



## Government Quality Management System for Safer Prosthesis Installation

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Materials, techniques and protocols for dental implant surgery and restoration have evolved significantly over the years and continue to evolve. **As practitioners and teachers, we are obligated to seek out new knowledge and information, to maintain high professional standards for our patients.** Looking back, with the knowledge that we had, we may have all exposed some patients to risk factors for peri-implant disease. Can we do better now? I know we can, but it may require some procedural modifications.

**Did you know that abutment manufacturers must comply with Government imposed ISO 14801:2016 Standards, to sell their products in Canada or the USA?** These standards assume that the dentist will install these abutments according to the manufacturer's specifications and thus optimize the implant-abutment connection. Do you think dentists should know how to install abutments onto dental implants according to the manufacturer's specifications? Does your installation technique comply with the spirit of ISO 14801:2016 Standards? Does the installation technique that you are teaching, allow the user to optimize the implant-abutment connection(s)? Are your students made aware of this problem and its potential implications?

**Unfortunately, the current screw-in prosthesis installation systems make it unlikely that dentists can consistently comply with these regulations.** The basis of the problem rests in the fact that all dental models are inaccurate, and thus the prosthesis made to fit a dental model is also inaccurate. The screw-in installation technique dictates that the abutments are to be attached to the prosthesis on the dental model, before being installed into the mouth. The abutments are thus constrained by the inaccurate prosthesis, and their fit onto their respective dental implants cannot be optimized. It exposes our patients to the known "technique related" risk factor for peri-implant disease, known as the **implant- abutment misfit or macrogap.**

Support for this claim is mounting in the literature. It is discussed as "The Dreaded Macrogap" by Scott Froum (2017) and in a recent systematic review by Ramamoorthi et al. (2017), "A meta-analysis of retention systems for implant-supported prostheses in partially edentulous jaws". In a 2017 review of the "Misfit of implant prosthesis ..." by Katsoulis et al., they determined the misfit to be between 95 and 232 microns. **This can't be good for the mechanical stability of this subgingival joint, nor its ability to exclude oral pathogens!**

**Intra-oral cementation solves the macrogap problem.** Adding an intra-oral cementation step to the screw-in technique, can solve its macrogap misfit problem. That process was described in my "Retrievability Article" in Oral Health 2016, as the "Svoboda Modification". **Now before you close your mind to the cement-in prosthesis installation technique, I assure you that I am not proposing the "Old Cement-in Technique" that we all learned at dental school.** Based on my original research on this process, I am proposing a cement-in technique that involves the use of "well designed" custom abutments, prostheses and supporting techniques that are **sensitive to the Gingival Effects**, as discussed in my Oral

Health 2015 article titled, “Controlling Excess Cement During the Process of Intra-oral Cementation: Overcoming the Gingival Effects”. Now, I am also talking about preventing cement voids at the margins of the prosthesis and preventing open margins and overhangs. To date I have restored over 700 dental implants with my “safer intra-oral cementation system”, and have not found anything that is inconsistent with my logic or published work.

I invite you to set aside a little time to review my work at [www.reversemargin.com](http://www.reversemargin.com) and to study my most recent presentation, **Preventing Peri-Implantitis by Safer Prosthesis Installation**. I have already presented my topics in Boston, Chicago, Las Vegas, Vancouver, Waterloo and in Mississauga at the October 5, 2017 Halton-Peel Dental Association meeting. In 2018, I have already presented at the AAID Maxicourse (TexMax) near Houston and TiMax in Waterloo. I will also be speaking at other “information sharing” venues, and am hoping to spawn some University and Industry based research. **Making dental implant treatment safer benefits us all, and it is our responsibility.**

My work presents a rich vein of new knowledge to be explored by the participants in Graduate Programs around the world. My presentation is part of the reference material accessed by 10 AAID Implant Education Maxicourses World-wide. **If you are a teacher, I encourage you to expose your students to my concepts for safer prosthesis installation. They really should understand the Gingival Effects and how they can cause the advent of residual subgingival cement.** Intra-oral cementation is much more complex than I originally thought, and it is the cornerstone of oral prosthesis installation for both dental implants and natural teeth.

In addition to energetically supporting your research efforts, I am available to answer your questions and to help you implement my safer prosthesis installation systems into your daily practice. Your new experience with my system will be your best teacher. Reducing complications related to the implant-abutment misfit and residual subgingival cement will make for a less stressful professional career. After you review my work, perhaps you will contribute some refinements to my safer installation systems. Your students and patients will thank you for your foresight and diligence.

**Who can be blamed for implant complications, if abutments are not installed according to manufacturer's specifications?** Is the treating dentist alone liable or are those who teach installation systems that cannot comply with Government regulations also complicit? Are implant manufacturers that do not warn dentists of common complications can arise from the use of their prosthetic components as part of prostheses installation systems that make it difficult or impossible to comply with Government Regulations also complicit?

Governing bodies are charged with protecting the public. Are Governing bodies that do not make dentists aware of faulty installation systems that prevent them from complying with manufacturers installation specifications and Government Regulations complicit? Are they liable if they do not actively promote new research and dissemination of promising new information? These are all interesting questions and I suspect that dentists are not the only ones to blame for inherent technique related complications. Patients don't like to be subjected to risk factors that can cause complications, especially when those risk factors can be prevented.

**In my practice, I install all my implant abutments according to the manufacturer's specifications and my installations comply with ISO 14801:2016 Standards and the intent of Government regulations. Shouldn't this requirement be universal?**

It has taken me some time to experience, research and solve the technique related problems caused by existing prosthesis installation techniques. Now it is my time to share what I have learned with the whole implant industry. Let the spirit of Pierre Fauchard (1678-1761) move you forward. Thank you for taking the time to read my letter and I hope to work with you soon.

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