Clinical Outcomes Measures for Assessment of Longevity in the Dental Implant Literature: ORONet Approach

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The Oral Rehabilitation Outcomes Network (ORONet) Longevity Working Group undertook a search of the literature from 1995 to 2009 on randomized controlled trials related to longevity of osseointegrated implants. Outcomes measures used in these studies were identified and subjected to the OMERACT component criteria of truth, validity, and feasibility. Through this process, it was a challenge to identify clinical outcomes measures that fully met the criteria. An attenuated version of the component criteria was applied, and clinical measures were identified for implant outcomes, prosthetic outcomes, and indices. A recommendation on standardized reporting periods was also presented for future consideration. The endpoint of the evaluation process is to develop consensus on clinical outcomes measures that can be applied across broad populations for osseointegrated implant care. The present ORONet initiative represents a beginning toward continual improvement and consensus development for clinical outcomes measures for osseointegrated implants. *Int J Prosthodontics 2013;26:323–330. doi: 10.11607/ijp.3402*

The longevity of device performance has been a central theme of research reported in the osseointegrated implant literature. Early reports documented the need for scientific scrutiny of success with osseointegrated implants and long-term follow-up for reporting of outcomes.[1] This approach was a remarkable departure from the previous history of dental implants, which involved anecdotal clinical reporting. The early literature also made an important contribution in that it required that success criteria be applied to clinical studies considering the outcomes of osseointegrated implants. This work led Albrektsson et al[2] to provide a formulation of success criteria to be applied to clinical outcomes of osseointegrated implants. These outcome criteria considered immobility, peri-implant radiolucency, vertical

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bone loss, absence of persistent and/or irreversible signs, and a success rate at 5- and 10-year periods.[3]

These early studies also ushered in the understanding of survival versus success of implants and appeared to be largely focused on bone response. With establishment of the predictability of osseointegrated implants, later studies began to focus on the soft tissue response and on aspects of prosthesis performance. This was heightened further with particular interest in esthetic consideration and loading protocols. Outcomes measures for esthetic outcomes were proposed.[4]

The literature is replete with papers on outcomes with osseointegrated implants. Reports of investigations on the longevity of dental implants and prostheses exhibit a wide variety of outcomes measures. This creates a significant challenge to summarizing effects across studies when there is such a diversity of outcomes measures. Additionally, there is a lack of clarity as to which longevity outcomes have tangible impact to the patient receiving care and therefore should be emphasized as meaningful to provider–patient decision-making. A further challenge is the confusion between prognostic measures, those that pertain to or predict a future event or condition, versus outcomes measures, the future event or condition. The combined result of these challenges is that there is no consensus regarding an accepted inventory of longevity outcomes measures that have been subjected to scrutiny to determine whether the measures are valid, possess discrimination, and are feasible in application.

The present paper provides the findings of the Oral Rehabilitation Outcomes Network (ORONet) Longevity Working Group for osseointegrated implants. The intent of ORONet is to apply the rigor used by OMERACT[5,6] to establish consensus on clinical outcomes measures that may be applied across broad populations for osseointegrated implant care.

Materials and Methods

The Longevity Working Group was provided with written instructions for the protocol as well as a number of spreadsheets and tables for data entry to be submitted to the Working Group Leader. Following receipt of the initial list of references to survey (see Search Strategy), each member reviewed a set of abstracts and determined those that were of interest in identifying longevity outcomes measures. These were retrieved in article form and reviewed in detail for clinical outcomes measures of interest. The identified clinical outcomes measures were entered into categories of outcomes measures (success, time to retreatment, biologic, mechanical, soft tissue complications, and bone loss) and subjected to judgment according to the OMERACT component criteria. This process linked categorization of the identified clinical outcomes measures to OMERACT component criteria.

The results of each reviewer were consolidated, and a summary was produced for presentation to the entire ORONet group at a general meeting. Each finding was discussed until consensus was reached on acceptance or rejection of the clinical outcomes measure.

Search Strategy

To develop the list of references to be scrutinized by the Longevity Working Group, the strategy adopted was to survey randomized controlled trials related to longevity of osseointegrated implants. The rationale was that attempting to identify high strength of evidence studies would likely yield clinical outcomes measures that were applied with some degree of rigor. The assistance of two librarians (one in Finland and one in Canada) was obtained to develop the literature search strategy. The search included literature from 1995 to 2009 using the Medline database. The literature search strategy is provided in Appendix A

Results

Literature Assessed

The literature search yielded 266 papers. Three papers were considered inappropriate and were excluded, leaving 263 suitable for inclusion. These were divided into roughly equal groups and provided to the five members of the Longevity Working Group as abstracts. The abstracts were reviewed for relevance and 64 were found not to be applicable. The full papers for the remaining 199 abstracts were reviewed in detail and 181 papers were found to contribute to identification of clinical outcomes measures (Table 1). While the search strategy sought to include only randomized controlled trials, a number of papers were of lower level in the hierarchy of strength of evidence. Nonetheless, where papers were considered to be of value, they were included.

General Findings

In reviewing the 181 papers meeting the study criteria, it was found that clinical outcome measures for longevity of osseointegrated implants could be placed into three categories of measurement type: direct measures, surrogate measures, and combined success measures.

Table 1 Literature reviewed by the Longevity Working Group

	Reviewer					
Item	1	2	3	4	5	
Period reviewed	1995–1997 2001–2003	1997–2000	2003–2006	2006–2008	2008–2009	Total
No. of abstracts reviewed	55	53	51	54	50	263
No. of abstracts found relevant	34	52	38	42	33	199
No. of papers reviewed	31	40	36	41	33	181

Direct measures evaluate conditions that are directly attributable to that clinical measure. An example of a direct measure would be radiographic evaluation of bone height, representing bone resorption/deposition around an implant. Surrogate measures evaluate conditions that are indirect measures of clinical conditions. An example of a surrogate measure is implant stability as a measure of the health of the bone–implant interface. Criteria for combined success measures are those aggregations of clinical outcomes measures that are used collectively to describe treatment outcomes.

In addition, seven broad classifications of measurements could be identified: periodontal parameters, bone height, implant stability, sensory change, complications, success/failure indices, and perceptual measures.

Periodontal Measures

Over 10 periodontal parameters were identified. In these approaches, nine designs of periodontal probes were advocated. These measures were used on two, four, or six surfaces with scales that were dichotomous or multilevel assessments. In considering the periodontal parameters, numerous measures were identified but seldom appeared to be used as treatment outcome parameters. As recognized previously by Naert et al,[7] periodontal parameters primarily appeared to be included for prognostic purposes and not as clinical outcomes measures.

Bone Height Measures

Radiographic evaluation with intraoral as well as panoramic radiographs was the most commonly reported method for assessment of bone height. It appeared that radiographic evaluation of bone height was the most widely accepted clinical outcome measure when evaluating implants. However, it was found that no standard method had found wide acceptance for intraoral radiographic outcomes measures. Nonstandardized long-cone, paralleling, and custom positioner devices were all used in various radiographic studies. Panoramic radiographs have been used but may not present a high level of resolution. Measurement of bone height on analog radiographs also employed a wide range of approaches, including naked eye, ×2 to ×7 magnification lenses, graticules, rulers, analog calipers, and digital calipers. Digital radiographic measurement systems were also used with increasing frequency; however, the image and measurement calibrations were not always detailed. While radiographic evaluation of bone height was a widely accepted clinical outcomes measure, there appeared to be no common and accepted protocol for standardizing and measuring the images.

Implant Stability

Implant stability was commonly evaluated through bimanual manipulation and by use of instrumentation. The bimanual manipulation approaches used included dichotomous scales (yes/no) and multilevel scales (Miller and Tetsch indices). Instrumental measurement included use of the Periotest and Ostell devices. The literature reviewed showed increasing interest in attempting to correlate Periotest values and Implant Stability Quotients to biologic and clinical parameters. It appeared that this may represent an uncertainty about the validity of these measures and consequently a search for clinical outcomes relevance of these implant stability measures as surrogate measures of interface integrity.

Sensory Measures

Sensory change was, it appeared, reported with less frequency than other measures as a qualitative clinical outcomes measure. Typically, sensory change is rated as anesthesia, paresthesia, and neuropathy. The reporting of sensory change was based on clinical evaluation and was not typically reported objectively with quantitative methods.

Table 2 Clinical outcomes measures

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
Implant loss	Yes	Yes	Yes
Implant stability (manual)	Yes	Yes	Yes
Implant stability (digital)	?	?	?
Periodontal parameters	?	?	Yes
Radiographic evaluation	?	Yes	Yes

Table 3 Image-production methods for outcome–bone loss

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
IO nonstandardized	No	No	Yes
IO long cone/paralleled with/ without custom device	Yes	Yes	Yes
Panoramic image	No	No	Yes
Panoramic image with Groningen evaluation system (Meijer et al[8])	Yes	Yes	Yes
CBCT	?	?	No

CBCT = cone beam computed tomography.

Complications

In general terms, complications were found to be poorly reported. Complications could be classified as hard tissue, soft tissue, or component based. There appeared to be a diverse range of examiner-generated assessment of complications and it was considered surprising that there was no commonly accepted means of cataloging complications. Complications were thought to be an important clinical outcomes measures but were not found to be well accounted for in the literature.

A few studies in the literature considered time to retreatment as a clinical outcomes measure. On reflection, ORONet considered this to be a valuable outcomes measure, but it was seldom addressed in the literature.

Success/Failure Indices

Indices represent a more common approach to clinical outcomes measures encountered in the literature. Indices are not discrete clinical outcomes measures but are an analysis of aggregated or cumulative clinical outcomes or other measures. In the use of indices, researchers aggregate a number of measures that were used to assess the clinical outcome of an osseointegrated implant or a treatment approach. Indices were identified as being diagnostic or treatment outcomes based. Examples of those considered treatment outcomes based were: life table plus cumulative success rate, 4-field table, 6-field table, Misch implant quality scale, success criteria, ICOI Pisa implant quality of health, and clinical implant performance scale.

From the wide variety of indices encountered in the literature, it appeared that there was no widely adopted consensus on rating of success of clinical outcomes of implant care. One aggregate measure, the Clinical Implant Performance Scale, was found to be of particular value (Meijer et al[8]). This index made use of outcomes measures that were thought to be more closely aligned to OMERACT component criteria.

Perceptual Measures

Perceptual measures were either clinician or patient driven and consisted primarily of a wide variety of unique examiner-created questionnaires. Often, the content of the instruments were not specified and frequently appeared to be clinician administered. Where perceptual measures were assessed, validated questionnaires seldom appeared to be used.

Table 4 Image-assessment methods for outcome–bone loss

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
Naked eye	No	No	Yes
Magnifying lens (×2–×7) with graticule or caliper (analog/digital)	?	Yes	Yes
Digital magnification with calibration	?	Yes	Yes

Table 5 Methods of evaluating prosthetic care for clincial outcomes measurement

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
Prosthesis survival	Yes	Yes	Yes
Prosthesis success (patient report: dichotomous)	Yes	Yes	Yes
Prosthesis success (patient report: graduated)	?	?	Yes
Esthetic outcome (clinician report)	?	?	Yes
Esthetic outome (patient report)	?	?	Yes

Properties Important for Clinical and Research Use—OMERACT Filter

In the application of the OMERACT process to the dental implant literature, a great challenge was encountered. If the OMERACT filter criteria of truth, validity, and feasibility were rigidly applied to the dental implant literature, then few of the clinical outcomes measures would pass the process as the measure might only satisfy one or two of the criteria. Where clinical outcomes criteria did meet the OMERACT filter, they were included. As a result, until more reliable clinical outcomes measures are developed or agreed upon, attenuated OMERACT component criteria were applied to longevity measures (Tables 2 to 8). The attenuated clinical outcomes measure was included if the measure was:

- thought to have certainty to measure what it is stated to measure (provide self-evident method in recording the measure)
- able to have a high possibility of providing discrimination (limit levels of measurement to a minimum to prevent confusion in level selection)
- feasible in an average clinical practice environment (be readily applicable across clinicians and clinical sites)

In cases where only two of the three component criteria could be applied, consensus of the entire ORONet group was sought to include the measure as an attenuated measure or reject the outcomes measure. Where the clinical outcomes measure was accepted as an attenuated measure, feasibility had to be an accepted criterion. So that studies can be applied over broad populations, in applying the above measures to clinical outcomes studies, it is important that study measures be non-narrative in form.

The intent of this first attempt of application of the OMERACT process to the clinical outcomes for osseointegrated implant longevity was not to develop the ne plus ultra inventory of clinical outcomes measures. Rather, the intent was to identify a point of initiation of OMERACT-based clinical outcomes measures that met the OMERACT criteria. The outcomes of the process of applying the OMERACT filter criteria was revealing in that it provided a remarkably short list of clinical outcomes measures. Through this process, the following clinical outcomes were identified.

Implant Outcomes Measures

- Implant loss through clinician report: dichotomous (present/absent)

Table 6 Methods of Evaluating Complications for Clinical Outcomes Measurement

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
Implant-related inventory	Yes	Yes	Yes
Abutment-related inventory	Yes	Yes	Yes
Prosthesis-related inventory	Yes	Yes	Yes
Function	?	?	?
Esthetic (clinician or patient reported)	?	?	?

Table 7 Methods of Evaluating Time to Retreatment for Clinical Outcomes Measurement

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
Groningen (Meijer et al[8])	Yes	Yes	Yes

Table 8 Indices for Evaluating Clinical Outcomes

	Truth (valid?)	Discrimination (reliable and sensitive to change?)	Feasibility (easily applied?)
Modified 4-field table	Yes	Yes	Yes
Life table	Yes	Yes	Yes
Cumulative success rate	Yes	Yes	Yes
Clinical implant performance scale	Yes	Yes	Yes

- Implant stability through bimanual palpation (clinician report: dichotomous–mobile yes/no)
- Radiographic bone level measurement
  - Intraoral radiographic magnifying lens (×2–×7) with graticule or caliper (analog/digital). Details of approach to be specified (attenuated)
  - Panoramic image
- Assessment levels (after Meijer et al[8]): 0 = no apparent bone loss; 1 = bone loss ≤ ⅓ length of implant; 2 = bone loss > ⅓ but < ½ length of implant; 3 = bone loss ≥ ½ length of implant

Evaluation of radiographic bone levels with digital magnification may not be feasible in an average clinical practice environment and also not readily applicable across clinicians and clinical sites. However, since this technology is rapidly developing, it is acknowledged in the present Longevity Working Group report. The application of this technology to clinical outcomes measurement requires a full description of the technology as well as the calibration and measurement process.

Prosthetic Outcomes Measures

- Prosthesis survival (clinician report: dichotomous–yes/no)
- Prosthesis success (patient report: dichotomous–yes/no))
- Complications: number of incidents within defined time period (after Meijer et al[8])
  - broken abutment screws
  - broken prosthetic coping screws
  - repaired bar/superstructure
  - new bar/superstructure
  - new clips/adjustment of loose clips
  - relining of prosthesis
  - repair of prosthesis or denture teeth
  - adjustment of occlusion
  - new prosthesis
- Time to retreat: recorded in months

Additional Considerations

There were two areas related to outcomes measures that were also considered by the ORONet Longevity Working Group. The first was indices for evaluating clinical outcomes. It was considered that indices should not be confused with clinical outcomes measures as they are not discrete outcomes measures but rather represent an analysis of outcomes and possibly other measures. Commonly used indices were considered by subjecting them to the OMERACT filter. The result of this led the Longevity Working Group to identify the following indices that met all three OMERACT filter criteria.

- 3-field table (individual implant survival/loss/unaccounted)
- life table
- cumulative success rate
- clinical implant performance scale (after Meijer et al[8]): 0 = success, no complication; 1 = minor complication; 2 = complications with a chance of recovery or stabilization of the present situation; 3 = serious complication that may lead to failure of implant system; 4 = failure of implant system

The second consideration was the reporting period. Of interest to the Longevity Working Group was the fact that there appeared to be little or no consensus on standardized reporting periods for clinical longevity outcomes measures. While not part of the process applied to longevity outcomes measures, after due consideration, the Longevity Working Group proposed reporting of applicable clinical outcomes measures at the following stages of care:

- at time of implant placement
- functional loading (prosthesis connection)
- 1 year after loading
- 5-year intervals after functional loading

Conclusions

The reviewed literature revealed that there are a considerable number of outcomes measures applied to osseointegrated implant care. The OMERACT approach to acceptance of clinical outcomes measures is well established with Cochrane Collaboration and World Health Organization acceptance of the methodology. In the application of the OMERACT rigor to longevity clinical outcomes measures for osseointegrated implant care, it was found that few measures met acceptance. The OMERACT process was modified to provide for at least two of the three OMERACT filter criteria, with feasibility being one of the two criteria. This modification provided for identification of several other potential outcomes measures. With the ORONet approach to using the OMERACT filter criteria, specific clinical outcomes measures were identified for implant loss, implant stability, radiographic bone level management, prosthesis survival, prosthesis success, complications, and time to retreatment. A recommendation on implant outcomes indices and standardized reporting periods was also provided for future consideration. The Longevity Working Group considered the findings to be of concern as few clinical outcomes measures fully met the OMERACT filter criteria. Clearly, the present ORONet Longevity Working Group initiative represents a beginning toward continual improvement and consensus development for longevity clinical outcomes measures for osseointegrated implants.

Acknowledgment

The authors reported no conflicts of interest related to this study.

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Appendix: Literature Search Strategy

exp Dental Implants/ae [Adverse Effects] (1132)	1. exp Dental Implants/ae [Adverse Effects] (1132)
exp Dental Implantation/ae [Adverse Effects] (1099)	2. exp Dental Implantation/ae [Adverse Effects] (1099)
exp Dental Implants/ (10990)	3. exp Dental Implants/ (10990)
exp Dental Implantation (13773)	4. exp Dental Implantation/ (13773)
1 or 2 or 3 or 4 (19029)	5. 1 or 2 or 3 or 4 (19029)
exp Treatment Outcome/ (432460)	6. exp Treatment Outcome/ (432460)
5 and 6 (1699)	7. 5 and 6 (1699)
limit 7 to (abstracts and English language and humans and yr="1995-2009" (1331)	8. limit 7 to (abstracts and English language and humans and yr="1995 - 2009") (1331)
limit 8 to randomized controlled trial (145)	9. limit 8 to randomized controlled trial (145)
3 or 4 (19029)	10. 3 or 4 (19029)
Exp Reoperation/ (54371)	11. exp Reoperation/ (53471)
Exp Bone Restoration/ (26320)	12. exp Bone Resorption/ (26320)
13. exp Morbidity/ (272757)	13. exp Morbidity/ (272757)
Exp Retreatment/ (3866)	14. exp Retreatment/ (3866)
Exp Dental Restoration Failure/ (4064)	15. exp Dental Restoration Failure/ (4064)
Implant Loss$.mp. (204)	16. implant loss$.mp. (204)
Implant Failure$.mp. (1505)	17. implant failure$.mp. (1505)
11 or 12 or 13 or 14 or 15 or 16 or 17 (357909)	18. 11 or 12 or 13 or 14 or 15 or 16 or 17 (357909)
10 and 18 (414)	19. 10 and 18 (4141)
Limit 19 to (abstracts and English language and humans and yr="1995 -2009") (2761)	20. limit 19 to (abstracts and English language and humans and yr="1995 - 2009") (2761)
Limit 20 to randomized controlled trial (223)	21. limit 20 to randomized controlled trial (223)
9 or 21 (266)	22. 9 or 21 (266)
23. From 22 keep 1-100 (199)	23. from 22 keep 200-266 (67)

Literature Abstract

Predictors for tumor recurrence after primary definitive surgery for oral cancer

Information on the clinical and pathologic characteristics of oral cancer recurrence is inconsistent and insufficient. The purpose of this study was to identify significant predictors that may favor oral squamous cell carcinoma relapse after successful surgical treatment. This retrospective cohort study was performed in consecutive metastasis-free patients treated for oral squamous cell carcinoma. Variables included sex, age, tumor site, macroscopic pattern of the lesion, coexisting disorders (diabetes, hepatic and cardiac disorders, other tumors or diseases), degree of differentiation, and pathologic TNM (tumor, node, metastasis) stage. Tumor recurrence was considered the dependent variable (outcome). Tumor recurrence was 44.9% among 118 patients during the follow-up period (10% local, 29.7% regional, and 5% distant). The mean period that had elapsed prior to recurrence was 15 months (1.5 to 81.8), with most recurrences (66%) during the first year after treatment (84.9% before 2 years). Multivariate Cox regression analysis demonstrated the presence of a coexisting disorder (P = .02) as the most relevant prognostic factor for relapse when patients with associated diseases had a 2.44-fold risk of recurrence. Tumor stage IV (P = .04), poorly differentiated cell carcinoma (P = .02), and ulcerated macroscopic patterns of the lesion (P = .02) were significant prognostic factors for tumor relapse. The authors concluded that the risk profile for oral cancer recurrence included patients younger than 60 years who were diagnosed at an advanced stage with a poorly differentiated tumor with coexisting diseases and whose primary tumor presented as an ulcerated lesion.

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