

# Oral Rehabilitation Outcomes Network—ORONet

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The published literature describing clinical evidence used in treatment decision-making for the management of tooth loss continues to be characterized by a lack of consistent outcome measures reflecting not only clinical performance but also a range of patient concerns. Recognizing this problem, an international group of clinicians, educators, and scientists with a focus on prosthodontics formed the Oral Rehabilitation Outcomes Network (ORONet) to promote strategies for improving health based on comprehensive, patient-centered evaluations of comparative effectiveness of therapies for oral rehabilitation. An initial goal of ORONet is to identify outcome measures for prosthodontic therapies that represent multiple domains with patient relevance, are amenable to utilization in both institutional and practice-based environments, and have established validity. Following a model used in rheumatology, the group assessed the prosthodontic literature, with an emphasis on implant-based therapies, for outcomes related to longevity and functional, psychologic, and economic domains. These systematic reviews highlight a need for further development of standardized outcomes that can be integrated across clinical and research environments. *Int J Prosthodont* 2013;26:319–322. doi: 10.11607/ijp.3400

**M**anagement of tooth loss has grown in scope over the past three decades due to the demonstrated predictability of dental implants. Fixed and removable prostheses, with and without the use of implants, are options available to patients seeking tooth replacement. Conscientious clinicians using a shared decision-making<sup>1</sup> approach of informing patients as

to the different options available to them are faced with a challenge. Evidence to support the various options for managing tooth loss are hampered by a lack of consistently applied outcomes,<sup>2,3</sup> a dilemma that largely stems from a lack of standardized outcomes in prosthodontics.<sup>4</sup> This situation is common to other health care providers.<sup>5,6</sup>

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For meaningful use in shared decision-making for prosthodontic patients, clinical outcome evidence requires inclusion of the patient's perspective of the care provided, as well as evidence that spans a period of time that has significance relative to care expectations.<sup>7</sup> Given that tooth loss is a permanent condition for an anatomical entity with a lifetime longevity potential, the expectation of replacements providing adequate performance for an extended period of time is understandable. In this context, tooth loss is similar to other chronic conditions, such as diabetes, and requires long-term management<sup>8</sup> of the time-dependent events that are often unique to the selected prosthetic management option.<sup>9</sup>

These factors suggest that the evidence challenge is characterized by a need for consistently applied standardized outcome measures of the impact of prosthodontic care, measures that reflect meaningful outcomes from a patient's perspective, and measures that are monitored over time to capture time-dependent differences that are of value to shared decision-making needs.

### What is ORONet?

The evidence challenge was recognized by a group of prosthodontic clinicians and educators in the mid-1990s who began discussing how best to address this problem. The group was aware of precedent work in the field of rheumatology, which faced the same challenges and in 1992 sought to develop standardized outcomes.<sup>5</sup> Given the challenges of health care procedural research, it was also realized that the best use of standardized outcomes will occur if they can be applied in clinical practice and trial settings.<sup>10,11</sup>

The Oral Rehabilitation Outcomes Network (ORONet) was formed with a goal of pursuing methods for improving patient health through broader understanding of patient-centered outcomes in prosthodontics. Since initial discussions in 1996, ORONet has met for six workshops (La Bretesche, France, 2008; Paris, France, 2009; Rochester, Minnesota, 2010; Banff, Alberta, Canada, 2010; Chicago, Illinois, 2011; and Rochester, Minnesota, 2012) to refine our understanding of concepts and methods of outcomes standardization, to identify similar precedent activity in medicine to consider as a model, and to identify previous outcomes common to prosthodontics.

### What Does ORONet Hope to Accomplish?

The immediate goal is to work for consensus on a set of standardized outcomes, a goal addressed by other fields in health care.<sup>12</sup> The benefit of having a set of

standardized outcomes is an enhancement of the knowledge base for prosthodontics through creating opportunity for pooling data from various sources. Prosthodontic research is too often limited in scope (ie, number of clinically important outcomes) and length of follow-up. The scope limitation is hampered by funding and research constraints common among "procedural" disciplines such as surgery and prosthodontics.<sup>10</sup> When clinical trials are accomplished, there often are concerns as to generalizability, the use of a variety of discordant (surrogate) outcomes, and short-term outcome applicability or meaningfulness.<sup>13</sup> What is needed are complementary methods for systematic observation, ie, research, in prosthodontics in the context of both clinical trials and clinical practice,<sup>14</sup> and a major limitation is a lack of accepted, standardized prosthodontic rehabilitation outcomes that have tangible value to patients.

### What Does Outcomes Research Mean?

Outcomes research has meant various things to different groups over the past few decades. Lee et al<sup>15</sup> provided an historical perspective of the reasons behind the variety of definitions and summarized the current understanding of outcomes research as being fundamentally concerned with improving the practice of medicine as applied to patients treated outside clinical trials. Specific to the field of prosthodontics, outcomes are the consequences of management decisions for missing and defective teeth. These management decisions are made at the individual patient level, involve multiple factors of importance to the patient, and are based on the clinical findings of the clinician. A fundamental principle involved in the patient-provider interaction is that the patient elects to pursue care for reasons that are self-defined. Therefore, all factors important to a management decision must have value to the individual electing the intervention.<sup>4</sup> Consequently, pertinent outcomes should be identified as consistent with patient expectations, helpful to providers in quality assurance monitoring relative to meeting treatment targets, and providing data for summary and sharing with patients who are considering care.

### Why is This Important?

An effort to standardize outcomes has many benefits. It provides the opportunity to synthesize clinical care results from multiple sources to gain more precise data with a better chance for generalizability. It creates the opportunity to establish a core set of outcomes believed to best represent the important

**Table 1** OMERACT Outcomes Filter

Truth	Represents validity and requires demonstration that the outcome measures what it intends to measure. Valid outcomes for an intervention study include both benefit and toxicity.
Discrimination	Captures reliability and sensitivity to change features of an outcome. It represents the ability to demonstrate statistical significance for a minimal clinically important difference within the designated sample size.
Feasibility	The measure has to be usable and must work within the practical constraints of a study or clinical practice.

OMERACT = an international initiative to improve outcome measurement in rheumatology.

results of care that should be monitored (including favorable and unfavorable events). It allows for the opportunity to distinguish outcomes that are consistent with patient expectations and is critical for elective pursuits in health care.

The establishment of outcomes useful to both clinical trial and clinical practice sources would enhance evidence applicability for patient care—the intended application for all health care research pursuits. Such collaboration addresses the current tension between evidence-based directives that seek the rigorous randomized controlled trial as the means to best evidence and the practice-based evidence assertion that clinical trials lack generalizability, miss important outcome observations due to short-term follow-up, and do not translate into practice settings.<sup>13,16,17</sup> It is important to establish consistent measures of the impact of what is done in health care so that, regardless of what type of design may be chosen,<sup>18</sup> synthesis of all efforts can be accomplished to the benefit of the intended patient.<sup>19</sup>

Complementary roles for clinical trial-based evidence (used for systematic reviews) and practice-based evidence are facilitated by the recognition that standardized outcome measurement is crucial. With this in mind, the greatest benefit is derived if all research efforts include at a minimum a core set of standardized outcomes, and that both evidence sources have limitations that require attention moving forward.<sup>20–22</sup>

### What is ORONet Trying to Accomplish?

The process involves seeking to better understand patient outcomes in the practice of prosthodontics through collaboration among the international prosthodontic community, standardizing clinical outcomes applicable for long-term clinical research or practice, and, eventually, being positioned to provide multicenter collaborative long-term clinical practice

outcome data complementary to ongoing evidence-based efforts. Such broad use of standardized health care assessments allows practice-based evidence to complement ongoing clinical trial efforts. The outcome emphasis on feasibility directly impacts the ability to have longitudinal, practice-based efforts involved: a focus directly responding to a recent governmental stimulus program designed “to encourage the development and use of clinical registries, clinical data networks, and other forms of electronic data to generate outcomes data.”<sup>23</sup>

The group is dedicated to a unified mission of improving patient health through development and application of comprehensive evaluations of the effectiveness of therapies for oral rehabilitation. Central to the work of ORONet is the development of outcomes measures that are clinically relevant and patient-centered, are practical to apply, can be used for monitoring individual practices, and are applicable to development and execution of clinical trials.<sup>24</sup> An initial step of outcome development involves identifying outcomes from various domains that have been used in prosthodontics and evaluating their suitability for use in both clinical practice and trial applications.

### What This Article Series Provides

Following the model from rheumatology, this initial effort is a collection of systematic reviews of outcomes used in prosthodontics (under the domain headings of longevity, functional, psychologic, and economic). The approach for review is unique in that the goal was not to compare outcomes among themselves but to identify all outcomes used in the respective domains. Following a delineation of outcomes, each was judged against an outcome “filter” to identify whether it was “endorsed” for use.<sup>5</sup> A measure is endorsed when it meets the three component criteria of truth, discrimination, and feasibility in its intended setting (Table 1).

The greatest challenge in summarizing the collective outcomes was realized when assessing their feasibility for use in both clinical practice and trial settings. The lack of demonstrated use of outcomes in practice-based applications was clearly evident and precluded being able to identify outcomes ready, in their current state, for use in both settings. This does not suggest current outcomes are not useful, as many are more than adequate when applied in settings appropriate for their use. It does suggest that for collective synthesis of evidence from all sources (explanatory and pragmatic trials<sup>18</sup> or practice-based and trial-based<sup>13</sup>) meaningful measures require a new mindset.<sup>19</sup>

## Conclusion

The general finding from this collective systematic review of relevant outcome domains pertaining to prosthodontic care is that significant work is required to establish a core set of outcomes. Efforts should be directed toward developing patient-based outcomes for functional and psychologic impacts of care (as represented by patient-related outcome work in medicine), longevity measures that have value to patients and can be collected as part of routine care, and economic outcomes critical to delineating care value.<sup>25</sup>

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