

# The Potential Role of Dental Patient-Reported Outcomes (dPROs) in Evidence-Based Prosthodontics and Clinical Care: A Narrative Review

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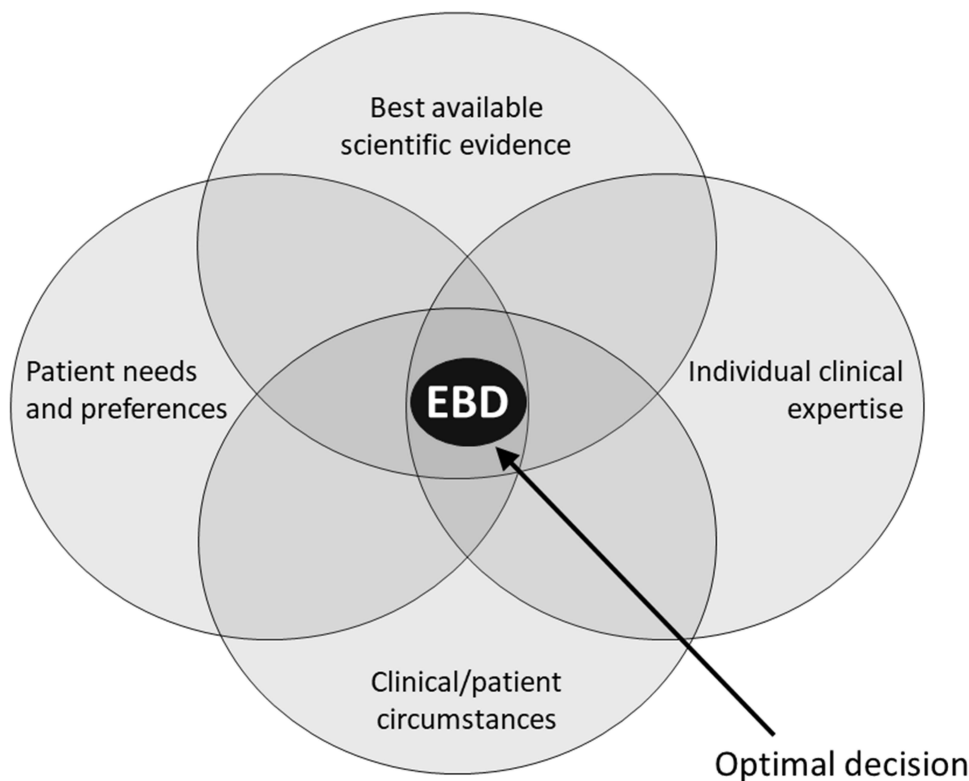
**Abstract:** Oral health problems are associated with poor quality of life, with the potential to cause functional, aesthetic, nutritional, and psychological difficulties, in addition to pain and suffering. Traditionally, dental treatment outcomes are measured using purely clinical parameters; however, this may be ineffective as these parameters cannot adequately capture the full impact of poor oral health on the patient, or their respective coping strategies. From this perspective, there are significant benefits when the patient's perception of their care is considered, and included in treatment planning and delivery. The impacts perceived by the patient on their treatment outcomes can be measured using patient-reported outcomes (PROs), or more specifically with dPROs, focused on dental patient-reported outcomes. Although there are some instruments available for measuring these outcomes in clinical trials, very little information is available for explaining the context in which these outcomes are considered, and also how to capture this information using appropriate instruments, specially in evidence-based dental practice. This article aims to review the literature, seeking to describe what has been considered about assessing patient's outcomes, as well as how to measure them, and explore the potential benefits of using dPROs in evidence-based prosthodontics and clinical care of partially and fully edentulous patients.

**Keywords:** evidence-based practice, dentistry, prosthodontics, patient-reported outcomes

## Background: Evidence-Based Clinical Practice

Evidence-based clinical practice is a process of combining research utilization, clinical expertise, and appreciation of the unique needs of patients to achieve better quality of care and improved healthcare outcomes.<sup>1</sup> This concept has been applied to all areas in health sciences, including clinical dentistry. Indeed, Evidence-based Dentistry (EBD) aims to integrate the dentist's clinical expertise, the patient's needs and preferences, and the most current, clinically relevant evidence. These elements are then combined within the decision-making process for provision of patient-centered oral care (Figure 1). Evidence-based practice has 5 steps that must be considered,<sup>2</sup> and it is described in Table 1.

The adoption of all the steps for evidence-based practice is challenging and demands a comprehensive set of educational and technical skills. One crucial element of the EBD process is the outcome assessment of an intervention through the definition of an appropriate endpoint within a clinical study. The selection of an appropriate endpoint in a clinical trial has important implications for the inferences that will ultimately be drawn from the study results and translation into clinical practice.<sup>3,4</sup> Moreover, the selected outcomes of a clinical trial should meet three criteria: (1) be interpretable and measurable, (2) be sensitive to the purpose of the study, and (3) be clinically relevant. Identifying



**Figure 1** The components of evidence-based dentistry (EBD). The formal process of using the skills for identifying, searching for and interpreting the results of the best scientific evidence, which is considered in conjunction with the clinician’s experience and judgment, the patient’s needs, preferences and values, and the clinical/patient circumstances when making optimal patient care decisions.

a clinical endpoint, which reliably reflects treatment effects and that can be reasonably and practically used in clinical studies remains a challenging task, which should be properly addressed during the conception and planning of the study.

The principles for choosing appropriate endpoints for evidence-based clinical practice in dentistry, and specifically in prosthodontics, will be addressed in the following sections.

### Outcomes and Endpoints in Clinical Trials

Initially, it is important to know what is the outcome, endpoints, and their relevant impacts. In a clinical trial, this refers to the findings, endpoints, or “results” observed at the end of the study. The term “outcome” usually refers to the measured variable (eg, bone loss around a dental implant), whereas an endpoint refers to the analyzed parameter (eg, change from baseline to 1-year in mean bone loss). In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial.<sup>5</sup> The endpoints of a clinical trial should be clearly indicated in the study objectives including survival rates, relief of symptoms or treatment of disease.

**Table 1** The Five Basic Skills Needed to Apply the Evidence-Based Decision-Making Model

1. ASK	Ability to convert information needs/problems into clinical questions so that they can be answered.
2. ACCESS	Ability to search and select relevant scientific literature with maximum efficiency for accessing the best external evidence with which to answer the question.
3. APPRAISE	Ability to critically appraise the available evidence for its validity and usefulness, as well as its clinical applicability within the patient/clinician/setting context.
4. APPLY	Ability to effectively apply the results of the appraisal, or evidence, in clinical practice, using the best of the clinician’s technical performance.
5. ASSESS	Ability to assess the process and your performance based on appropriate assessment of treatment outcomes.

**Note:** Data from Straus et al.<sup>2</sup>

Since all health interventions have different levels of expected benefits and risks, the reasons involved in patient willingness to consent to an intervention would be related to the perceived improvement of their previous condition and prevention of further problems. However, it is essential that the resulting benefit be detectable by the patients themselves, for example, in terms of perceived improvement in symptoms, improvement in functional capacity, or decreased chances of developing a condition or disease complication that is itself clear to the patient and is undesirable for maintenance of a healthy condition (eg, future tooth loss). Therefore, within the context of a clinical trial, a primary endpoint should be a direct measure of a treatment outcome that is important to the patient, which means that clinically meaningful endpoints should directly capture and measure how a patient feels, functions, or survives.<sup>6,7</sup> Endpoints may be measured either objectively or subjectively. They can be assessed through the clinician's judgment or interpretation of clinical signs or events (such as radiographic remission of a lesion, reduction in blood pressure or peri-implant infection), assessment by standardized performance measures (chewing performance test), patient-reported (PRO) – which are directly reported by patients (such as self-reported symptoms or function, or a measure of perceived quality of life), or observer-reported, such as a parent's report of bruxism activity in a child.<sup>8</sup>

Non-clinical endpoints may also objectively measure a biological or pathogenic process as a response to treatment intervention. Biomarkers assessed in haematological samples, histopathological results, diagnostic imaging, or physiological measures (including blood pressure) are commonly used for diagnostic, prognostic, monitoring, or predictive purposes.<sup>6</sup> These endpoints may be clinically important even though they are non-clinical and not meaningful to all end-users since they are strongly associated with a meaningful outcome, and therefore influence clinical decision-making.

An exception to the use of primary clinical endpoints is that of surrogate endpoints, which are used when the primary endpoint is undesired (eg, death), or when the number of events is very small, thus making it impractical to conduct a clinical trial to gather a statistically significant number of cases that reach a specific endpoint. A surrogate endpoint is usually a laboratory measure or a physical sign intended to be used as a substitute for a clinically meaningful endpoint. In a clinical trial, surrogates are used as a measure of effect of a specific intervention that may correlate with a primary clinical endpoint but does not necessarily have a guaranteed relationship. For example, surrogate endpoints, such as the level of marginal bone loss around periodontally compromised teeth, are commonly used when the primary clinical outcome, tooth loss, can take a long time to manifest. They can also be used in cases where the clinical benefit of improving the surrogate endpoint, such as controlling the level of periodontal disease, is well understood by the patient. Another use of surrogate endpoints is in cases where conducting a clinical endpoint study would not be feasible or clearly unethical. Nevertheless, before an appropriate surrogate endpoint can be accepted to substitute a clinical outcome, extensive evidence must be demonstrated from epidemiological studies and clinical trials.<sup>9</sup>

Since the early development and application of evidence-based methods in oral health, major limitations related to the quality of study design and reporting has been identified due to the variety of non-standardized selection and measurement of endpoints used in clinical trials.<sup>10</sup> The most common outcomes assessed in oral healthcare were summarized by Bader and Ismail,<sup>11</sup> which included effects associated with biological outcomes (physiological, microbiological, and sensorial status), clinical outcomes (survival, mechanical features, diagnostic and functional statuses), psychosocial outcomes (satisfaction, perception, preferences, oral health-related quality of life), and economic outcomes (direct and indirect costs). More recently, there has been also an increased interest in oro-facial function, -hypofunction and -fitness, especially in geriatric dentistry.<sup>7,12</sup> Hence, considering the diversity of potential outcome measures, and that all endpoints have properties and characteristics that have strengths and limitations critical to their interpretation, efforts should be made to include those endpoints, which will directly influence clinicians' decision-making and policy-makers. Poor selection of endpoints makes interpretation and implementation of findings difficult or impossible, limits evidence synthesis, and thereby diminishes the value of the research, resulting in wasted use of resources.<sup>6</sup>

As illustrated by Hujuel<sup>13</sup> in the field of periodontology, primary endpoints are tangible to the patient and directly measure how a patient feels, functions, or survives (eg, tooth loss or pain or oral health-related quality-of-life measurements), while surrogate endpoints are often intangible to the patient, such as changes in probing attachment level or gingival crevicular fluid level. For years, there was a tendency to focus on surrogate endpoints or outcomes, although there is now an increased focus on oral health-related quality of life measures. Consequently, the lack of a rigorous scientific basis for the measurement of periodontitis has led to changing opinions as to what measures should be used to

assess periodontal treatment efficacy and how to interpret changes in both interventional and observational studies.<sup>13</sup> Therefore, if primary endpoints are not feasible to be measured, efforts should be focused on evaluating which surrogates are most reliable and provide strong evidence that the treatment effect on the primary endpoint may be mediated through the surrogate endpoint.

In summary, although primary endpoints are essential for outcome assessment since they reflect unequivocal evidence of tangible benefit to patients, surrogate endpoints can also include measures that are not of direct practical importance but are believed to reflect outcomes that are important as part of a disease/treatment process, and could be helpful for preliminary evidence (Table 2).

## Assessing the Effectiveness of the Evidence-Based Decisions Through Appropriate Outcome Measures

Evaluating the process of evidence-based decision-making may include a range of activities such as examining outcomes related to the health/function of the patient and its experience, such as patient satisfaction. This process has become a crucial outcome measure for healthcare professionals and a mechanism to guide quality improvement.<sup>14</sup> However, as discussed previously, one of the most significant aspects of evaluating the efficacy of health interventions in the literature is the lack of consistent, valid, reliable, and clinically relevant outcome assessment. In addition, the impacts of disease on health conditions are multifactorial and may vary across patients.

Oral diseases are associated with symptoms and self-perceived conditions that negatively affect patients' quality of life, with consequent functional constraints, nutritional impairment, and psychological impacts. Traditionally, oral treatments, including prosthodontic care, are mainly focused on controlling and rehabilitating tissue damage and tooth loss, minimizing oral pain and suffering. Consequently, the assessments of the results of oral and dental interventions are often based on disease-orientated outcomes, such as the control of symptoms, repair of physical damage, and replacement of missing teeth. The ultimate objectives of treatment are to provide satisfactory restoration of oral function and aesthetics and prevent further deterioration of dental and oral structures. However, successful prosthodontic treatments may not target solely the control of the disease and the replacement of oral tissues using state-of-art techniques and materials. Treatment outcome assessment is ineffective if it does not adequately address the impact of problems and suffering from the patients' perspective and articulate what matters most to patients.

Outcome assessment is an essential part of evidence-based practice because it is directly linked to what the patient expects from treatment. Therefore, the selection of relevant outcomes should consider patient perspectives at the core of any healthcare system. This means that the outcomes of a clinical intervention obtained directly from the patient themselves: patient-reported outcomes (PROs) are increasingly considered as more important than any other outcomes

**Table 2** Differences Between Primary and Surrogate Outcomes in Clinical Trials in the Field of Prosthodontics

Primary Outcomes	Surrogate Outcomes
Reflect unequivocal evidence of tangible benefit to the patient	Include measures that are not of direct practical importance but are believed to reflect outcomes that are important as part of a disease/treatment process
Examples <ul style="list-style-type: none"> <li>● Tooth survival</li> <li>● Secondary caries</li> <li>● Implant survival</li> <li>● Patient satisfaction</li> </ul>	Corresponding examples <ul style="list-style-type: none"> <li>● Pocket depth</li> <li>● Open margins</li> <li>● Peri-implant bone level</li> <li>● Prosthesis retention/support</li> </ul>
Endpoints are "harder" and difficult to measure and studies can be more expensive.	Endpoints are "softer" and easier to measure and studies are relatively inexpensive.
Can have a direct impact on changes in clinical practice and/or changes in public health policies.	Do not have a direct impact on changes in clinical practice or changes in public health policies.

**Note:** Adapted from *Dent Clin North Am*, 58(1), Bidra AS. Evidence-based prosthodontics: fundamental considerations, limitations, and guidelines. *Dent Clin North Am*. 1–17. Copyright 2014, with permission from Elsevier.<sup>35</sup>

including clinical, physiological or caregiver-reported.<sup>15</sup> The judicious selection and use of patient-reported outcome measures (PROMs) aim to empower patients and help to define positive outcomes when assessing the results of healthcare interventions. Consequently, PROMs may guide healthcare systems and professionals to (1) achieve appropriateness and efficiency in the selection and provision of different treatment options that have levels of complexity, invasiveness, and costs; (2) lead to better-shared decision-making when considering PROMs as key factors for appropriately setting patient expectations and guiding decision-making in terms of whether or not the patient feels the benefit of an intervention; and (3) demonstrate value and transparency to patients.<sup>16</sup>

Although experienced clinicians may be able to make objective and accurate observations of signs, impairment, and disability, only patients can truly report on their symptoms and impacts on quality of life.<sup>17</sup> Patient reported outcomes can be structured using many instruments and tools, many of them developed specifically for a condition or procedure. Previous evidence shows that enhanced treatment adherence and outcomes can be obtained by giving attention to patient feedback on healthcare outcomes and patient behaviour change in the clinical setting.<sup>15</sup>

Although it is common to collect feedback on satisfaction or experience with care from patients, those data are frequently not used as structured resources to assess the quality of healthcare and long-term support services. Patients' experiences and perceptions are valuable sources of information on outcomes beyond experience with care.<sup>18</sup> For example, in the case of prosthodontic treatments, when long-term support services for patients are required to control biological and mechanical complications and to provide maintenance care, asking them about outcomes they value, such as increased functional performance, better oral comfort, ability to maintain proper oral hygiene, and improved social interactions is crucial.

Although health technologies allow measurements of patients' physical, physiological, or biochemical data, diagnostic tools and devices cannot capture all relevant information about the treatment of the disease. Some data can be obtained only from patient reporting, as exemplified in Table 3. Outcomes may have different measuring attributes. Symptoms may have a one-dimensional property while others are multidimensional, such as health-related quality of life measures. The manner in which a PROM is structured depends on the rationale behind its development and manner of scoring. For example, questionnaires which measure a single construct, such as pain symptoms, are described as unidimensional, and the items (questions) are added to yield a single overall score. Conversely, a multidimensional questionnaire aims to provide a profile of scores.<sup>19</sup> This is exemplified in the Oral Health Impact Profile-short form (OHIP-14) questionnaire, which is a generic multidimensional PROM comprising 14 items, which are scored to provide information on each of the seven domains associated with the subject's oral health-related quality of life – OHRQoL (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap).<sup>20</sup> The OHIP-14 is a widely accepted OHRQoL instruments used in many cross-sectional and longitudinal studies worldwide.

## Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs)

Patient-Reported Outcomes (PROs) are defined as any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.<sup>21</sup> PRO domains

**Table 3** Examples of Disease or Treatment Outcomes Reported by the Patient

<ul style="list-style-type: none"> <li>• Symptoms not obvious to observers</li> <li>• Psychological symptoms</li> <li>• Symptoms in absence of observer</li> <li>• Frequency of symptoms</li> <li>• Severity of symptoms</li> <li>• Nature and severity of disability experienced by the patient</li> <li>• Impact of the disease or condition on daily life and quality of life</li> </ul>	<ul style="list-style-type: none"> <li>• eg fatigue, headache, burning mouth</li> <li>• eg depression, anxiety</li> <li>• eg sleep disturbances</li> <li>• eg Do the symptoms occur daily, weekly, occasionally?</li> <li>• eg Pain is mild, moderate, or severe?</li> <li>• eg How burdensome is the disease for the patient?</li> <li>• eg Does the oral condition interfere in patient's daily life?</li> <li>• eg Did the treatment impacted the patient's quality of life?</li> <li>• eg How do the patient feel about being edentulous?</li> <li>• eg Is the patient satisfied with the prosthodontic treatment given?</li> </ul>
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**Note:** Data from Deshpande et al.<sup>15</sup>

comprise the patient's health-related quality of life (including functional status associated with healthcare or treatment), symptoms and symptom burden, previous experience with care, and health behaviours.

PROs may be measured in absolute terms, such as a patient's rating of the severity of pain after surgical treatment. PROs can also be used to report changes from a previous measure, such as the improvement in chewing function following the provision of new dentures. In prosthodontics, traditional outcomes are focused on disease-oriented aspects of treatment, usually related to the incidence of biological and mechanical failures, and physiological impacts of treatment measured by imaging and force measuring devices. Although these factors are relevant to assure the integrity of the prostheses and supporting tissues health and survival, the effectiveness of any prosthodontic therapeutic intervention should include patients' functional and aesthetic expectations, and also the benefit felt by patients, according to their values, as a result of receiving the intervention. A variety of instruments or tools are available to assess the improvements in functional status, service satisfaction, and quality of life in prosthodontic patients.<sup>22</sup>

As the importance of PROs alongside markers of health improvement has been recognized in clinical dentistry, there was a need to create identifiable, valid, and reliable patient-reported measures (PROMs). PROMs can be defined as instruments, scales, or single-item measures used to assess the PRO concept perceived by the patient, obtained by directly asking the patient to self-report. Therefore, to access a PRO, it is necessary to develop a patient-reported outcome measure (PROM). PROMs are captured by instruments or tools that collect and measure information through oral discussion, questionnaire research, self-assessment, interview discussion, network research, and other methods. The results obtained should be reliable and consistent and may reflect changes in the health status, functional status, health-related quality of life, symptom and symptom burden, personal experience of care, collateral effects, and health-related behaviors such as anxiety and depression.<sup>22</sup> PROMs can be used to assess a wide variety of health-relevant concepts that can be summarized into five main categories that are related to health-related quality of life, functional status, symptoms and symptom burden, health behaviors, and the patient's healthcare experience (Table 4).<sup>23</sup>

PROMs can be either general or disease-specific. General instruments assess common aspects related to a variety of different health conditions and allow comparison across these conditions for evaluation and implementation of new methods of care and

**Table 4** Main Characteristics of the Five Major Categories of Patient-Reported Outcome Measures

PROM Category	Main Characteristics	Main Strengths	Main Limitations
Health-related quality of life (HRQL) Functional status	<ul style="list-style-type: none"> <li>• Is multidimensional</li> <li>• Can be generic or condition-specific</li> <li>• Reflects ability to perform specific activities</li> </ul>	<ul style="list-style-type: none"> <li>• Yields a global summary of well-being</li> <li>• Can be used in addition to performance-based measures of function</li> </ul>	<ul style="list-style-type: none"> <li>• May not be considered a sufficiently specific construct</li> <li>• May reflect variations in self-reported capability and actual performance of activities</li> </ul>
Symptoms and symptom burden	<ul style="list-style-type: none"> <li>• Are specific to type of symptom of interest</li> <li>• May identify symptoms not otherwise captured by medical workup</li> </ul>	<ul style="list-style-type: none"> <li>• Are best assessed through self-report</li> </ul>	<ul style="list-style-type: none"> <li>• May fail to capture general, global aspects of well-being considered important to patients</li> </ul>
Health behaviors	<ul style="list-style-type: none"> <li>• Are specific to type of behavior</li> <li>• Typically measure frequency of behavior</li> </ul>	<ul style="list-style-type: none"> <li>• Target specific behavior categories</li> </ul>	<ul style="list-style-type: none"> <li>• Validity may be affected by social desirability</li> <li>• May produce potential patient discomfort in reporting socially undesirable behaviors</li> </ul>
Patient experience	<ul style="list-style-type: none"> <li>• Concerns satisfaction with health care delivery, treatment recommendations, and medications (or other therapies)</li> <li>• Reflects actual experiences with health care services</li> <li>• Fosters patient activation</li> </ul>	<ul style="list-style-type: none"> <li>• Is an essential component of patient-centered care</li> <li>• Is valued by patients, families, and policy makers</li> <li>• Relates to treatment adherence</li> <li>• Relates to health behaviors and health outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• May be a complex, multidimensional construct</li> <li>• Requires confidentiality to ensure patient comfort in disclosing negative experiences</li> <li>• Does not provide sufficient evidence that activation enhances health care decision making</li> </ul>

**Note:** Table adapted from Table 2 in Cella, D., Hahn, E. A., Jensen, S. E., Butt, Z., Nowinski, C. J., Rothrock, N., & Lohr, K. (2015). Patient-reported outcomes in performance measurement. RTI Press Book No. BK-0014-1509. RTI Press. <https://doi.org/10.3768/rtipress.2015.bk.0014.1509>. Licensed under Creative Commons BY-NC-ND 4.0.<sup>23</sup>

facilitate cost-effectiveness analysis.<sup>24</sup> For example, the EuroQol EQ-5D is a generic PROM that comprises five questions seeking information that best describes the patient's health that day, covering mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D is a widely used measure of patient-reported outcomes worldwide. It has been used in clinical trials, observational studies, population health surveys, and routine data collection in healthcare systems. This instrument allows to calculate QALYs (quality-adjusted life years) and has become the cornerstone of health technology assessment (HTA) as a parameter of the effectiveness of new technologies in cost-effectiveness models. However, within the context of a clinical trial for a specific disease condition, a generic PROM such as EQ-5D may not be sensitive enough to elicit subtle changes, which occur as a result of an intervention for a particular condition.<sup>25</sup>

In contrast, disease-specific PROMs are constructed more purposely to measure specific symptoms and their impacts on the patient's condition due to the particular disease.<sup>26</sup> Consequently, disease-specific PROMs have greater face validity compared to generic PROMs, although comparisons cannot be made across a variety of different conditions or diseases.<sup>22</sup> Nevertheless, well-constructed and structured PROM instruments will yield quantitative data that enables comparison of patient groups or providers, and are powerful instruments for both patients, policy-makers, and other stakeholders to improve the management of care, quality of services, access to care equity, and health resource priorities disease.<sup>26</sup>

There are several benefits from including specific-disease PROMs, especially in clinical trials assessing the effects of treatments. PROMs elicit information that is unique for the study participants and that considers the participants' values related to the treatment. PROMs minimizes the risk of observer bias which may occur when the study personnel attempt to make judgments about what participants are experiencing. Further advantages include an increase in public accountability, improvement in understanding of costs and benefits of the intervention.<sup>25</sup>

## Dental Patient-Reported Outcomes (dPROs) and Dental Patient-Reported Outcome Measures (dPROMs)

Oral health is a component of health in general, and dental patients represent a subset of patients undergoing oral care. Since they suffer from oral diseases and receive dental interventions, the terms dental patient-reported outcomes (dPROs) and dental patient-reported outcome measures (dPROMs) were coined in 2018.<sup>27,28</sup> Similarly to PROs and PROMs, dPROs and dPROMs capture what matters to dental patients, targeting four major areas related to patients' suffering and reasons why they typically seek care: improvement in oral function and orofacial appearance, pain control, and reduction in psychosocial impacts associated with oral conditions.<sup>27</sup>

Currently, dPROs are used in clinical studies as the main outcomes in all areas of clinical dentistry. The main advantages of using dPROs include the efficacy for capturing a wide range of oral symptoms, the levels of desired treatment effects, and the impact of treatment failures. For example, tooth loss can result in impacts on quality of life and performance of oral functions; specific dPROMs can assess these impacts. Depending on the extent of tooth loss, these negative impacts can vary with implications for perceived aesthetics (mainly anterior teeth), psychological, or functional (mainly posterior teeth).<sup>29</sup> Other advantages of dPROs include their reliability, which is relatively stable across the population, easy and flexible administration, easier data collection with savings on time and money, and their broader scope (capable of covering the patient as a whole).<sup>30</sup>

In addition to oral-related benefits from dental treatments, the scope of their impacts is wider and may also have a positive influence on general well-being. Oral health-related quality of life (OHRQoL) is an integral part of general health and well-being. It is considered one of the most important dental outcomes reported by the patient. OHRQoL is defined as a multidimensional construct that includes the subjective evaluation of the individual's oral health, functional well-being, emotional well-being, expectations and satisfaction with care, and sense of self.<sup>31</sup>

Multidimensional dPROMs such as the Oral-Health Impact Profile (OHIP) instrument is a construct that has demonstrated sensitivity to change in OHRQoL in different populations of patients with specific oral-related health conditions. It also provides more easily interpretable results and should be preferred when assessing treatment effects in typical dental patients compared to general health-related quality of life instruments.<sup>32</sup> In addition, this instrument is effective in detecting edentulous patients with oral and prosthetic problems.<sup>33</sup> Nevertheless, the conceptual basis of several psychometric instruments used in dentistry, such as the OHIP, take a marked negative approach to oral

impairment and disability, as it is focused on qualifying the presence and levels of the negative or bothersome impacts of oral impairment. This negative approach of OHIP benefits the theoretical foundation in sick-role theory, and may overlook the positive behaviours and beliefs along with the coping and adaptive strategies of many disabled people.<sup>34</sup>

## Assessing dPROMs in Prosthodontic Care

In prosthodontics, the definition of endpoints is especially challenging since clinical outcomes are multifaceted due to the inherent nature of the treatment. Some examples are the different perspectives that discriminate aspects like success versus survival, complications versus consequences, and prosthesis outcomes versus patient-centered outcomes.<sup>35</sup>

Although the focus of rehabilitative treatment has been traditionally more focused on the disease itself than on the patient's self-perception of the treatment, there have been significant changes since the adoption of evidence-based concepts in dental practice. An example of a disease-related outcome is when one seeks to improve oral health with the limited objective of replacing missing teeth, without considering the whole spectrum of functional and psychosocial

**Table 5** Instruments Frequently Used in Prosthodontic Research That Comprise the Dimensions of OHRQoL

<p>Geriatric Oral Health Assessment Index (GOHAI) Atchinson &amp; Dolan, 1990<sup>37</sup></p>	<ul style="list-style-type: none"> <li>● Assesses the functional and psychological burdens, such as pain and discomfort to and oral condition.</li> <li>● Potential to assess the quality of life of edentulous patients, considering how much impact an oral disease has on his quality of life.</li> <li>● Provides qualitative and quantitative information.</li> <li>● Divided into three domains (physical, psychological and pain and discomfort), and includes 12 items that belongs to these domains.</li> <li>● Can place greater weight compared to OHIP-14 in terms of functional limitations, pain, and discomfort.</li> <li>● A higher score indicates better oral health in ADD-GOHAI (range from 12 to 60), or indicates poor perception of oral health in SC-GOHAI (range from 0 to 12).</li> </ul>
<p>Oral Impacts on Daily Performance (OIDP) Adulyanon &amp; Sheiham, 1997<sup>38</sup></p>	<ul style="list-style-type: none"> <li>● Assesses OHRQoL in terms of adverse impacts that oral conditions can have on everyday life experiences.</li> <li>● There is an association with clinical indicators and what the patient reports about their health.</li> <li>● Measures the physical, psychological and social aspects of performances.</li> <li>● Limitations: There is little evidence if the use of this instrument is suitable to measure whether changes that occur in oral health are due to age or as a consequence of treatment. The priorities of the participants, according to their clinical status, vary from what is depicted in the instrument.</li> </ul>
<p>Oral Health Impact Profile (OHIP) Slade &amp; Spencer, 1994<sup>20</sup></p>	<ul style="list-style-type: none"> <li>● Assesses the functional and psychological burdens, such as pain and discomfort to and oral condition.</li> <li>● Potential to assess the quality of life of edentulous patients, considering how much impact an oral disease has on his quality of life.</li> <li>● Provides qualitative and quantitative information.</li> <li>● OHIP-14: a short version of OHIP, including 14 items.</li> <li>● OHIP-EDENT: a more specific questionnaire for edentulous subjects, including 19 items that belongs to seven dimensions (functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap). This instrument comprises issues related to masticatory function and changes in perception of oral health after prosthesis treatment, such as difficulty chewing and food stuck.</li> <li>● OHIP-14 and OHIP-EDENT are related to the social impacts of oral disorders.</li> </ul>
<p>Dental Impacts on Daily Living (DIDL) Leao &amp; Sheiham, 1996<sup>39</sup></p>	<ul style="list-style-type: none"> <li>● Allows access measures of oral health related to quality of life.</li> <li>● Comprises items evolving appearance, pain, comfort, eating restrictions, and general performance.</li> <li>● Differentiates the subjective impacts according to which social class, group and sex the patient belongs.</li> </ul>

**Note:** Data from these studies.<sup>20,37–39</sup>



benefits of oral rehabilitation and how it is perceived by the patient.<sup>36</sup> Several OHRQoL instruments have been considered appropriate for capturing all patient relevant impacts of impaired oral health due to tooth loss. A list of relevant instruments that have been used in prosthodontic research is provided in Table 5.<sup>20,37–39</sup> Therefore, OHRQoL instruments are a recommended set of outcome measures when evaluating the effects of prosthodontic treatments.<sup>30</sup> In the last decade, prosthodontists have been gradually recognizing the need to go beyond symptoms and actually seek patient's perspectives regarding treatment outcomes. When incorporating patient-oriented outcomes, there are advantages related to the ease of obtaining outcome data, including low cost, in addition to improving clinical care.<sup>30</sup>

For checking the patient's perception, considering the need for assessing the performance of clinical research and practice in prosthodontics, there are six steps as a pathway for identification and selection of dPROs and dPROMs. This process is summarized in Table 6, which shows the critical steps in developing a dPRO and dPROM-based.

The first step is a clear understanding of the clinical issue or problem in the target population of interest. Some questions to consider include: is the clinical problem relevant as perceived by the patient? Does the clinical problem address a relevant health feature within the context of the target population or healthcare service? For example, a complex implant-based treatment may not be feasible or appropriate when there are limited technical or financial resources, or the target population is frail older adults who have expressed a preference for simple oral care interventions.

Secondly, as person-centeredness is a key principle for developing dPROMs instruments, identifying outcomes of value to the target population is a critical early step in the pathway. Hence, the word "patient" is often used as a catch-all term to comprise patients, families, caregivers, and consumers more broadly. This term includes those receiving support services, such as patients with disabilities or dependent older adults. It may also address a range of healthcare services, which extend beyond a particular clinical setting for care delivery.<sup>18</sup> The identification of relevant outcomes should consider those that are responsive to the intervention provided and, therefore, patients may be only asked to provide PROM data that are directly applicable to their care and treatment. Providers' performance should be measured solely on

**Table 6** A Proposed Pathway for Identification and Selection of dPROs and dPROMs in Prosthetic Dentistry (Adapted from

Outcome Parameter	Steps	Application
dPRO	<ol style="list-style-type: none"> <li>1. Identify the clinical problem of interest (eg, rehabilitation of edentulous subjects with implants).</li> <li>2. Identify outcomes that are meaningful to the target population and are amenable to change due to the specific clinical care</li> <li>3. Determine whether patient-reported information (PRO) is the best way to assess the outcome of interest</li> </ol>	<ul style="list-style-type: none"> <li>• Include input from all stakeholders, including professionals, patients, relatives, caregivers, insurance companies, industry, and others, that has an interest in decisions made.</li> <li>• Ask persons who are receiving the care and services</li> <li>• Identify evidence from the literature that the outcome responds to the selected intervention</li> <li>• In case the select outcome is unethical or unfeasible to be assessed, consider the use of surrogate endpoints</li> <li>• If a PRO is appropriate, proceed to step 4</li> </ul>
dPROM	<ol style="list-style-type: none"> <li>4. Identify existing PROMs for measuring the outcome (PRO) in the target population of interest</li> <li>5. Select a PROM suitable for use in the target population</li> <li>6. Use the PROM in the real world with the intended target population and study setting</li> </ol>	<ul style="list-style-type: none"> <li>• Many PROMs (instrument, scale or single-item) were developed and tested primarily for research in the field of the study</li> <li>• A comprehensive literature search is essential to identify disease-specific or generic PROMs that are suitable for the purpose of the study</li> <li>• Identify reliability, validity, responsiveness, feasibility of the instrument</li> <li>• Assess status or response to intervention, provide feedback for self-management, plan and manage care or services, share decision-making</li> <li>• Test feasibility of using and collecting PROM data to develop and test an outcome performance measure</li> </ul>

**Note:** Data from National Quality Forum.<sup>18</sup>

outcomes influenced by the care they provide, from the patients' perspective (note that the outcomes impacted by oral rehabilitation may encompass a broad scope of primary endpoints that are related to oral and general health).

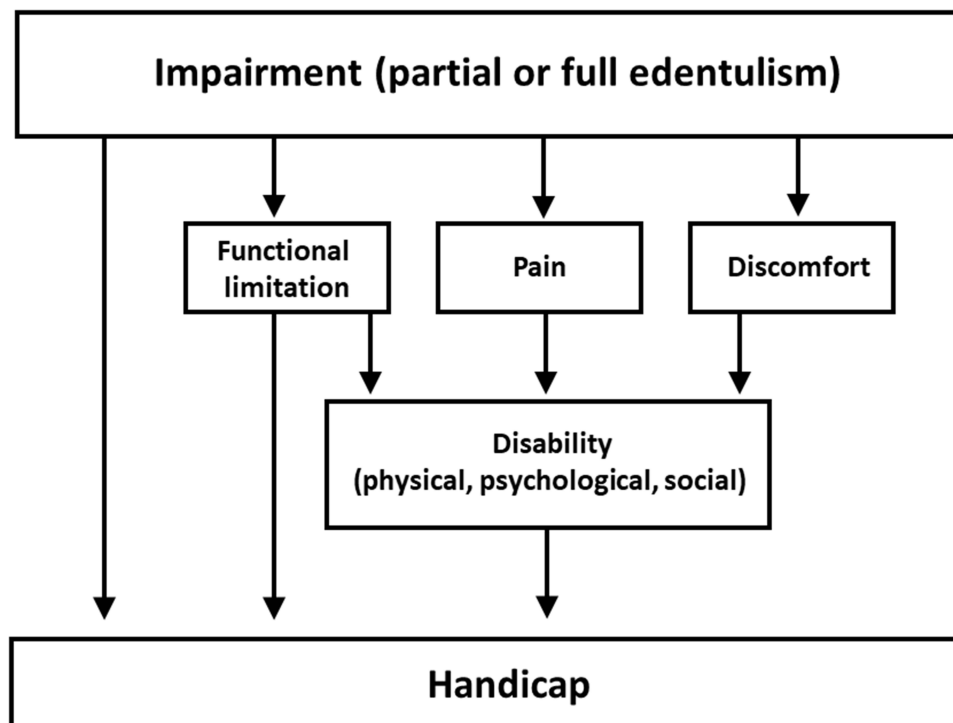
Thirdly, it is essential to question whether patient-reported information is the best way to assess the outcome of interest. Although prosthodontic interventions usually directly impact how a patient feels or functions, several other surrogate outcomes are relevant from the clinical perspective and may influence overall prosthesis survival, as cited in [Table 2](#). For example, periodontal and peri-implant outcomes such as increased pocket depth, accelerated marginal bone loss, periimplantitis may affect treatment success and implant/prosthesis survival, which are ultimately the most relevant endpoints from the patients' perspective. Moreover, oral prostheses tend to deteriorate and lose their functionality in long-term usage. Changes in the supporting tissues as a consequence of progressive bone resorption and the consequent loss of fit of the prosthesis may also compromise oral comfort and function. Therefore, the incidences of biological and technical complications are relevant causes of treatment failure and are meaningful surrogate outcomes that complement dPROs assessment.

The following steps refer to the appropriate use of dPROMs. Some valuable criteria for choosing appropriate PROMs for implant-related treatments were recommended in a consensus report:<sup>40</sup> (1) the choice of which PROMs to use should be restricted to those most appropriate for the study question that have been validated in previous studies; (2) at a minimum, PROMs data should be gathered at two-time points – at baseline and a designated point post-treatment, with multiple assessments desirable to discriminate short-versus long-term treatment effects; and (3) well-controlled randomized trials are needed to determine the appropriate standard of care based on clinical and patient-reported outcome measures.<sup>40</sup> As it is expected that many dPROMs are already available, various strategies such as literature and/or web searches and outreach to experts in the field should be used to identify PROMs that measure the outcome of interest in the target population, rather than simply developing new tools. Other novel strategies such as PROMIS® (Patient-Reported Outcomes Measurement Information System®) were developed as a set of person-centered measures that provide self-reported item banks to evaluate and monitor several dimensions of physical, mental, and social health in the general population and with individuals living with chronic conditions.<sup>41</sup>

There are several dPROMs that are reliable, valid, and responsive for people receiving prosthodontic treatments. Repeated use of a PROM instrument is a strong indication of external validity, which means that the instrument was effectively designed to measure what it set out to measure. However, if no specific dPROM seems suitable for the target population, one or more PROMs could be adapted to the target population or a completely new PROM could be developed and tested for the assessment of specific endpoints in the target population. In such cases, the instruments should be rigorously tested to demonstrate reliability and validity, based on data derived from a pilot or preliminary studies, considering the clinical issue and performed in the real-world setting with the target population for whom the dPROM will be implemented.

A comprehensive systematic review by Mittal et al<sup>36</sup> which assessed generic multi-item dPROMs for adult patients identified 20 questionnaires, which contained 36 unique dPROs, and 53 dPROMs. All identified dPROs were grouped into four categories: oral function, orofacial pain, orofacial appearance, and psychosocial impact. These categories were based on the conceptual model of oral health from Locker et al,<sup>42</sup> representing the four main dimensions of OHRQoL. The 53 dPROMs that measures the 36 identified dPROs expressed the currently available multi-item tools to measure self-assessed dental patients' suffering with oral health-generic instruments. Narrowed and broader dPROs and dPROMs were listed as representing different aspects of patients' perceived oral health.

Locker's conceptual model of oral health<sup>42</sup> proposes that there are five consequences of oral disease – impairment, functional limitation, pain/discomfort, disability, and handicap – and that these are sequentially related ([Figure 2](#)). Impairment (structural abnormality, eg, edentulousness) leads to functional limitation (restrictions in body functions, eg, difficulty chewing) and pain/discomfort (self-reports of physical and psychological symptoms), which, in turn, lead to disability (limitations in performing daily activities, eg, unsatisfactory diet) and then to handicap (social disadvantage, eg, social isolation), and functional limitation may also lead directly to handicap.<sup>43</sup> These dimensions of OHRQoL are captured in instruments such as the Geriatric Oral Health Assessment Index (GOHAI), Oral Impacts on Daily Performance (OIDP), Oral Health Impact Profile (OHIP), Dental Impacts on Daily Living (DIDL), and others commonly used for older adults and in prosthodontic research. These questionnaires comprise a wide range of target d-PROMs that



**Figure 2** Locker's conceptual model of oral health that is applied to OHRQoL instruments.

measure different aspects of oral function (chewing, functional limitation, jaw mobility, etc), orofacial pain (pain, discomfort, and disability), appearance (orofacial aesthetics, aesthetic concerns, etc.), and psychosocial impact (psychological distress, social impact, dental self-confidence, interference with general activities, etc.). Detailed information about these PROMs, which embrace the dimensions of OHRQoL, can be assessed in [Table 5](#). The most common limitations of many of these dPROMs are related to incomplete knowledge about their dimensionality, which affects their validity, and missing recall period challenges clinical utility of dPROMs, in particular, the assessment of dental interventions' treatment effects.<sup>36</sup>

## Conclusions

This narrative review summarizes the main topics related to the use of dPROs and d-PROMs to measure outcomes of oral health intervention, specifically within prosthodontic care. It was observed that, traditionally, clinician-assessed outcomes were the primary outcomes in treatment success evaluation. However, these results are frequently not patient-perceived. Therefore, to determine treatment efficacy is necessary to assess the patient's perceived impacts after treatment, which are captured by patient-reported outcomes (PROs). In dentistry, the assessment of dPROs is an essential part of an evidence-based approach to oral care of patients with missing teeth. The use of standardized health-specific measures should be a essential means of assessing the benefits of different forms of prosthodontic treatment.

The patient's assessment must be used as an adjunct to objective dental findings in order to decide which interventions work and in which settings. Tooth loss impacts different aspects of oral health-related quality of life, resulting in oral pain and discomfort, impaired oral function, negative impact on the perception of facial and dental appearance, and psychological well-being. Appropriate dPROMs can assess these impacts and capture desired treatment effects and the impact treatment failures. However, choosing and using valid instruments can be challenging and requires calibration and additional training. The findings of this review support the importance of using dPROs, as well as dPROMs, for assessing treatment effectiveness based on patient-centered outcomes.

## Disclosure

The authors report no conflicts of interest in this work.

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