoms, tooth discoloration) and Oral Health–Related Quality of Life. dPROs are important following endodontic treatment because they assist clinicians and patients when they discuss and select the most appropriate management options, help clinicians make decisions on pre-operative assessment, prevention and treatment, and improve the methodology and design of future clinical studies. Clinicians and researchers in endodontology should prioritize patient welfare and undertake routine analyses of dPROs using appropriate and robust measures. Due to the lack of agreement over the reporting and definition of endodontic treatment outcomes, a project to define a "Core Outcome Set for Endodontic Treatment Methods (COSET)" is currently ongoing. In the future, a new and exclusive assessment tool should be developed to reflect the viewpoints of patients receiving endodontic treatment more accurately.

KEYWORDS

Endodontics, Oral Health–Related Quality of Life, Pain, Patient reported outcomes, Patient-reported outcome measures

INTRODUCTION

PATIENT-REPORTED OUTCOMES and PATIENT-REPORTED OUTCOME MEASURES

Patient-reported outcomes (PROs) are reports of a patient's health status that come directly from the patient without interpretation by a clinician,[1] whereas clinician-reported outcomes (CROs) are a report of a patient's health status by a trained healthcare professional.[2] Patient-reported outcome measures (PROMs) are objective or subjective measurements used to evaluate the effectiveness of an intervention using tools or instruments, generally in the form of self-reported questionnaires. [3] It should be noted that although by definition the patient's interpretations should be unfiltered by a clinician, a PRO in reality represents more, with the subjective views of the patient including personal weights, emotions and the consideration of both values and expectations being considered. The role of PROs is significant in enhancing clinical care because it strengthens the relationship between clinicians and patients[4] and places the patient at the center of the process.

PROs include:

- Symptoms associated with a disease/condition or therapeutic side-effects such as pain, anxiety, or and the need for pain relief;
- Functional outcomes such as physical, emotional, or cognitive functioning; and
- Multi-dimensional categories such as Health-Related Quality of Life (HRQoL).[5,6]

DENTAL PATIENT-REPORTED OUTCOMES and DENTAL PATIENT-REPORTED OUTCOME MEASURES

In dentistry, any report of a patient's oral health status (or wider general health if relevant to oral health) that comes directly from the patient, without interpretation by a clinician or anyone else, is referred to as a dental patient-reported outcome (dPRO).[7] dPROs are being utilized increasingly in oral health research to explore patients' perceptions of the success and impact of dental treatments.[8] A dental patient-reported outcome measure (dPROM) is an instrument, questionnaire, scale, or survey that measures or captures dPROs.[7] The dPROM scores can be reported numerically or

graphically to the clinician at chairside,[9] and variations between pre- and post-treatment dPROM ratings can be utilized to determine the outcome of treatment as well as assist patients in making more informed treatment choices.[10] Notably, a methodological study by Tao et al., identified only 76 of 315 randomised controlled trials in orthodontics used dPROs as either primary or secondary outcomes.[11] dPROs are critical for the development of evidence-based dentistry in a pragmatic primary care setting,[12] as they help to improve research impact and 'real world' relevance.[13] They are essential for value-based oral health care, which is concerned with improving oral health outcomes for patients in relation to the associated costs.[14] The principle dPRO used to date is the Oral Health-Related Quality of Life (OHRQoL), which is defined as "people's perspective on their oral health status including eating, sleeping and engaging in social interaction; their self-esteem; and their satisfaction with respect to their oral health".[15]

SCOPE OF ENDODONTOLOGY

Endodontology is "concerned with the study of the form, function, and health of, injuries to and diseases of the dental pulp and periradicular region, their prevention and treatment; the principal disease being apical periodontitis, caused by infection".[16] The principal treatment interventions include vital pulp treatment, root canal treatment, root canal retreatment, surgical endodontics, and regenerative endodontic therapies.[17] Endodontic treatment focuses on the prevention or resolution of pulp and apical disease with the overarching aim being to improve the patients' quality of life by preserving their natural teeth. As a consequence, patients can function optimally, allowing them to speak, eat, and smile more naturally, as well as improve their dentofacial esthetics, self-confidence, and psychosocial wellbeing.[17–20]

AIM OF THE REVIEW

Clinicians and researchers working within endodontology should be concerned about the welfare of patients and are well-placed to routinely assess PROs using relevant tools and measures. Hence, the aim of this review is to provide an overview of dPROs and dPROMs to allow better understanding of the patient experience, consider the need to place the patient at the center of the outcome to ultimately improve patient care, as well as to promote dPRO research in endodontology.

dPROs IN ENDODONTICS

Assessing the outcome of endodontic treatment has traditionally focused on CROs such as clinical and radiographic examinations, microbial culture and analysis, and pulp sensibility testing. On the other hand, PROs such as pain, and quality of life have been undervalued.[16,21,22] For example, De-Deus & Canabarro[23] reported that CROs (*e.g*. radiographic healing) were the primary outcome of clinical research comparing single- versus multiple-visit root canal treatment. The range of clinical procedures in endodontics have been adopted not only for their efficacy and biological consequences but also for their ability to minimize patient suffering.[24] The results of a recent scoping review revealed that there are 300 CROs but only 114 PROs contained within studies on root canal treatment, retreatment, and apexification published during the last four decades (1980–2020).[25] Evidently, PROs are underutilized in endodontics when compared with CROs.[25] As a result, there is a paucity of evidence linking endodontic treatment outcomes to patient-reported factors, such as pain, discomfort, the need for medication, and the cost of the procedure.[26,27]

In general, the use of PROs in clinical studies has risen in recent years, with 6168 (45.1%) of the 13,666 trials recorded in the Australian New Zealand Clinical Trials Registry incorporating a PRO.[5,6] Regulatory bodies including the US Food Drug Administration and the European Medicines Agency both urge that data from PROs be considered in the assessment of clinical trial endpoints. Within the development of clinical guidelines using a GRADE-framework, there is an insistence that outcomes consider the patient and are patient-centered, as a minimum.[21] In the last four decades, a decrease in the reporting of CROs such as radiographic healing and success of endodontic treatment, which includes root canal treatment, retreatment and apexification , while a small but steady increase in the reporting of PROs such as pain assessment, and quality of life has occurred.[25]

PROs can be used at any time and provide the patient's perspective for a specific health status; however, they are most often used to evaluate the outcome of treatment and the overall quality of care, both of which are crucial to the well-being of patients. For example**,** when it comes to understanding whether root canal treatment is successful or not, the individual patient, who is generally unaware of the condition of the periapical tissues of their root-filled tooth, may not always agree with the criteria considered by their

clinician. If the tooth remains symptom-free following root canal treatment despite radiographic indications of ongoing periapical pathosis, the treatment may still be judged successful by the patient.[28,29] On the other hand, the patient may be dissatisfied with the treatment even if no objective evidence of periapical pathosis is present, as pain or other problems may persist.[30] As a result, a holistic view for evaluating the outcome of endodontic treatment should ideally include a set of core criteria assessing the patient's perspective on the outcome of treatment.[29,31,32]

IMPORTANCE of dPROs in ENDODONTICS

The importance of dPROs following endodontic treatment includes[6,19,33,34]:

- Helping clinicians and patients select the most appropriate treatment by providing a more comprehensive view of treatment costs and benefits. For example, a recurring debate in clinical practice involves whether to save a natural tooth by initiating root canal treatment, or whether to extract followed by replacement. This is not a simple cost-benefit analysis; however, preserving the natural tooth offers other benefits with tooth loss being shown to have a negative influence on the overall OHRQoL.[19,35]
- Providing guidance to aid clinical decision-making in the assessment, prevention, and management of pulpal and periapical diseases. For example, a study comparing patients' quality of life following surgical endodontic treatment using two different techniques (a traditional technique without an operating microscope and a technique using an operating microscope and minimal osteotomy). The results of this study will be useful for the clinician to select the most appropriate technique, from a patient's perspective, when performing surgical endodontics.[36]
- Developing clinical practice guidelines in endodontology and other disciplines should always include essential PROs, ranked into those that are "*most critical*," "*critical*," or "*important*".[22,27] The *European Society of Endodontology* (ESE) is in the process of developing clinical practice guidelines for pulpal and periapical diseases. PROs play an important role in the development of these guidelines as the patient is a key stakeholder in guideline development.[22]
- Analyzing the perspective of the patient on the effectiveness of treatment are valuable sources of information that can be overlooked when the assessment and

opinion of the clinician is used to filter the patient's perspective of the clinical intervention. The effects of many intervention are not well understood by clinicians, so it is important to obtain the patient's perspective and view of the treatment itself and its outcome.[1]

- Allowing an estimation of treatment benefits and risks separately from effectiveness measures used traditionally, allows PROs to be used as effective research endpoints for the development and evaluation of new drugs and treatments. For example, during vital pulp treatment the use of some hydraulic calcium silicate cements is associated with tooth discoloration, albeit with excellent healing outcomes.[37] An assessment of aesthetics as an important component of OHRQoL has led to shifts in the criteria for evaluating new endodontic materials and therapies.
- Helping to improve the quality of future clinical trial methodology and study design.

dPROs FOR ENDODONTIC TREATMENT – *EUROPEAN SOCIETY OF ENDODONTOLOGY* (*ESE*) INITIATIVE

The ESE is currently engaged in the process of developing new practice guidelines for the treatment of pulpitis, the non-surgical treatment of apical periodontitis, the surgical treatment of apical periodontitis and the regenerative treatment of apical periodontitis for the benefit of both clinicians and patients.[21] To assist robust systematic reviews of the literature, online Delphi surveys and meetings were conducted to identify and rank (*critical,* and *important*) the relevant patient and clinician-reported outcome measures with follow-up intervals. As part of this project, recommendations were also offered regarding the acceptable minimum follow-up duration. In summary, the results of the Delphi survey and online meeting concluded that the "*critical*" outcomes were "pain and tenderness" whereas "*important*" outcomes were "tooth function, need for further intervention, adverse effects , and OHRQoL".[22]

dPROs USED IN ENDODONTICS

Pain

Pain arising from the pulp or periapical region before, during and after endodontic treatment is of prime concern for both patients and clinicians.[26] Pain is a subjective feeling that can occur spontaneously or in response to touch or biting (tenderness) and is the primary reason people seek dental care.[38] In dentistry, pain is an important dPRO in addition to its association with the Oral Health Impact Profile (OHIP) tool[39] and has a major impact on one of the four dimensions of OHRQoL (orofacial pain).[40] The outcome measurement tools commonly used for objective assessment of pain are clinical examination, numerical rating scale (NRS), visual analogue scale (VAS), verbal rating scale (VRS) and Likert-scale.[41–43] The VAS used to record patients' self-reported pain ranges from either 1to 10 or 1 to 100.[41,44] In the VRS, patients are requested to score the intensity of pain ranging from 1 to 4 as none, slight, moderate and severe.[43] Similarly, in an 11-point NRS ranging from 0 (no pain) to 10 (worst pain), patients are asked to mark a numbered line on a chart corresponding to their level of pain.[45] Pain levels can be further divided or dichotomized into: 0 = none, 1-3 = mild, 4-7 = moderate and 8-10 = severe.[46]

The majority of endodontic outcome studies do not consider pain as a criterion for failure possibly because of its subjective nature.[47–50] However, pain on tooth percussion can indicate failure of endodontic treatment as this sign is an indicator of underlying periapical inflammation that may not be captured by radiographic examination alone. [51] Pain may also play an important role in a patients' decision-making process in selecting between root canal treatment (tooth retention) versus extraction followed by an implant-supported crown.[52] Notably, the pain experienced by patients during their current treatment may influence their future treatment decisions, depending on their personal endurance limits.[53]

Other subjective pain-related outcomes that do not have dedicated outcome measurement tools include: 'flare-up' and need for medication, which can be recorded through a careful clinical history and be considered as "*critical*" outcomes.[22] A 'flare-up' is an unpleasant experience of severe pain and swelling following endodontic treatment that necessitates an unscheduled emergency visit to a clinician.[54] The reported incidence rate of a 'flare-up' after root canal treatment ranges from 2.3 to 3.2%[55,56] as opposed to 10.4% in regenerative endodontic procedures.[57] It is usually relieved by prophylactic

antibiotics, steroidal and non-steroidal anti-inflammatory drugs, opioid and non-opioid analgesics, but in a true 'flare-up' the treating clinician is contacted.[58] Although there is no tool to measure the need for medication,[43] this can be recorded at subsequent clinical visits or by a patient in a diary.[22]

Oral Health–Related Quality of Life (OHRQoL)

OHRQOL is the most significant dPRO and a major element of HRQoL, as it is directly related to the effects of oral disease and dental treatment on patients.[59] To measure OHRQoL, instruments (questionnaires) are employed to gather patient-perceived impact, and instrument scores are utilized to quantify patient suffering.[59] OHQRoL is a global outcome measure that encompasses other measures considered by the European Society of Endodontology.[60] Nonetheless, some instruments used in this field are often not sufficiently broad to capture all aspects of OHRQoL.[60] OHRQoL is highly beneficial in areas with limited oral health care resources because it can be used to direct limited resources to the patients who require them most,[61] though only in conjunction with the relevant clinical outcome measures.[39]

Overall, root canal treatment is associated with an improvement in OHRQoL.[18,62–65] Similar OHRQoL scores have been reported where root canal treatment is compared with other treatment interventions in the primary care setting.[64] Such findings assist in discussing the negative perception of root canal treatment reported by patients compared with other dental treatment modalities. Similarly, negative beliefs regarding endodontic surgery have been confuted with regard to OHRQoL.[66] Recently published clinical endodontic studies highlight a lack of correlation between the healing of apical periodontitis, a commonly assessed outcome in endodontics, and OHRQoL;[63,67] however, association with other PROs remains a possibility.[63]

Inconsistent findings regarding OHRQoL have been demonstrated when endodontic treatment is compared with extractions. One study reported no significant differences,[64] whereas another, with a shorter recall period, highlighted that participants receiving root canal treatment had a significant improvement in OHRQoL compared with those having an extraction.[19] It should be noted that in the above studies, teeth were also extracted for non-endodontic reasons. Therefore, direct comparison of the management of endodontic

diseases may not be appropriate. Subjects receiving rehabilitation of an edentulous space with a single implant-supported prosthesis versus root canal treatment reported comparable OHRQoL scores.[33] It appears that no study has directly compared endodontic treatment with monitoring of apical periodontitis, the latter being a highly prevalent disease globally.[68] Notably, a high prevalence of apical periodontitis associated with root-filled teeth has been reported,[68] therefore, the presence of endodontic diseases may influence OHRQoL scores.

As clinical outcomes can be influenced by pre-, intra- and post-operative factors;[69] the same should be expected for OHRQoL. Pre-operative factors may encompass both subject-level and tooth-level factors. Subject-level factors that have been associated with better OHRQoL include patient age and gender, with the elderly (those over 65 years of age) and female subjects reporting better quality of life;[70] however, there are partially contrasting findings in a second comparable study where men and subjects younger than 35 years of age had poorer health outcomes in some factors.[26] The latter study also reported greater OHRQoL scores amongst those of higher socio-occupational status.[26] Pre-operative tooth-level factors include the type of tooth, with anterior teeth having a more significant association with higher OHRQoL scores compared with molar teeth.[26,70] The presence of pre-operative pain was also associated with negative outcomes,[70] with improvement of OHRQoL scores being more pronounced in teeth with vital pulps compared with those with necrotic pulps with a history of missing teeth.[62] Intra-operative factors have focused mostly on instrumentation protocols, with limited differences amongst them.[71–74] Considering the multitude of potentially relevant tooth-related and/or intra-operative factors such as diagnosis, irrigant solution sequence and delivery, number of sessions, use of intra-canal medications, root canal filling material and techniques, it is difficult to reach a definitive conclusion on the role of a specific treatment step on OHRQoL. Finally, the role of the operator may also influence the OHRQoL. Some studies have reported no difference in outcomes of root canal treatment when it is carried out by either dental students, general dentists or specialists,[62,65] whereas another study suggested more favorable responses in some domains when treatment was carried out by general dentists, which was justified by the likely increased complexity in the cases managed by specialists.[75]

The following quality of life questionnaires have been used in Endodontics :[20] OHIP-14, Modified health- related quality of life index, OQOL measure 6-item and 12-item Versions, OHIP-17, Modified OHIP-49, Ad hoc post-operative QoL questionnaire (POQol), American chronic pain association quality of life scale (QoLS) and Patient Perception questionnaire. An important concluding note is that endodontic research does not necessarily use previously validated OHRQoL instruments. Most studies use versions of OHIP, while other studies use instruments that appear to be created *ad hoc* for the purposes of the study. This, together with the high variability of clinical techniques adopted globally, makes reaching a definitive conclusion regarding the impact of endodontic treatment in OHRQoL difficult. Further understanding of the association between endodontic treatments and OHRQoL may be supported by the application of a disease-specific instrument for the measurement of this crucial outcome in the discipline. The development and validation of the latter should take into consideration the Food and Drug Administration Guidance on the development of PROs in medicine.[76]

Function

Being able to bite and chew with an endodontically-treated tooth is considered an "*important*" outcome.[22] This has been indirectly evaluated by recording the incidence of vertical fractures,[77] chewing ability[63] and patient comfort/discomfort.[26] Objective assessment of vertical root fractures of root canal treated teeth is difficult due to the fact that such teeth are often extracted and are unavailable for further analysis. The reported incidence rate for vertical root fractures (1.2%) has been evaluated during subsequent treatment procedures, including periapical surgery.[77] Chewing ability following root canal treatment has been evaluated using a subjective patient-centered questionnaire.[63] Similarly, patient comfort following any endodontic treatment could be assessed via a VAS ranging from 1 to 10[26] or an NRS-11 ranging from 0-10.[45]

Adverse effects

Adverse effects associated with endodontic treatment, for managing teeth with pulpitis and apical periodontitis, are also considered "*important*" outcomes.[22] Discoloration due to the leaching of root canal sealers or endodontic materials in the pulp chamber is one of the most common adverse effects of root canal treatment. Discoloration can be measured subjectively or objectively measured using a spectrophotometer.[78] That said

although discoloration can be used as a quantifiable outcome measured that does not make it a PRO, achieving that would involve questions such as to whether the discolored tooth made the patient feel emotional distress, lack confidence or have esthetic impairment. Many outcome assessment studies have recommended thorough debridement of the pulp chamber and internal bleaching to prevent sealer-induced discoloration.[79–81] Other rare adverse effects include allergic reactions to certain chemical constituents of dental materials including root canal sealers containing formaldehyde or zinc oxide,[82–84] intracanal medicaments such as tetracycline in Ledermix paste[85] and root canal irrigants such as sodium hypochlorite[86] and chlorhexidine.[87] Calcium hydroxide extrusion beyond the root apex can also result in damage to connective tissue and skin necrosis.[88] All such adverse effects are likely to impact on the OHRQoL of patients.[89]

Patient satisfaction

Patient satisfaction is the feedback on the quality of treatment delivered adds value when assessing the patients' perception of a successful or unsuccessful treatment and is usually measured by means of a questionnaire.[28] Satisfaction is dependent on various factors, such as tooth retention, healing, functionality, absence of symptoms, and the patient's own perception of care.[28,30,31] Therefore the tool should be comprehensive including all relevant aspects (outcome-related and process-related quality of care) of satisfaction.[31] An example includes one that consists of eight items measuring the patients' perception of root canal treatment, present pain intensity, satisfaction, chewing ability and cost of treatment that was used in a cohort study conducted in the Swedish public dental health service.[29] In that study, 75% of patients were satisfied with the root canal treatment procedure and were willing to undergo the procedure again.[29]

REPORTING OF ENDODONTIC OUTCOME STUDIES

An increase in the number and quality of studies reporting the outcomes of different endodontic treatment modalities has recently been reported.[90] These studies varied in design and included mostly comparative prospective and retrospective cohort studies, randomized control trials and case series. This variability in study design is a well-known cause of heterogeneity that negatively impacts the synthesis of evidence. This is compounded by evidence of great variability in the reporting outcomes included in these

studies,[91,92] The ambiguity and variation in how outcomes are described across different studies is a universal problem in medical research[93] that results in inconsistencies and inefficient use of clinical research findings that greatly impact clinical care.

Attempts has been made to develop classifications and taxonomies for mapping outcomes into specific domains to facilitate consistent reporting. For instance, Fletcher and Fletcher's[94] 5Ds model mapped outcomes into 5 domains: death, disease, discomfort, disability, dissatisfaction. This model has adopted and modified with addition of a 6th domain "destitution" to map endodontic treatment outcomes into patient-centered outcomes.[25]

Other systems/classifications such as that developed in the Patient-Reported Outcomes Measurement Information System (PROMIS),[95] provides a structure for classifying patient-reported measures only, whereas outcomes collected by health care providers, and those affecting wider society are not included. An ideal taxonomy/classification for outcomes must clearly differentiate between high-level outcome types and cover potential outcomes in a logical hierarchical structure of sufficient scope and granularity to be applied across different outcome studies.[96] In this regard Dodd et al.[96] developed a comprehensive 38-item taxonomy for reporting outcomes in heath research. Using this taxonomy, outcomes are mapped to 5 main core areas: survival, clinical/physiological changes, life impact, resource use and adverse events. Within each core area disease and treatment specific outcome measure domains are created adding more granularity and scope. This taxonomy has been created to provide a high-level difference between outcome domains in order to improve uniformity of outcome classification in electronic databases and it has been adopted in the development of many core outcome sets (COS) projects, systematic reviews and clinical trials. The taxonomy has the added advantage of flexibility in mapping outcomes to specific outcome domains within each core area. For instance, within the clinical and physiological core area, many patients and clinician reported outcome measures such as pain, healing, success/failure of treatment can be mapped, while OHRQoL measures are covered in the functionality core area and health economics outcomes in use of resources core area. The main problem, however, with using this or other outcome classifications is the lack of consensus on the definition of endodontic treatment outcome itself. For example, the definition of success has been

modified over the years with earlier classifications using terms such as stringent or lenient where in the former, success is characterized by clinical and radiographic normalcy while the latter requires only an absence of clinical signs and symptoms.[97] Others have adopted strict and loose criteria for success, where strict is defined as absence of clinical signs and symptoms and radiographic evidence of complete healing, whereas success based on loose criteria is defined by absence of signs and symptoms and radiographic evidence of incomplete healing.[98,99]

CORE OUTCOME SET (COS) IN ENDODONTICS

The lack of consensus in reporting and defining endodontic treatment outcomes has stimulated recent initiatives for development of COS for endodontic treatment. Using a scoping review methodology, Azarpazhooh et al.[100] developed a framework for standardized data collection and reporting of endodontic outcome studies. Although this provided valuable information and identified problems with outcome reporting, the final outcome was not a consensus-based COS development. COS is defined as an agreed, standardized set of outcomes that should be included, measured and reported as a minimum in all trials and outcome studies in a particular field.[93] The process involves identification of reported outcomes through literature searches, followed by a consensus Delphi process to agree on the most important outcomes for inclusion. The contribution of appropriate stakeholders is essential.[93] Therefore, the creation of a Core Outcome Set for Endodontic Treatment modalities (COSET) using a standardized and approved methodology in line with the Core Outcome Set-STAndards for Development (COS-STAD) and Core Outcome Set–STAndards for Reporting the (COS-STAR) recommendations[101,102] is currently underway.

An *a priori* protocol for the development of the COSET project was published[32] and registered in COMET.[103] The is an international collaborative project and will be carried out into two phases: (1) a structured scoping review to identify all outcomes reported for the range of endodontic treatment modalities including non-surgical root canal treatment, surgical root canal treatment, vital pulp treatment and revitalization. (2) a consensus process using the Delphi methodology and semi-structured interviews to agree upon the most important outcomes. This project is different to other COS studies in dentistry in that it puts the patients at the center of the process and considers their

perspective in the COS to be developed. The expected outcome will be the development of a consensus-based list of outcomes for each endodontic treatment modality, how these outcomes are measured and the optimal timing for their measurement.

FUTURE DIRECTIONS

- Several reports have confirmed a lack of clinical studies employing dPROs in endodontics.[23,100] Future clinical studies should incorporate dPROs such as discomfort, and OHRQoL along with important evidence based CROs. dPROMs used in clinical trials must be reliable and valid. This would lead to a patient-centered, evidence-based practice of dentistry, thereby reducing research waste, and ultimately increasing the value of treatment and research in endodontology.
- Research has demonstrated that disease-specific assessment is important, for example, sarcoma and autosomal hereditary bleeding disorders in patients.[104,105] Most of the PROMs employed in endodontics have been generic. Hence, a need arises to develop a validated dPROM that is specific to endodontology to standardize the outcome evaluation to guide further research and enhance patient care.
- Future studies should be conducted to identify the dPROMs that can be used in endodontics and map those outcome measures to the 4-dimensional framework (Oral function, Orofacial appearance, Orofacial pain, and Psychosocial impact). This will eventually result in the selection of the most appropriate outcome measures for patients undergoing endodontic treatment in the future.
- It is critical that future research adheres to a standardized approach for recording and reporting OHRQoL.[20] It has been noted in a previous systematic review analyzing OHRQoL in endodontology, that meta-analyses were not possible due to the lack of a standardized method for recording and reporting OHRQoL scores.[20] The standard approach should include OHRQoL scores obtained prior to the intervention and a sufficient recall period (e.g. 6 months). It is recommended to assess this dPRO using previously validated instruments and, if possible, an endodontic disease-specific tool.

CONCLUSION

With the development of dPROs and an awareness of what is important to patients, both practitioners and researchers now have the ability to improve endodontic treatment and research, ultimately benefiting the profession, individual patients and society. Appropriate use of dPROs is critical in endodontology to appropriately reflect the impact of pulpal or periapical diseases or endodontic treatment on patients. However, currently endodontic-specific PROMs are lacking. A new and specific measuring instrument should be developed to better reflect the perspectives of patients receiving endodontic treatment.

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