Fixed Prosthesis Installation: An Aviation Analogy Considering 3-D Position, Yaw, Pitch and Roll

Emil LA Svoboda PhD, DDS

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What is an optimized fit and what does that have to do with 3-D Position, Yaw, Pitch and Roll? In dentistry, the fit and stability of implant parts are important from both a mechanical and biological point of view. Optimized fit terminology can be used to describe a connection between parts that can be expected to remain most stable under functional load over time. Optimally fitting parts can also be expected to be best at preventing the passage and proliferation of oral microbes in and about them. The ability to reduce or exclude oral pathogens from moving between implant parts reduces the size of the microbial challenge to the patient's immune system to prevent peri-implant disease. This is good.

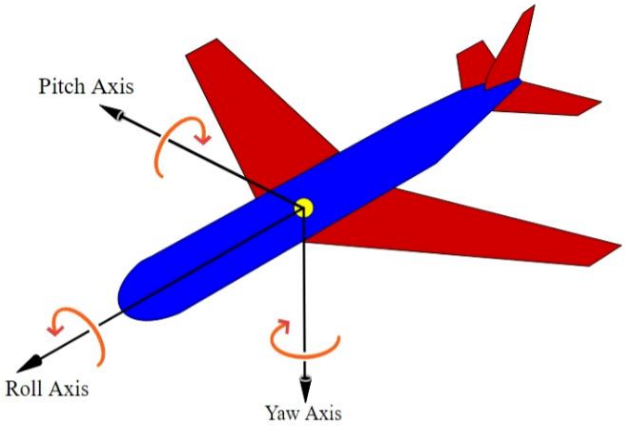

Figure 1: Yaw, pitch and roll describe an aircraft's orientation in terms of its principal axes. https://commons.wikimedia.org/w/index.php?curid=9441238

Yaw, pitch, and roll are terms used to describe the orientation of an aircraft in regards to its principal axes. The pilot uses controls to manage the yaw, pitch and roll of the aircraft during take-off, flight and landing. Along with location, this is important to the health and safety of the pilot flying the plane. (Figure 1)

The same principles can be used to understand the physical relationship of an abutment connector to an implant connector during its installation. In this analogy, the implant connector is the destination or landing site. It has an exact and rigid 3-D position in the patient's jawbone. The implant internal and external surfaces have physical constraints with yaw, pitch and roll attributes. When abutments are installed individually, like they are in the cement-in system of installation, their 3-D position, yaw, pitch, and roll are free to adjust themselves to mimic that of the implant. Thus, the fit of every connection is determined by the precision and accuracy of the manufactured parts, and there are no contacts with adjacent teeth to frustrate the optimal seating of the parts. Other adjacent tissues like fluids, gingiva and bone still need to be managed, but this is relatively simple compared to the screw-in installation system described below.

When installing one or more abutments using the screw-in prosthesis installation system, the abutments are affixed to the prosthesis to fit a dental model before installation. The dental model and its embedded components are not exact replicas of the mouth. Indeed, nobody knows how accurately and precisely any dental model represents the mouth. The 3-D position, jaw, pitch, and roll of the abutment connectors are now determined by the precision and accuracy of the prosthesis and the dental model on which it was constructed. When the abutments are constrained within the prosthesis, their position and alignment are

also no longer free to adjust themselves to mimic the position, yaw, pitch and roll of the implant connectors. Contacts with adjacent teeth, tissues and other implants can further frustrate the dentist's efforts to seat the prosthesis optimally. This makes prosthesis installation much more complicated. If the prosthesis is less precise and accurate than the abutments can tolerate, this process guarantees a suboptimal fit of parts. Misfit parts provide more space for oral pathogens to move between parts and multiply within the vast caverns inside the implant body. Every bite can spew these oral pathogens and their toxic byproducts into the peri-implant environment. Is this what we want?

Oral pathogens are ±1 micron in diameter. We know that many turning and milling machines can make parts with a tolerance of ±5 microns. The best we can expect for a prosthesis is about ±50 microns.[1] The screw-in prosthesis installation system is flawed and promoted by many large implant companies. Are implant companies willing to accept responsibility for treatment complications related to their installation instructions … or are dentists left to stand alone in the courtroom? Who else is culpable when a patient is unhappy with treatment results? Are our schools and regulating bodies culpable? These are important questions.

Implant companies inform their manufacturers about the expected tolerances of the parts they wish manufactured for sale to dentists. Tighter precision tolerances can have a huge effect on the price of manufactured components. The implant companies often crow about the fit of their manufactured parts, but do not reveal these tolerances to dentists as part of the sale process. Wouldn't that be important information to share with dentists? Also, shouldn't their instructions indicate whether the optimized fit of their parts can be achieved in the mouths of our patients as a result of their installation instructions?

Tighter tolerances like ±5 micron may still allow dentists to optimally install abutments and prosthetic connectors individually but can make it impossible for dentists to do so using the screw-in installation system. Do implant companies actually make the fit of their abutments and prosthetic connectors closer to ±50 microns to help dentists install prosthetics by the screw-in system? How can dentists know? How can dentists decide what parts are best and which installation system is best for their patients? Dr. Henrik Andersen[1] of ELOS MedTech, an implant manufacturing company, recommends intra-oral cementation to compensate for manufacturing errors. I agree, but specifically advocate the use of an installation system, like the Reverse Margin System, that has been specifically designed for safer cementation. To be safer, the system needs to be able to mitigate the root causes of complications. More about that later.

Who thinks the stability of mating implantable parts is important? Health Canada and the FDA in the United States do. [2] Government regulators feel that joint stability is crucial for implantable devices. The stability of a joint is determined by the precision, accuracy and geometry of the mating parts, the materials from which those parts are made, and their means of fixation. Stability tests are done in ISO-certified testing facilities, where the implant parts are assembled according to the manufacturer's directions. They must meet Health Canada and FDA stability requirements to be sold to dentists in Canada and the USA.

What is missing from these Government tests? The mouth is missing with its many tissues and embedded implants. The dental model is missing with its implant analogues. The prosthesis is missing along with its inherent errors. What is also missing is the installation instructions that could allow dentists to optimize the fit of implant parts in the mouth. Why shouldn't dentists expect such directions? After all, the parts are specifically made to be installed into the mouths of patients to retain

and support implant prosthetics. Where are those installation instructions and the disclaimers that indicate the shortcomings of those directions?

In **Figure 2** the axes of the abutment and implant connectors are the same, and there is nothing to prevent or interfere with the optimal seating of the abutment. Do the Government Regulators assume that these tests represent a condition that can be reproduced by dentists in the mouth? I would assume that is the main purpose of the government tests.

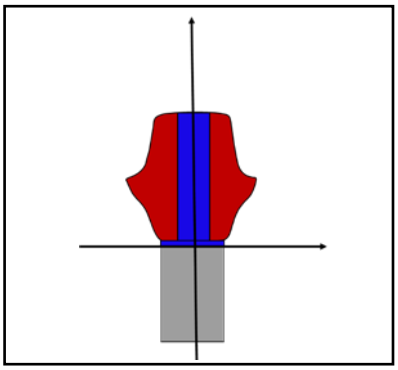

Figure 2: The axes of the abutment (red & blue) and implant connectors (grey) are the same and determined by the geometry of the connecting parts. There is nothing to prevent the optimal seating of the abutment. The Government testing is done in a laboratory rather than in the mouth.

Unfortunately, government tests do not consider the effects of Prosthesis Dimensional Error (PDE) and the Tissue Effects (TE) on the fit of implant parts and they are not designed to mitigate the root causes of treatment complications. (Figure 3) Thus, patients are subjected to known risk factors for complications related to misfit parts when the screw-in system of prosthesis installation is employed.[3,4] The prevalence of peri-implant disease continues to be troubling.

I believe Health Canada and FDA regulations would be more effective if **dentists were provided with instructions on how to assemble implant parts in the mouth optimally.** It is not clear who is charged with this responsibility. Is it the manufacturer of implant parts? Are the educational institutions responsible or is it the Government Regulators like the RCDSO? Is it the sole responsibility of the dentist who installs these parts or is it a combination of all the above? In any case, I am unaware of any manufacturer's instructions that can guide the dentist to consistently optimize the fit of parts in the mouths of their patients without exposing them to risk factors for complications like subgingival cement and poor margins. [7]

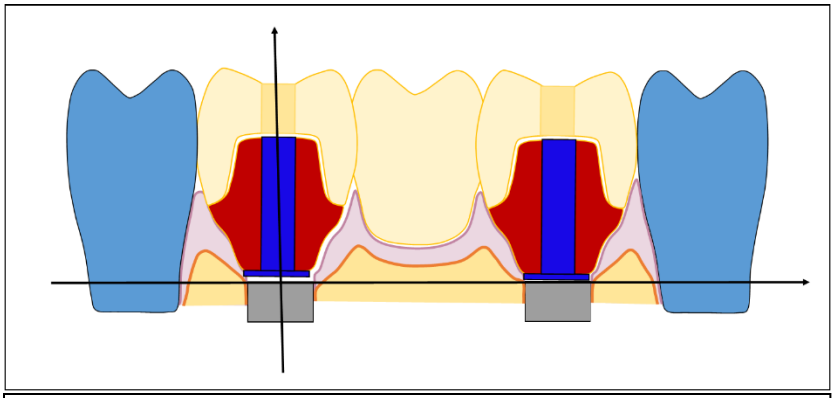

Figure 3: This 3-unit bridge is being installed as a single unit by a screw-in installation technique. The axes of the abutments-bridge complex and implant (grey) retainers are not the same. The position and orientation of the abutment connectors are now determined by the prosthesis. Hence their 3-D position is compromised by PDE as well as the misalignment of yaw, pitch and roll during seating. In addition, the TE can interfere with the optimal seating of connectors. In this diagram, the abutment on the left is prevented from seating optimally because of the misalignment of its abutment connection. This is causing the abutment-connector to bind against the implant connector, the adjacent tooth, and the gingiva.

With effective installation instructions lacking, dentists are left on their own to restore implants and patients continue to be unknowingly and unnecessarily exposed to multiple risk factors for complications. [6] It's a shame that rather than developing or using systems that are sensitive to the root causes of complications, the industry is forging ahead with apparent impunity. Why are manufacturers actively promoting treatment modalities that are known to expose patients to risk

factors for peri-implant disease? Why are they using dentists and their dental licenses as shields rather than helping them make implant treatment better? Why do dentists and their patients need to suffer the ravages of unnecessary complications without those who are complicit?

Multiple research studies indicate that 67% of our implant patients are expected to suffer the consequences of peri-implant disease and 14% are expected to suffer implant loss.[7] Combine those numbers and a glaring 81% of our patients are expected to have serious treatment complications. Why does our Profession persist in accepting such low standards? Shouldn't we be actively seeking improvements? Imagine if the Airline Industry was allowed to persist with such low standards!

Misfit parts can present as loose screws, loose prosthetics, peri-implant disease and indeed caries and periodontal disease in peri-prosthetic environments. They can subject patients to inaccessible and difficult to maintain plaque traps that expose them to disease. [8,9,10]

Is it possible for dentists to attach implant parts into the mouth in an optimized way? Yes, this is possible when dentists install each abutment individually, before installing the prosthesis.[8] **Figure 4** depicts two Reverse Margin™ (RM) abutments installed optimally onto their implant retainers. The installation process can be managed in a controlled and simple manner. The expected behaviour of these optimally fitting parts can now be extrapolated from the Government ISO testing results. That is a meaningful goal.

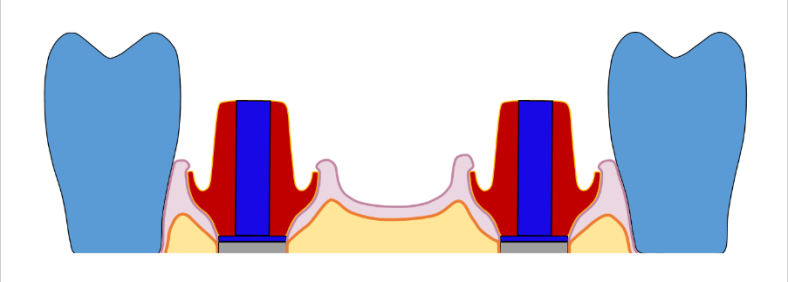

Figure 4: Illustrates the placement of RM abutments individually to best manage the TE. The axes of each implant is optimally aligned to each abutment retainer. The fit of parts can be consistently

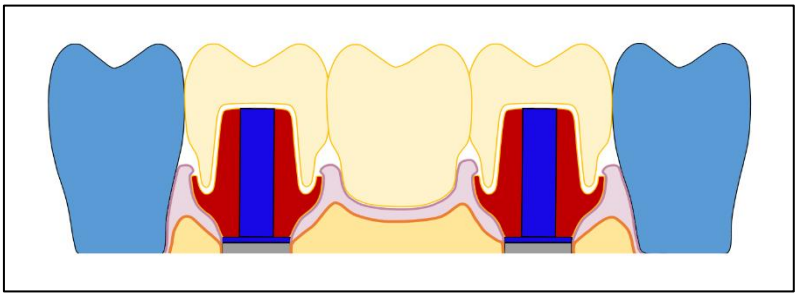

Figure 5: Illustrates both the RM abutments and the RM bridge cemented into place. The design of the abutments prevents the prosthesis from interacting with the gingiva adjacent to the retainers, and thus mitigates the TE. It is easy to place the prosthesis in and out of the mouth without traumatizing the tissues during adjustment of contacts and tissue interface under its pontic. The RM system manages PDE through its continuous cement space between the prosthesis and its retainers. This space can be enlarged to tolerate expected PDE without causing open and overhanging margins. The prosthesis can also self-centre during installation and be installed under low pressure conditions. Low pressure cementation has been shown to prevent the occurrence of submarginal cement when using the RM System. Wow, optimized fit of parts and preventing the submarginal cement!

Figure 5 depicts the RM prosthesis safely cemented into place without causing open and overhanging margins and subgingival cement. Note, the tissues adjacent to the margins are kept out of contact with adjacent tissues. This makes installation easier and reduces trauma-induced tissue bleeding during prosthesis try-in and adjustment activities.

The implant manufacturing industry has made great strides in making high-precision parts with the aid of CAD/CAM-directed turning machines. They can make parts with connectors with tolerances of

±5 microns and better. The manufacturers of prostheses appear to work at a much higher tolerance for error due to the complexity of this customized manufacturing process made to fit a dental model. In the literature, there are references to ±150 micron tolerances being acceptable, ±120 microns being quite good and even reference in a manufacturer's webinar to the amazing ±50 microns.[1] These tolerances are all significantly greater than the potential tolerances of the machined parts that are made from digital plans rather than made to fit dental models.

Nobody seems to know how inaccurate any specific prosthesis is and it appears to be very difficult to measure. If there is no practical way of validating the achievement of some acceptable standard, should dentists assume perfection or some vague concept about a "clinically acceptable fit" when we are trying to prevent disease caused by oral pathogens? Jokstad & Shokati [11] found the vertical misfits between abutments and prosthetic connectors range from 95 to 232 microns for multi-unit prostheses attached to five dental implants in the mandible. Should this range of misfits remain *clinically acceptable* today, when we know it is possible to optimize the fit of parts simply by modifying the installation system? Remember, oral pathogens are about 1 micron in diameter and many can swim.

I believe that implant manufacturers are or should be fully aware of this problem.[1] Have dentists been knowingly misled by industry to accept these misfitting parts as "good enough" just to support the screw-in installation system? Is it time for the implant industry to step up and help dentists do a better job at protecting their patients? Dentists and their patients want more predictable results with fewer complications. I am sure that we can all do better.

Today implant companies sell their parts to dentists boasting claims of great precision of fit. However, **manufacturers do not share their technical information with dentists to support these claims**. Yes, when dentists purchase implant parts from any manufacturer, they are not given the technical information regarding their manufacturing tolerances. Without this information and working installation instructions, **how can a dentist take sole responsibility for treatment outcomes?** If not the dentist, who is then responsible for misfits and their consequences? Is it realistic for implant companies to treat dentists like mushrooms, keeping them in the dark then expecting them to take full responsibility for their patient's disappointing treatment results? Without such transparency, cooperation and respect across the industry, we will continue to flounder down the runway of Implantology, unable to attain new heights of excellence for the patients we serve.

How can we fix this problem of misfit parts? Today, the best solution is to install all implant manufactured parts optimally before installing the prosthesis. This way, dentists can easily install parts with ±5 microns of tolerance, or perhaps even better. Then the prosthesis, with adequate cement space to tolerate PDE can be used to pick up the implant parts in the mouth. Prosthetic components can be picked up the Svoboda Way or using the Svoboda Modification of the Screwmentation Technique. [4,8] A more efficient alternative would involve using the RM System of Installation, which is effective at preventing submarginal cement and safely tolerating both PDE and the TE. (Figures 4&5) [10]

In Conclusion: I believe that it is vitally important for manufactures to provide dentists with technical information regarding their designs and their manufacturing tolerances so that dentists can make informed choices about whose products they would like to purchase for their patients.

All companies selling implant parts should provide dentists with clear instructions for optimal assembly of their parts in the mouths of patients. These instructions should include probable risk factors for inherent mechanical deficiencies related to those instructions.

These recommendations are intended to make implant treatment better for all.

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Emil LA Svoboda Ph.D., DDS is a general dentist practicing implant dentistry at ParkPlace Dental Centre in Brampton. He is a Fellow of the AGD, an Honored Fellow of the AAID and a Diplomate of the ABOI/ID. He has lectured and published widely about making implant treatment better by design and protocol. He invented the Reverse Margin System to enable dentists to optimize the fit of parts and prevent the advent of residual subgingival cement. His articles are available for free download at www.ReverseMargin.com.

"A new standard of care is on the horizon for our patients. The dental industry has evolved tremendously and can make site-specific custom parts with microscopic levels of precision from biocompatible materials that are both esthetic and functional. We are lucky! Dentists must continue to be empowered by industry to fully exploit current technology for the benefit of their patients."