# Do dentists receive the support they need from educators, dental laboratories, implant manufacturers, implant sellers, and Government regulators to enable them to do a better job for their patients?

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***Abstract:*** *This article reveals the perspective of a dentist who has spent 40 years providing oral health care for his patients, doing focused research to identify the root causes of prostheses installation related complications, and sharing his results with colleagues. To his dismay, he found that the dental health care system seems to have lost its patient-centric focus. Do dentists receive the support they need from education sources, dental laboratories, implant manufacturers, implant sellers, and Government regulators to enable them to do a better job for their patients? Does their dental support team still deserve the dentist's trust, or have they covertly shifted their focus to maximizing sales by misleading dentists about the safety of the procedures they promote? Are they using dentists as shields to protect themselves from the wrath of patients disappointed with treatment results? Really, how can dentists accept the full brunt of responsibility for treatment results when they are not provided with pertinent information about the dental implant products they buy, nor given manufacturer's installation instructions along with disclosure of the related risk of complications? How can they even provide their patients with a proper consent process? These are the issues discussed in this article, along with some suggestions to improve implant treatment for patients.*

***Key Words:*** *dental implants, dental implant companies, implant manufacturers, Government regulators, Health Canada, FDA, peri-implant disease, peri-implantitis, implant failure, treatment complications, prosthesis dimensional error, tissue effects, resistance to displacement, gingival effects, dental implant prosthesis, implant-retained crowns and bridges, implant-abutment misfits, subgingival cement, Reverse Margin System, Chamfer Margin System, screw-in prosthesis installation system, intraoral cementation.*

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After 40 years of practice, I wonder whether Dentistry has lost its focus on advancing the quality of patient care. Let's look at this problem from different perspectives.

## Patients

If you are a patient, you may wonder whether you are wasting your hard-earned money on implant treatment. You may have heard about some treatment nightmares, including multiple surgeries, pain, disfigurement, and failure. Is treatment involving dental implants worth its high cost? Have you been provided with an accurate appraisal of the risks and benefits involved in treatment? Can you trust that your dentist understands the risks inherent to your proposed treatment? Will your dentist do what is necessary to prevent exposing you to known risk factors or are you just signing up for a lot of problems? **Yes, those thoughts will keep plenty of patients up at night.**

## Dentists

What about dentists? They love providing their patients with the fantastic benefits of implant treatment. The consideration and use of implants impact almost every treatment decision. Frankly, I am still amazed by their positive effect on the quality of care I can deliver to my patients. I am often optimistic when presenting such treatment to my patients (Figure 1) However, dentists like me worry about complications and their dire consequences for my patients and myself. Managing disappointed patients with difficult-to-treat problems can be

expensive and not fun for dentists. Are our worries about complications justified?

Figure 1: Dr. Svoboda discussing implant treatment with a patient. The dentist and the patient are optimistic and happy. We are proposing a solution to her problem.

The literature paints a rather bleak picture. Up to 81% of patients can expect to suffer the consequences of peri-implant disease and implant loss.[1] 5% of dental implants may be lost within two years of treatment.[2] (Figure 2)

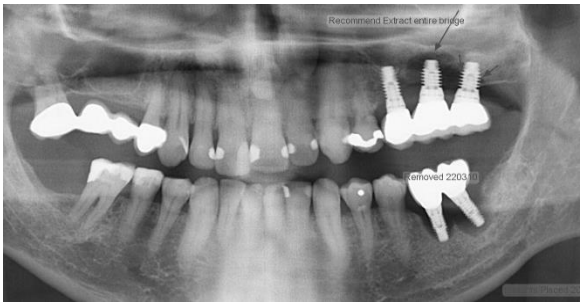


Figure 2: The patient is faced with loosing all the failing implants on the left side. The patient is disappointed. How will the dentist manage this problem?

**Do dentists also worry that their patients "do not really" accept the risk of complications reviewed during their "consent to treatment" process?** Will patients feel that their dental problems are now their dentist's fault? Are they right to consider this possibility?

Dentists know that the patient's poor health, diet and maintenance can increase the risk of treatment complications. What about the risk factors inherent to the prosthesis installation system they chose to use? Researchers report that implant-abutment and abutment-prosthesis misfits are risk factors for peri-implant disease.[3] **Do patients assume that their dentist will have connected their prosthesis to implants in their mouth in an optimized fashion?**

If a dentist cannot optimize the fit of implant connections, should that dentist inform their patient about this problem? Similarly, if the dentist cannot prevent residual subgingival cement, open and overhanging margins, and poor access to care, should the patient also be informed? What about the other known risk factors?

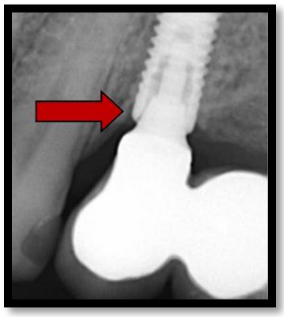

Figure 3: This x-ray image (red arrow) shows an implant-abutment misfit.

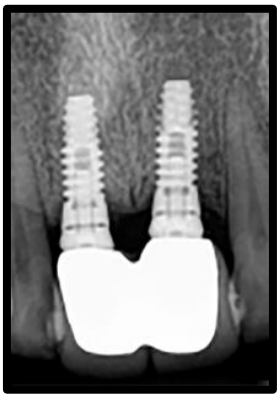

Figure 4: This x-ray image shows open and overhanging margins between the crowns and their abutment retainers.

**Can you think of any case where misfit connections would likely improve treatment for a patient?** (Figures 3 and 4) I cannot think of any such situation. Undoubtedly, the goal of the dentist is to connect implant and prosthetic parts optimally for the best results. Other goals likely include preventing open and overhanging prosthesis margins and the occurrence of residual subgingival cement. However, misfit joints, poor access to care, poor margins and

subgingival cement are consequences of the most prevalent prosthesis installation systems used today. They are also all risk factors for the dreaded peri-implant disease.[3] These risk factors for complications are now preventable, and patients don't like to suffer treatment complications that their dentist can prevent.

**Revisional treatment for peri-implant disease can be unpredictable, uncomfortable and more costly than the initial treatment.** Regardless of their cause, the management of treatment complications may not be perceived positively by the patient. The suffering patient may no longer trust the dentist's motives, knowledge and experience or be willing to accept additional treatment costs. **Trying to manage unhappy patients are likely to keep dentists up at night.**

Figure 5: This is an image from the internet that shows a deer on a highway caught in the headlights of a vehicle.

Would the dentist feel like **"a deer in the headlights"** if challenged to explain how they optimized the fit of implant parts and prevented subgingival cement, open and overhanging margins during their prosthesis installation process? (Figure 5)

**Wouldn't the dentist feel more comfortable** if they could explain to the patient and/or the judge, how their installation system had prevented the above risk factors for peri-implant disease? Wouldn't they have reduced their need for those explanations by preventing the related treatment complications in the first place?
The prevalence of treatment complications inherent to installation systems that cause misfit joints (screw-in system) and residual subgingival cement (cement-in system) are similar and troubling. (Figure 6)

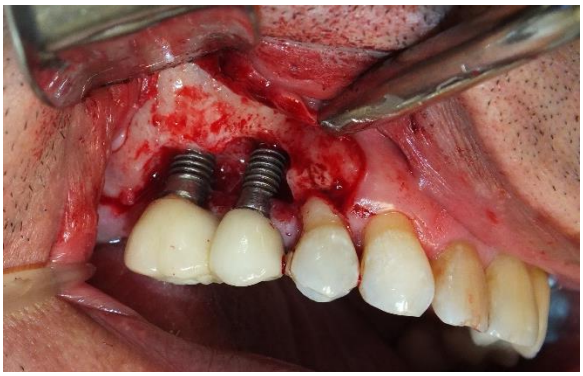

Figure 6: This is picture showing implants with gingiva reflected. Note the large volume of bone loss. Despite best efforts, treatment of such peri-implant defects has been unpredictable and is often associated with unesthetic results.

Research results by Wilson[4] suggests that preventing residual subgingival cement can already reduce the prevalence of peri-implant disease by 60%.

Imagine the benefits of reducing peri-implant disease by 60% by using an installation system that has been designed to prevent multiple risk factors for treatment complications, including residual subgingival cement.[7,9] (Figure 7)

However, preventing risk factors for disease requires an understanding of their root causes. **Wow, what if the root causes of installation-related complications already existed as well as a system that could mitigate their negative effects.**[5,7] Wouldn't that make it possible to make dental treatment better than ever and usher in a new standard of care?


Figure 7: This picture compares the efficacy of the Chamfer Margin System (Left side) and the Reverse Margin System (Right side) at preventing subgingival cement.

I am a practicing dentist as well as a researcher with a PhD in oral biology earned at the Faculty of Dentistry at the University of Toronto.

**What keeps me up at night** is the utter frustration I feel trying to motivate peers, specialty groups, educators and others in the dental health care system to even debate the concepts I have derived from my research. Has our health care system lost its focus? Are we all compelled to work together to make treatment better for our patients?

I do hear a lot of empty-concern about the troubling prevalence or peri-implant disease. I agree, it is troubling and still I experience whole meetings focused on understanding peri-implant disease and its problems without even hearing anything about implant-abutment misfits. That's incredible! There is a lot a great research that discusses these misfits and their negative effects on treatment.[3,8,10]

Why are our educators and dental specialists mute when it comes to discussing the root causes of prosthesis installation related complications? Why are they mute about processes that could be implimented to reduce complications? Couldn't discussions about the root causes of complications lead to some approaches to preventing peri-implant disease? Is the Reverse Margin System already a working model that can make implant treatment better? Where is the discussion by our leaders?

I wonder whether our dental health industry more focused on maintaining the status quo regardless of its predictable troubling effect on patients? At this time, dentistry does not even appear to have an adequate vocabulary to discuss the mechanisms by which patients are exposed to risk factors for complications. I have proposed some new terminology for that purpose.[5] Crickets. **Should I apologize for disturbing anyones sleep?**

## Dental Laboratories

**What about dental laboratories?** Laboratory technicians have little control over the quality of the impressions they receive. They make their prostheses on dental models of unknown accuracy and precision. They attach implant analogues with unspecified tolerances to those models and use digital design software with poor soft tissue management tools. These tools were designed to make prostheses that expose patients to multiple risk factors for peri-implant disease and implant failure.[8,9,13]

Also, dental technicians must interface with costly, rapidly evolving technologies with unspecified capabilities that require expensive maintenance routines to keep them running optimally. They work under short time lines and significant cost competition.

Lab technicians and lab owners know that treatment complications can make their dentist-customers unhappy and cause them to switch laboratories, or ask for costly "goodwill" services. To make that whole custom prosthesis construction process work at a competitive cost and get the esthetics right, sounds very challenging indeed.

**Perhaps it works because, at the end of the day, the dentist is responsible for treatment complications?** (Figure 8)

Yes, the responsibility for complications falls directly on the shoulders of the dentist. So as long as the lab can provide their dentist-customers with a prosthesis that they can install and the patient is willing to accept, the lab is golden.

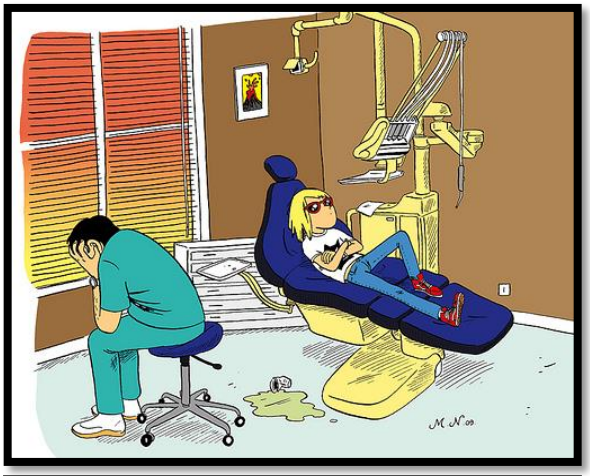

Figure 8: This picture shows a dentist having difficulty managing a disappointed an unhappy patient.

Managing some "good will" related to treatment failure is inefficient, but it can also build cutomer loyalty. If it gets too expensive to service any particular dentist, well sometimes the lab just needs to say goodbye.

So, you see, it dosen't really matter that their products are known to expose patients to risk factors for complications. As long as the consequences of those risk factors don't show themselves until some time after the prosthesis is installed, who will hold them accountable? After all, it's the dentist who ordered the prosthesis and it is the dentist that installed it. **Dentists are the final quality control and they are deemed responsible for their work.** Is that not the way it is?

This transfer of responsibility for outcomes to their dentist-customers, allows the labs to focus more on making their products more efficiently to stay competitive and grow their market share. This is important to them, as **loosing dentist-customers due to price considerations is what keeps lab owners up at night.** Both dentists and patients appear to be very price conscious.

## Implant Manufacturers and Sellers

**Is the same true for implant manufacturers and sellers?** Are they also leaning on the licenses of their dentist-customers to save themselves harmless from the high cost of complications related to the installation of their products?


Figure 10: is a picture of the ELOS MedTech building expansion proposal in Nashville Tennessee. This company has been making implant products Nobel Biocare for over 25 years. Both Nobel and ELOS know the manufacturing tolerances of their products.

**Do implant manufacturers provide their dentist and laboratory customers with the manufactured tolerances of their products?** Would this information help dentists and dental laboratory technicians make better informed decisions about which products to buy for their customers? Would this type of information help dental laboratories better support their dentist-customers? Would this help dentists provide better treatment for their patients?

**Do implant sellers, like NobelBiocare, Straumann, Dentsply-Sirona and others provide their dentist-customers with installation instructions for their implant parts and do they provide disclosure of inherent risk factors for complications related to their instructions?** Why not?

I have not seen evidence of maufacturers and sellers of implant parts providing the tolerances of their parts nor their installation instructions with related side effects. So I must ask, **"How can dentists provide their patients with a proper informed consent as proposed by the RCDSO? How can dentists take full responsibility for treatment complications?"**

**I believe that dentists have long been the scapegoats for the implant companies by protecting them from legal action initiated by unhappy patients.**

**The Royal College appears to be unaware of this problem.** Does this lack of guidance for dentists by implant manufacturers fail to "Protect the Public". I wonder whether the RCDSO will be inspired to communicate with manufacturers or government counterparts to correct this glaring problem.

## Health Canada and FDA Regulators

Let's dig a little deeper with regards to the implant parts manufacturers. Besides hiding behind the licenses of dentists, **perhaps the manufacturers and sellers are also hiding behind Health Canada and FDA Regulations.**

Health Canada and the FDA regulators in the USA need to approve implantable devices before they can be sold to dentists in Canada and the USA. The approval includes tests of joint stability under load. Clearly Health Canada and the FDA feel that joint stability is important for patients. These tests for stability of joints apparently try to simulate 5 years of function in the mouth. Why? Perhaps to provide some desired minimum expectation of predictability in the mouth and thus to protect the patient.

**Perhaps the manufacturers believe**, once their parts have passed the Government tests, they become free of responsibility. Is that true? Perhaps the intent of these tests is also important. The laboratory stability tests involve the optimized connection of individual parts according to manufacturers directions. **Perhaps the government regulators assume that manufacturers will also provide dentists with directions that will to enable them to assemble parts in the mouth in an optimized fashion.** Unfortunately, this is simply not true.

**First:** The stability tests prescribed by the Government regulators do not include the complexities of the intra-oral environment nor the common practice of incorporating abutments and prosthetic connectors within a prosthesis prior to installation. Resistance to displacement by oral tissues, Incongruent Paths of Insertion and **Prosthesis Dimensional Error (PDE)** can prevent the optimal connection of implant parts in the mouth. These root causes of misfit parts become increasing significant when the parts are incorporated into a multi-unit prosthesis intended for connection to multiple implants. **These common intra-oral uses of implant parts appear to be completely missing from the Government testing process.** Why?

**Second:** Permission granted by the Government Regulators for connection of implant parts in the mouth do not seem to be predicated upon the manufacturers providing dentists with installation instructions for optimizing the fit of their parts in the mouth. If the provided directions cannot consistently result in optimized connections, would it not be appropriate for manufacturers to disclose this fact along with possible side effects? In absence of this information, how can the Government regulators be effective at protecting patients from complications? How can dentists be held

solely accountable for complications. Have they been wilfully misinformed by industry ? Misfit joints are a risk factor for implant treatment complications, that are far too prevalent.[1,3]

**Perhaps this messy situation could be improved by Government Regulators** asking manufacturers and other stakeholders in the delivery of dental care, to follow the "spirit of their regulations" and thus strive to help dentists to optimize the fit of parts in the mouth.

I am sure that dentists could do a much better job for patients if they were provided with installation instructions and an honest disclosure of their related risk factors for complications. This information will likely also provide dentists with incentive to find solutions to revealed problems and better inform their patients about their possible impact on the treatment. Isn't that what a proper informed consent process is supposed to do?

**I think implant company managers would likely sleep better if they followed the "Spirit of Health Canada and FDA Regulations" to become better protected from the wrath of patients with complications. Class action suits can be expensive.**

## Dental Educators

**Do dental educators disclose risk factors related to different installation systems they teach? Do they already do that in dental schools?** Do they have systems in place to actively persue promising new ideas for making treatment safer for patients? Could fresh ideas be elicited from clinicians and others that work outside the walls of the institution? Could new ideas be derived from science fair type competitions? **Do the universities value knowledge over industry sponsorship?**

Has dental health care education become so dependent on industry sponsorship that they have abandoned their responsibility to "first and foremost" help dentists provide excellent dental care for their patients? Is this problem a result of continued inadequate Government Funding?

Excellent dental care is a moving target and requires proactive activity by those in charge. Are dentists just easy scapegoats for biased training and systems that are based on obsolete ideas?

**I am not sure whether those involved in dental education sleep well a night.** I guess dentists and their patients will still have the hardest time sleeping, as it is hard to sleep with dental pain and conflict.

**How can we make dental treatment better for patients?** All the stakeholders that are involved in dental health delivery need to support the efforts of the dentist with the best high quality information possible. The products made available to dentists should include relevant information like the tolerances of parts and disclosure of specific side effects reated to their recommended installation instructions. Other stakeholds involved with the support of dental care delivery must also accept their share of responsibility for patient complications. Marketing without disclosure is misleading for dentists and bad for patients. It is logical that misleading marketing should expose product sellers to risks of compensation, should dentists and/or patients be harmed.

## Dr. Svoboda's Opinion

**I think it is high time that we all stop fooling each other and our patients** that everything is alright, and the current installation systems are the best we can do. It is time to acknowledge the root causes of implant treatment complications and help to coordinate our efforts to mitigate their negative effects.

Do we continue quote those impressive implant survival rates to patients and each other, or do we discuss expected patients' experiences with

peri-implant disease and implant loss as reported in the review by Lee?[1] Those statistics are quite different. The 10 years implant survival rates, "implants still in the mouth", are an impressive 92%.[2] However, a not so impressive 81% of patients can expect to suffer the consequences of peri-implant disease and implant failure.[1] The 10 year 65% survivability of an implant-retained full fixed arch is not so good either. Arlin (pg24)[2]

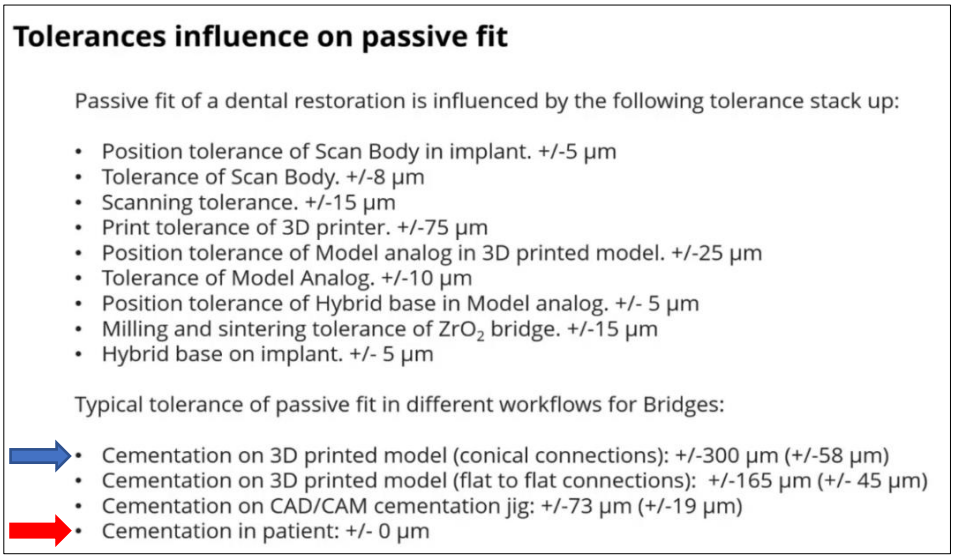


**Figure 11:** Data from Andersen[8] who works for ELOS MedTech. Note the error attributed to each step in the production of the prosthesis in the lab under ideal conditions. These combine to make up **PDE**. The commonly used conical connectors (blue arrow) add greater error than others. Dr. Andersen states "intra-oral cementation can compensate for **PDE"** (red arrow). The Reverse Margin System, to be discussed later, is designed to both safely tolerate **PDE** & help the dentist manage the Tissue Effects encountered during intraoral prosthesis installation. Dr. Svoboda discloses how this is accomplished.

Learning how to prevent complications related to prosthesis installation can make treatment better for all.[6,7] In the healthcare industry, that is our job. Yes the educators and regulators also need to be involved in pro-actively seeking out and facilitating the development and dissemination of promising new information. Perhaps we all need to review the prosthesis installation process in the light of new information. This process offers the dentist the most control over results and thus is a very important aspect of dental treatment. Let's all work hard to make treatment as good as possible for patients.

## Review Promising Installation System

**Prosthesis Dimensional Error (PDE) is a root cause of misfit implant parts, misfit margins and residual subgingival cement. PDE** is largely unknown for any specific prosthesis and difficult to assess intra-orally. ELOS MedTech (www.elosmedtech.com and Figure 10) has been making dental implants for Nobelbiocare for over 25 years. Dr. Henrik Anderson, at ELOS MedTech has calculated errors inherent to each step of prosthesis construction under optimal dental laboratory conditions.[8] This was an in vitro study and not tested in the mouth. (Figure 11) I think we can safely conclude that dental laboratories may still find it impossible to produce a prosthesis at ±5 microns of error and verify its optimized fit in the mouth. Even after receiving today's most advanced impression information, the dental model still needs to be printed, implant analogues of unknown tolerances attached, the prosthesis constructed to fit that dental model, and then installed in the mouth by a dentist.

When dentists receive a prosthesis for installation into the mouth, they will also need to manage **another root cause of misfit parts and residual subgingival cement called the Tissue Effects.**[5] Yes, the dentist will need to know how

to effectively manage the **Resistance to Displacement Effects** encountered by the abutment and prosthesis while being connected to implants.

If the prosthesis will be cemented onto its abutment retainers, the abutment-prosthesis system will also need to mitigate the **Gingival Effects** to prevent the occurrence of residual subgingival cement. Unlike the Chamfer Margin System, the Reverse Margin System has been shown to successfully mitigate expected Prostheis Dimensional Error and both abovementioned Tissue Effects.[9]

Should our goals include a system of installation that is sensitive to and can mitigate the root causes of complications? Is there any excuse for dentists to use systems that unnecessarily and consistently expose patients to known risk factors for complications? Is there any excuse for implant manufacturers to promote their systems without installation instructions that also include their related risk factors for complications? Do dentists need to talk about these "unmentioned risk factors" with their patients?

**Is our dental services industry stuck? The implant survival rate has not changed over 30 years.**[2] Is that good? Is that progress? What is the problem? Who among the health care participants are going to step up and support the changes needed to make treatment safer for patients? **In his presentation, Dr. Henrik Andersen, of ELOS MedTech stated that intraoral cementation is key to safer prosthesis installation.**[8] He appears to believe that intra-oral cementation can safely tolerate the summed dimensional errors inherent prosthesis construction and eliminate misfit connections. I do not know how he can accomplish that goal with current margin systems that are dsigned to touch the finish line.

**In reality, any parts that are designed to touch will during the connection process will have little or no tolerance to Prosthesis Dimensional Error**.

Clearly it is cannot be too difficult to understand that embedding abutments with a low tolerance to error (±5µ) into a prosthesis that is less accurate and precise (±50 to 150 µ), and then trying to connect those constrained abutments to implant connectors (±5µ) in the mouth is impossible without causing implant-abutment misfits.[6] Is that what we want?

The same argument pertains to the all-on-x systems prosthetic connectors embedded in the prosthesis that are expected to connect optimally with multiunit abutments already in the mouth. In this case we would logically expect a abutment to prosthetic-connector misfit. I have proposed a solution for this.[16] Simply, assemble all implant parts in the mouth prior to picking up the prosthetic connectors in the mouth. Use cement space between the prosthetic connector and prosthesis to compensate for PDE and fill that space with cemnt during the pick-up process. Its easy once you understand the problem.

Misfits or sloppy fits between implant parts create space for oral pathogens to breed and from which to attack adjacent tissues. This problem is exacerbated when the misfit parts move during prosthesis function where oral pathogens and their toxic byproducts are actively pumped into the adjacent tissues.[10] Peri-implant disease is caused by oral pathogens and the tissue destruction seems to originate from the connections and crawl done along the implant surface towards its apex. Reducing the size of the inoculum of oral pathogens to within the limits of a patient's immune system defense capabilities is key to preventing disease.[7]

Further, Government tests that allow the sales of these implantable devices parts are based on

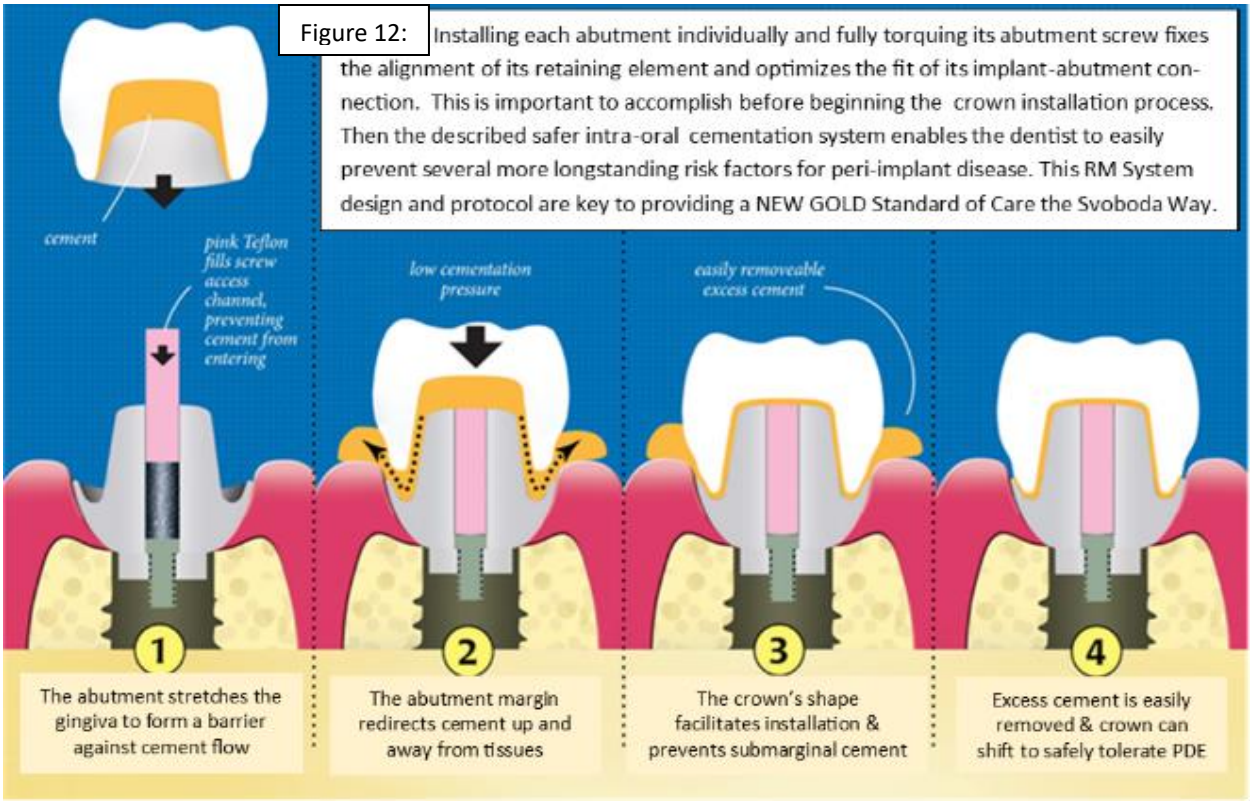


Figure 12: Installing each abutment individually and fully torquing its abutment screw fixes the alignment of its retaining element and optimizes the fit of its implant-abutment connection. This is important to accomplish before beginning the crown installation process. Then the described safer intra-oral cementation system enables the dentist to easily prevent several more longstanding risk factors for peri-implant disease. This RM System design and protocol are key to providing a NEW GOLD Standard of Care the Svoboda Way.

parts being optimally connected. These tests were designed to predict the stability of connected parts under function over time.[11] Why would it considered acceptable to install these parts in the mouths of patients in a misfit way? This does not make any sense at all.

If the dentist is able to install the abutments individually without being constrained within a prosthesis, then the dentist can consistently optimize the fit of the implant-abutment connections. That is the goal of proper abutment installation, is it not?[12,13] Figure 12 Step 1 shows a optimized abutment installation.

The next step will be the installation of the prosthesis. Wouldn't it be nice if there was a system that could provide dentists with adequate cement space to safely compensate for expected Prosthesis Dimensional Error and to also help manage tissue interactions during installation? The Reverse Margin System[13,14] of installation has such capabilities. Figure 2 Steps 2 to 4 shows how this works. The abutment shape prevents the tissues from interacting with the prosthesis.

With this system, the dentist can move the prosthesis in and out of the mouth without needing to displace and traumatize adjacent tissues in the peri-maginal area. Doesen't that make adjusting contacts and the tissue surface of pontics easier? It also allows the prosthesis to somewhat self-centre and self-level during installation, and it prevents open and overhanging margins and excess cement from travelling past the abutment-prostheis margin interface. This really makes an optimized installation easier for the dentist and probably reduces trips to the lab for porcelain addition to close contacts. More about this innovative system at www.ReverseMargin.com.[9,13,15,16]

**I any case, wouldn't the patient, the dentist and patient sleep better if they both suffered less complications?** The Reverse Margin System has been specifically designed to mitigate the root causes of complications. I sleep very well at night because I don't need to worry whether I have

protected my patients from several well-known risk factors for the dreaded peri-implant disease that can destroy their treatment and our professional relationship. I can easily explain how I done that to the patient and the judge. Wouldn't that be nice for you too?

**In Conclusion:** There are many stakeholders in the dental health care system. They all need to take a share of the responsibility for complications or at least be able to explain how they contributed to reducing them. Manufacturers and sellers of dental implants in particular, need to provide the dentist with adequate information about their systems to enable them to make informed decisions about their purchases and to properly inform their patients about the risks related to the intra-oral installation of their products.

Reducing complications will likely inspire more patients to accept implant treatment. That translates into a BIG WIN for the whole dental healthcare industry and will help **patients and their dentists sleep better at night.**

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"**A new gold standard of care is now available to our patients.**" Dental industry technology has evolved tremendously over the last 40 years and can make CAD/CAM directed site-specific custom parts from biocompatible materials with microscopic levels of

precision that are both esthetic and functional. **The Svoboda Way of Prosthesis Installation** enables the dentist to fully exploit these technological benefits by mitigating the root causes of installation related mechanical complications and preventing related biological complications like peri-implant disease.

This innovation can provide a new foundation for advancing dental treatment protocols. Research results on success and survival of implant treatment approaches can now be revisited without confounding variables like misfit implant parts, poor prosthesis margins and residual subgingival cement. Perhaps this will enable researchers to more easily tease out subtle treatment variables, that have long been obscured by previously unmanageable risk factors for complications. Perhaps this will help dentists to further improve the long-term prognosis of treatment involving dental implants.

To make implant treatment better, each group involved in the support and delivery of this amazing treatment must proactively look for ways to improve overall treatment results. They can do that by providing dentists with proper information regarding the tolerances of their connecting parts and installation instructions that include inherent risk factors for complications. This will empower the dentist to make informed choices about the purchase of implant components and to provide patients with a proper informed consent process."