

## Commentary

# Enhancing Periodontal Health Through Regenerative Approaches: A Commentary on the Need for Patient-Reported Outcomes

Marita R. Inglehart\*†

*Starting in the 1970s, social scientists have discussed the importance of assessing subjective indicators of well-being and quality of life. Medical researchers followed this line of reasoning since the 1990s, emphasizing the significance of understanding how disease and its treatment affect patients' quality of life. Since the start of the 21<sup>st</sup> century, oral health-related quality of life (OHRQoL) received increasingly more attention. While research concerning the effects of periodontal disease and its surgical and non-surgical treatment on patients' lives has been considered in numerous studies, research including patient-reported outcomes when assessing how periodontal health can be enhanced through regenerative approaches is largely missing. This commentary proposes to consider 1) OHRQoL and 2) patients' treatment satisfaction as patient-reported outcomes in conjunction with objectively measured patient-centered factors, and discusses the value of such an approach. J Periodontol 2015;86(Suppl.): S4-S7.*

### KEY WORDS

**Pain; personal satisfaction; practice management; quality of life; regeneration.**

Starting in the 1970s, researchers in the social sciences began to discuss the value of not only considering the quality of life of societies and countries, but to also assessing subjective indicators of well-being and quality of life by surveying individual respondents.<sup>1,2</sup> Medical researchers and clinicians followed this line of reasoning since the 1990s when they began to stress the significance of understanding how disease and its treatment affect patients' quality of life and in return patients' decisions to accept or refuse treatment recommendations.<sup>3-5</sup> This paradigm shift from analyzing objective treatment outcomes alone to additionally also considering

subjective patient-reported indicators became crucial when oncologists encountered patients whose decision to accept or reject a treatment was not merely based on the predicted length of survival, but instead also on considerations of the quality of their life during their final months or years.<sup>6</sup>

Since the start of the 21<sup>st</sup> century, oral health-related quality of life and patient-reported outcomes received increasingly more explicit attention.<sup>7</sup> A recent Ovid Medline literature search with the key words "quality of life" and "caries" resulted for example in 348 references and a search with "quality of life" and "periodontal disease" in 379 results. These numbers are impressive and show that dental researchers began to realize that patient-reported outcomes and esp. oral health-related quality of life (OHRQoL) are crucial components of understanding the effects of oral disease and treatment. The wide variety of research including oral health-related quality of life measures is also remarkable. Clinical research on the outcomes of all kinds of therapeutic interventions addresses such diverse topics as for example, the effects of full mouth rehabilitation of children with early childhood caries on their quality of life,<sup>8,9</sup> the effects of periodontal disease on adult patients' smiling patterns and quality of life,<sup>10</sup> or the effects of radiation therapy on adult cancer patients' xerostomia-related quality of life.<sup>11</sup> In addition, to these clinical and behavioral studies, Martha Somerman already discussed in 2002 that research on the regeneration of orocraniofacial tissues needs to consider subjective, patient-reported outcome factors when designing therapies aimed at improving the outcomes of new treatments that are based on these research findings.<sup>12</sup> This commentary first considers to which degree and how Martha Somerman's considerations were followed in research concerning the effects of regenerative approaches used to enhance patients' periodontal health, and then discusses how to include assessments of patients' OHRQoL and treatment satisfaction as patient-reported outcomes in conjunction

\* Professor of Dentistry & Adjunct Professor of Psychology, Department of Periodontics and Oral Medicine, School of Dentistry, University of Michigan, Ann Arbor, MI.

† Department of Psychology, College of Literature, Science & Arts, University of Michigan.

with objectively measured patient-centered factors in future studies.

### ***Enhancing Periodontal Health Through Regenerative Approaches: How Have Patient-Reported Outcomes Been Considered?***

A literature search on Ovid Medline with the key words “quality of life” and “Guided tissue regeneration, periodontal” resulted in one reference.<sup>13</sup> This 1998 review article however did not present any substantive outcome related findings related to patients’ quality of life. A second Ovid Medline search with the term “quality of life” and the key word “soft tissue root coverage” resulted in one reference.<sup>14</sup> This very recently published research did actually include a genuine oral health-related quality of life measure, the Oral Health Impact Profile – 14 (OHIP-14),<sup>15</sup> to assess patients’ quality of life after surgery for gingival recession. The results showed quality of life changes from baseline to a three month post treatment appointment and also pointed out that the OHIP-disability sub score was correlated with the amount of keratinized tissue and defect coverage. However, additional literature searches with the combination of the key word “quality of life” and either “furcation defects” or “regeneration of intrabony defects” did not result in any references.

While the key word “quality of life” did not receive much attention at all, a search with the key word “pain” resulted in significantly more references. Periodontists are clearly aware that pain is an outcome that deserves attention. Quite a number of researchers asked their patients to indicate their level of pain at different points in time after different types of periodontal surgery,<sup>16-20</sup> or they focused on the degree to which patients reported dentin hypersensitivity after certain procedures.<sup>14,19-21</sup>

While pain is one of the four components of patients’ OHRQoL,<sup>22</sup> the other three aspects, namely how a patients’ oral health affects their: 1) ability to function (e.g., chew, bite, speak), 2) psychological well-being, and 3) social well-being, have largely been neglected.<sup>23</sup> Instead, treatment satisfaction as an additional patient-reported outcome received some attention in studies of the effects of regenerative approaches patients’ periodontal health.<sup>20,24,25</sup>

However, overall it seems justified to conclude that patient-reported outcomes have been largely neglected in this research area. McGuire and colleagues’ recent publication<sup>26</sup> in the October 2014 issue of the *Journal of Periodontology* is therefore a welcome change because it did not only present an example of such an approach, but it also urged its readers to explicitly include patient-reported outcomes in periodontal clinical trials. The questions now are: 1) what the benefits are of considering these factors, and 2) how can clinicians and clinical researchers concretely achieve this objective?

### ***Inclusion of Patient-Reported Outcomes When Providing Regenerative Treatment: Why and How?***

Considerations of the reasons for including patient-reported factors when enhancing periodontal health through regenerative approaches can first focus on clinicians and their daily interactions with their patients, and then on researchers who conduct clinical trials to show the outcomes of these approaches. For clinicians, patient-reported factors are of crucial importance from the moment they make a diagnosis and a treatment recommendation to the long-term follow up of the treatment outcomes. Patel and colleagues<sup>27</sup> could for example show that patients’ anxiety levels and even more importantly: their relationship with their periodontist strongly affected whether they cooperated with their periodontist’s treatment recommendation to have periodontal surgery or declined this type of treatment. These findings clearly showed that gaining an understanding of patient-reported factors can make a difference in a practice, esp. in times when patients consider alternative treatments such as implants. In addition, while research found that providers were often unaware of the level of pain certain treatments cause and which pain management strategies their patients might utilize, including pain management strategies explicitly into the treatment plan can support a positive periodontist-patient relationship that might result in long-term treatment satisfaction. Understanding how much pain patients are likely to experience after different procedures and which factors might affect wound healing and pain experiences is therefore crucial. Finally, long-term patient-reported outcomes should definitely include patients’ satisfaction with the treatment.

Considerations concerning why researchers should include patient-reported factors in clinical trials that assess the effects of regenerative approaches can take all of these above described reasons into account. In addition, if researchers only consider clinical outcomes such as whether complete root coverage is achieved or whether the esthetic condition changed based on clinicians’ assessments, they lose contact with their patient’s reality. For example, their considered outcomes might be completely irrelevant for their patients’ considerations. An example of this fact is illustrated in Table 1. This table reports clinical variables assessed in chart reviews and survey responses from 705 adult patients. The question in this study was whether patients’ OHRQoL is equally affected by all types of oral health conditions. OHRQoL was measured with the OHIP-14<sup>15</sup> and a second scale, the Michigan Oral Health-related Quality of Life Scale (MOHRQoL).<sup>11</sup> Both measures correlated with the total number of missing teeth as well as the number of missing teeth in the esthetic zone. Patients are keenly aware of these two oral health issues and it affects their quality of life severely.

Patients' quality of life is also correlated with caries indicators such as the number of clinically determined decayed surfaces. However, the picture of the relationship among quality of life and periodontal health indicators is more complicated. Patients are aware of some periodontal health indicators such as teeth with mobility, recession in the esthetic zone, and bleeding on probing. The last indicator is likely to be known to them because they might find blood on their tooth brush or floss. These indicators are clearly correlated with their self-reported quality of life. However, there are other indicators of periodontal disease that patients might not be aware of such as the number of teeth with pockets of 4 mm or more and the number of teeth with furcation involvement, and Table 1 shows that these "silent" indicators do not correlate with patients' self-reported quality of life. Understanding which specific objectively assessed oral health parameters might affect patients' quality of life can therefore help clinicians to integrate patient-reported outcomes only when they are likely to reflect conditions of interest.

In consideration of the excellent points provided by McGuire and colleagues<sup>26</sup> and the reasons for inclusion of patient-reported outcomes provided above, the question arises how to best assess these outcomes. Concerning the concept of oral health-related quality of life outcomes in general, we suggest asking questions concerning the four components of patients' quality of life, namely how does a certain treatment affect a patient's 1) level of pain/discomfort and the use of pain medication or other means to manage pain, 2) functioning, e.g., how well he/she can eat/chew or whether the patient can speak clearly, 3) psychological well-being such as how esthetic they perceive the outcome to be, and 4) social well-being such as whether the treatment outcomes affect whether a patient avoids to eat or speak in front of others or socializes.<sup>21</sup> The MOHRQoL Scale<sup>29</sup> asks questions pertaining to all four issues and has the advantage that the reference point can be chosen by the researcher who uses the scale. For example when assessing the effects of xerostomia, the questions can be worded in reference to the dryness experienced,<sup>11</sup> while questions administered to patients' after periodontal surgery could inquire about the degree to which the patients' teeth and gums affect the different aspects of their quality of life.

Concerning the assessment of a patient's short and long-term treatment satisfaction, the use of the short and well validated Post-Surgical Patient Satisfaction Questionnaire (PSPSQ)<sup>30</sup> can be recommended. This 3-item scale was developed by Kiyak et al.<sup>30</sup> who suggested asking patients to use a 7-point answer scale (from 1 = not at all to 7 = very much) to indicate their responses to the questions: 1) "If you had to make the decision again, how likely would you be to have this

**Table 1.**

### Correlations Among Objective Oral Health Indicators and Patients' OHRQoL\*

Objective Oral Health Indicators	OHRQoL Scales	
	OHIP-14	MOHRQoL
Number of missing teeth	-.43 <sup>†</sup>	-.36 <sup>†</sup>
Number of untreated decayed teeth		
clinically determined	-.31 <sup>†</sup>	-.23 <sup>†</sup>
determined with x-rays	-.13 <sup>‡</sup>	-.10 <sup>‡</sup>
Number of decayed surfaces		
clinically determined	-.33 <sup>†</sup>	-.26 <sup>†</sup>
determined with x-rays	-.13 <sup>‡</sup>	-.12 <sup>‡</sup>
Number of abscesses	-.29 <sup>†</sup>	-.22 <sup>†</sup>
Percentage of bleeding points	-.15 <sup>‡</sup>	-.13 <sup>‡</sup>
Number of teeth with mobility	-.15 <sup>†</sup>	-.15 <sup>†</sup>
Number of furcation points	-.04	-.06
Pocket depth	-.07	.09 <sup>§</sup>
Dentin hypersensitivity: Yes	-.23 <sup>†</sup>	-.20 <sup>†</sup>
Bruxism: Yes	-.14 <sup>‡</sup>	-.13 <sup>‡</sup>

\* This table was part of an oral presentation by Inglehart MR, Yeung WS, Bagramian RA & Temple H entitled "OHRQoL – A Differentiating Analysis" at the IADR/AADR Meeting in Seattle, Washington, March 22 to March 25, 2013.

<sup>†</sup>  $P < .001$ .

<sup>‡</sup>  $P < .01$ .

<sup>§</sup>  $P < .05$ .

surgery?"; 2) "Considering that this was an elective procedure, how likely would you now be to recommend this surgery to others?"; and 3) "Considering everything, how satisfied are you now with the results of the surgery?" These questions have immediate face validity, esp. for clinicians who are interested in these answers for practice management related reasons.

In summary, it seems fair to conclude that until now patient-reported outcomes have been largely neglected in clinical studies that analyze the effects of regenerative approaches on patients' oral health. However, there is no doubt that there is value to including these measures in clinical trials. The question is how such an inclusion could be optimally achieved. This commentary suggests assessing patients' OHRQoL with the four central components as well as treatment satisfaction as a starting point for including patient-reported outcomes.

### ACKNOWLEDGMENTS

The author's OHRQoL research was supported by NIH Grant #R01DE14887-01A2, Bethesda, Maryland, and three grants by Colgate-Palmolive, Piscataway, New Jersey. The author reports no financial interests, either



directly or indirectly, in the products mentioned in this publication. The 2014 Regeneration Workshop was hosted by the American Academy of Periodontology (AAP) and supported in part by the AAP Foundation, Geistlich Pharma North America, Colgate-Palmolive, and the Osteology Foundation.

## REFERENCES

- Campbell A. Subjective measures of well-being. *Am Psychol* 1976;31:117-124.
- Andrews FM, McKennell AC. Measures of self-reported well-being: Their affective, cognitive and other components. In: Andrews FM, McKennell AC, (Eds.). *Social Indicators Research*. Dordrecht, Holland: D. Reidel Publishing; 1980;8:127-155.
- Aaronson NK, Meyerowitz BE, Bard M, et al. Quality of life research in oncology. Past achievements and future priorities. *Cancer* 1991; 67(Suppl. 3):839-843.
- Osoba D. Lessons learned from measuring health-related quality of life in oncology. *J Clin Oncol* 1994;12:608-616.
- Schipper H. Quality of life: Principles of the clinical paradigm. *J Psychosoc Oncol* 1990;8:171-185.
- Cimprich B, Paterson AG. Health-related quality of life: Conceptual issues and research applications. In Inglehart MR & Bagramian RA (Eds.). *Oral health-related quality of life*. Chicago: Quintessence; 2002:47-54.
- Inglehart MR, Bagramian RA (Eds.). *Oral health-related quality of life*. Chicago, IL: Quintessence; 2002.
- Inglehart MR, Filstrup SL, Wandera A. Oral Health Related Quality of Life and Children. Chapter 8. Inglehart MR, Bagramian RA. (eds.) *Oral Health and Quality of Life*. Chicago, IL: Quintessence; 2002:79-88.
- Filstrup SL, Briskie D, da Fonseca M, Lawrence L, Wandera A, Inglehart MR. Early childhood caries and quality of life: Child and parent perspectives. *Pediatr Dent* 2003;25:431-440.
- Patel RR, Richards PS, Inglehart MR. Periodontal health, quality of life, and smiling patterns — An exploration. *J Periodontol* 2008;79:224-231.
- Henson BS, Inglehart MR, Eisbruch A, Ship JA. Preserved salivary output and xerostomia-related quality of life in head and neck cancer patients receiving parotid-sparing radiotherapy. *Oral Oncol* 2001;37:84-93.
- Somerman MJ. Quality of life and basic research in the oral health sciences. In Inglehart MR & Bagramian RA (Eds.). *Oral health-related quality of life*. Chicago: Quintessence; 2002:7-12.
- Ishikawa I, Arakawa S. Awareness of periodontal disease — The role of industry. *In Dent J* 1998; 48(Suppl. 3 ):261-267.
- de Oliveira DW, Marques DP, Aguiar-Cantuaria IC, Flecha OD, Goncalves PF. Effect of surgical defect coverage on cervical dentin hypersensitivity and quality of life. *J Periodontol* 2013;84:768-775.
- Slade GD. Derivation and validation of a short-form oral health impact profile. *Community Dent Oral Epidemiol* 1997;25:284-290.
- Klooster PW, Eber RM, Inglehart MR. Anxiety, stress, depression, and patients' responses to periodontal treatment: Periodontists' knowledge and professional behavior. *J Periodontol* 2007;78:64-71.
- Nickles K, Ratka-Krüger P, Neukrantz E, Raetzke P, Eickholz P. Ten-year results after connective tissue grafts and guided tissue regeneration for root coverage. *J Periodontol* 2010;81:827-836.
- Ribeiro FV, Nociti Júnior FH, Sallum EA, Sallum AW, Casati MZ. Use of enamel matrix protein derivative with minimally invasive surgical approach in intra-bony periodontal defects: Clinical and patient-centered outcomes. *Braz Dent J* 2010;21: 60-67.
- Wang HL, Modarressi M, Fu JH. Utilizing collagen membranes for guided tissue regeneration-based root coverage. *Periodontol* 2000 2012;59:140-157.
- Rosberg M, Eickholz P, Raetzke P, Ratka-Krüger P. Long-term results of root coverage with connective tissue in the envelope technique: A report of 20 cases. *Int J Periodontics Restorative Dent* 2008;28: 19-27.
- Agudio G, Nieri M, Rotundo R, Franceschi D, Cortellini P, Pini Prato GP. Periodontal conditions of sites treated with gingival-augmentation surgery compared to untreated contralateral homologous sites: a 10- to 27-year long-term study. *J Periodontol* 2009; 80:1399-1405.
- Inglehart MR, Bagramian RA. Oral health-related quality of life: An introduction. In Inglehart MR, Bagramian RA (Eds.). *Oral health-related quality of life*. Chicago, IL: Quintessence; 2002: 1-6.
- Ozcelik O, Haytac MC, Seydaoglu G. Immediate post-operative effects of different periodontal treatment modalities on oral health-related quality of life: A randomized clinical trial. *J Clin Periodontol* 2007;34:788-796.
- Nieri M, Pini Prato GP, Giani M, Magnani N, Pagliaro U, Rotundo R. Patient perceptions of buccal gingival recessions and requests for treatment. *J Clin Periodontol* 2013;40:707-712.
- McGuire MK, Scheyer ET, Nunn M. Evaluation of human recession defects treated with coronally advanced flaps and either enamel matrix derivative or connective tissue: Comparison of clinical parameters at 10 years. *J Periodontol* 2012;83:1353-1362.
- McGuire MK, Scheyer ET, Gwaltney C. Commentary: incorporating patient-reported outcomes in periodontal clinical trials. *J Periodontol* 2014;85:1313-1319.
- Patel AM, Richards PS, Wang HL, Inglehart MR. Surgical or non-surgical periodontal treatment: Factors affecting patient decision making. *J Periodontol* 2006; 77:678-683.
- Krukemeyer AM, Arruda AO, Inglehart MR. Pain and orthodontic treatment. *Angle Orthod* 2009;79:1175-1181.
- Inglehart MR, Yeung WS, Bagramian RA, Temple H. Oral Health and Quality of Life: A Differentiating Analysis. Oral presentation at the IADR/AADR meeting in Seattle, WA, March 22-25, 2013.
- Kiyak HA, Hohl T, West RA, McNeill RW. Psychologic changes in orthognathic surgery patients: A 24-month follow up. *J Oral Maxillofac Surg* 1984;42:506-512.

Correspondence: Dr. Marita R. Inglehart, Dept. of Periodontics and Oral Medicine, University of Michigan School of Dentistry, 1011 North University Avenue, Ann Arbor, MI. 48109-1078. Fax: (734) 763-5503; email: mri@umich.edu.

Submitted October 9, 2014; accepted for publication December 9, 2014.