In recent years, advancements in diagnostic, surgical, and restorative techniques have reached new levels. Products for osseous regeneration, advanced radiographic systems, innovative implant designs and better restorative materials have created many therapeutic and esthetic options for patients. The comprehensive implant treatment that is the beneficiary of these advances almost always transforms patients’ lives and improves their quality of life (QOL).

Despite the potential benefits these advances provide, many procedures have not had the luxury of long-term observation. This situation often places elements of the treatment plan in a trade-off between the benefits of the new approach and its risks, costs, lower predictability, and uncertain long-term outcomes. Without a good “handle” on the less certain factors, it is difficult to accurately describe what to expect and therefore hard to quantify outcomes for the patients’ consideration.

The inevitable key factor for patient decision making is the question of clinical significance. Is it worth it? patients want to know. Will the results of treatment be worth the expense, and will I get what I want from the recommended treatment?

In order to best answer these questions it is important to recognize the perspectives of the 2 major stakeholders: the patient and the clinician. Both want to be satisfied at the end of the active treatment phase. The patient wants to look and feel better in the absence of disease, and the clinician desires to satisfy the patient while at the same time ensuring that the patient is healthy.

THE PATIENT’S PERSPECTIVE

All patients seek improvement in their QOL when treatment is complete. QOL measures include physical, psychological, social, and physical functioning and perceived well-being. This is the same for any medical or dental intervention. Although no standard definition exists, it is clear that QOL measurements and indicators must improve from the start of treatment until its completion—from surgery to smile. It is within the context of QOL that patients formulate their unique ideas about clinically important changes as a result of treatment. This complex, hard-to-precisely-define conglomeration of ideas, feelings, and attitudes makes up the patient’s concept of what constitutes “clinically significant.”

From the patients’ perspective the primary outcomes that are clinically significant are those that are palpable, ie, easily observable. Looking better, chewing better, and talking better are typically what patients want when seeking implant treatment. It matters little to them how much bone is integrated to the implant surface (a measure of success from the clinician’s perspective). The greater the improvement, the more clinically significant the change is going to be. Covering half of an exposed implant with gingiva is good, but covering all of it is much better.

Defining clinically important differences from the patient’s perspective is largely based on the values of the individual patient. Importance is further defined by the outcomes that are deemed worthy of the patients’ resources. For example, some patients may be willing to expend great resources if there is a high probability of realizing the expectations portrayed by the clinician, while others may choose less costly treatments so that they can use their resources some other way.

THE CLINICIAN’S PERSPECTIVE

Theoretically, QOL is defined from a patient’s perspective. But often the clinician’s interpretation of the patient’s functional status and “what is best” is frequently used as a substitute for the patient’s own perspective. From the practitioner’s standpoint, the clinical significance of a procedure or the entire plan of treatment can be defined as the smallest improvement that leads the clinician to recommend a treatment or therapy to the patient in the first place. If it’s worth doing, it must have some clinical significance. It must provide a benefit that can be translated into some QOL factor valued by the patient, or the procedure would not have been recommended in the first place.

When implants are involved, clinicians tend to focus on the most observable aspects of treatment such as physical functioning, esthetics, and long-term survival and maintainability of the prosthesis. This occurs in part because these aspects are most similar to the traditional focus of oral health care. Determining the value the patient places on the functional status change is one of the most important assessments.
that can be made. Many clinicians tend to be uncertain about how to quantify the clinical significance of the functional improvements and therefore are hesitant to discuss it. The recommendation to add a regenerative surgical procedure to potentially increase the amount of support for the implant is an example. How often do we really know if an additional 2 mm of bone attachment is clinically valuable and worth the extra cost of a regenerative surgical procedure to the patient?

DETERMINING THE MAGNITUDE OF A CLINICALLY IMPORTANT DIFFERENCE

The patient should be asked which QOL items are most important, and these should then be targeted for more in-depth discussion and assessment. A quantifiable change in QOL can be targeted if it can be described by the patient. However, there are situations in which a patient may not be able to evaluate QOL or to provide an accurate rating of clinically significant change, such as when distracted by anxiety or pain. Cognitive impairment may hinder the ability of older implant patients to provide accurate information about what is important to them and what they feel. Visual aids, such as “before” and “after” photos or videos are very helpful to start the discussion. Dentists have traditionally been successful using these to help patients clarify what is important to them.

Many clinicians seem to be more comfortable with the idea that if an individual reports he or she is doing well, without pain or mobility of the prosthesis, then treatment is successful. This is dangerous; reliance on patient report is not a substitute for systematic clinical observation by the dentist. There may be underlying pathology without symptoms.

Some practitioners determine clinical significance using traditional biological or physical measurements. These include the location and magnitude of bone support, mobility, occlusion, pocket depth, crown-to-root ratios, height of gingival margin, and many others. While these objective clinical measurements are associated with important differences, they are often intangible to the patient. Reliance on these to determine clinical success may lead to erroneous conclusions about clinical significance.

Clinical success is not always the same as clinical significance. For example, a patient may not perceive a successful surgery as having good results if his smile or speech has not materially improved. Traditional clinical measurements alone can fail to capture the idiosyncratic impact of treatment on an individual patient. It is important for clinicians to look beyond the physical dimensions and include the psychosocial aspects of QOL to determine whether clinical significance has been achieved.

In conclusion, more research is needed to provide clinicians and researchers with clear guidance about assessing and measuring clinical significance. While it is recommended that QOL be defined from the patient’s perspective, the reality is that QOL is often defined by clinicians solely in terms of observable events such as the ability to return to function with maximum esthetics and the absence of symptoms. By recognizing the 2 perspectives of clinical significance, practitioners can materially improve treatment outcomes.

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REFERENCES

These 3 articles provide background and in-depth discussion of this important topic. This editorial relied heavily on those articles and the reader is encouraged to refer to them.