Informed Consent—The Process Model

Informed consent is a widely accepted necessity for those of us practicing implant dentistry. How the consent is obtained and the degree of detail it contains is highly variable. It is well established by the courts that it is a common legal requirement for providers to obtain legitimate and well-informed consent before initiating treatment.[1] Simply obtaining a signed authorization for surgery or prosthetic restoration is a limited view of this vital component of treatment. Patients should have a conscious participation in the treatment decision-making process. Lidz et al[2] called the simple signature signing an "event model" that is now outdated. A "process model" should replace the event model. The process model focuses on efforts that promote the patient's active participation in making a shared treatment decision. If the process model is used, the patient takes ownership of the treatment decisions.

The suggested elements of the process model should include:

1. Discussion of current clinical issue(s) including the nature of the decision(s) to be made,
2. Discussion of various treatment options,
3. Discussion of pros and cons of the treatment options,
4. Discussion of possible unknowns associated with each option,
5. Assessment of a patient's understanding, and
6. Asking the patient precisely to express a preference.[2]

Options discussed should include:

1. Surgical vs nonsurgical treatments;
2. Teeth to be extracted;
3. Using sedation or not using sedation (including type of sedation);
4. Medications to be used including analgesics, antibiotics, and sedative agents;
5. Type of prosthesis;
6. Esthetic outcomes (including facial and smile evaluation);
7. Potential complications;
8. Patient expectations; and
9. Probability of success.

When these aspects of a thorough, informed consent are used there is evidence that the patient freely has made an educated decision and the clinician has treated the patient as a true partner in the decision-making.[3] Patients must take ownership of their decisions and not leave open the option for them to state later: "I had no idea what I was getting" or "I would have never done this had I been told this could happen." Treatment decisions must be a signed mutual agreement.

Patients and clinicians can expect to have success with dental implants. Success rates are quite high, however complications or complete failure can occur. The patient should know the potential risks and the chance of their occurrence.

In a systematic review regarding the survival and complication rates of implant-supported fixed dental prosthesis Pjetursson et al[4] estimated an implant survival rate of 95.6% after 5 years and 93.1% after 10 years.

Adler et al[5] recently examined the survival and complication rates in a long-term 9- to 15-year retrospective follow-up study regarding dental implant treatments. The findings revealed the implant survival rate up to 15 years was 82.6% (SE 4.1%). The occurrence of biological complications was 52% and technical complications occurred at a rate of 32% at some point in time. At least one complication was experienced by 65% of patients. When patients presented with a history of stage II-IV periodontitis, they were more likely to experience an implant fixture loss ($P = .008$). A history of smoking was a significant predictor of future peri-implantitis ($P = .006$).[5]

Complications include but are not limited to: (i) immediate postsurgical pain, (ii) infection (at any point), (iii) inflammation, (iv) edema, (v) bleeding, and (vi) other unforeseen issues.

Discussing the possible occurrence and frequency of complications prior to the commencement of treatment demonstrates an openness and honesty by the clinician. If a patient is forewarned of possible risks and the procedure is preformed without complication, then "all-the-better" the practitioner appears to be in the patient's eyes. However, if a patient is not told of the risks and a complication does occur, the patient thinks the clinician may have done something wrong; when in reality the clinician did nothing wrong. Unfortunately, it is human nature to try and place blame on others, and no clinician wants to be made the "scapegoat."

It is also important to identify patients preoperatively who may be at a higher risk of treatment complications. Is there a complex medical history that includes systemic illnesses or medications that can interfere with postoperative healing? Are there anatomical considerations that preclude the ideal surgical or prosthetic outcome? What is the patient's age? Does the patient have realistic cosmetic expectations? These issues are better addressed preoperatively.

Surgical and prosthetic clinicians should have a complete, sincere, and open discussion with all patients. This takes time and the financial reward for this time must be incorporated into the treatment fee. Establishing a "process model" for informed consent for you and your patients will establish a lasting mutual trust.

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https://doi.org/10.1563/aaid-joi-D-19-Editorial.4504

References

1. Appelbaum PS, Lidz CW, Meisel A. *Informed Consent: Legal Theory and Clinical Practice*. New York, NY: Oxford University Press; 1987.
2. Lidz C, Appelbaum P, Meisel A. Two models of implementing informed consent. *Arch Intern Med*. 1988;148:1385–1389.
3. Braddock CH 3rd, Fihn SD, Levinson W, Jonsen AR, Pearlman RA. How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting. *J Gen Intern Med*. 1997;12:339–345.
4. Pjetursson BE, Thoma D, Jung R, Zwahlen M, Zembic A. A systematic review of the survival and complication rates of implant-supported fixed dental prostheses (FDPs) after a mean observation period of at least 5 years. *Clin Oral Implants Res*. 2012;23(Suppl 6):22–38.
5. Adler L, Buhlin K, Jansson L. Survival and complications: a 9- to 15-year retrospective follow-up of dental implant therapy. *J Oral Rehabil*. 2019. [In press].