Below is a guest editorial by Dr. Dan Buser of Switzerland in the most recent AO News Magazine, advocating for a Hybrid Design ("HD") implant surface as being essential to avoiding peri-implantitis. It was accompanied by a second Article by Dr. Dennis Tarnow from Columbia University that went even farther, stating "Many companies who rejected the hybrid implant concept early on may have unintentionally contributed irreversible bone loss and implant failure, " This would include companies selling bone-level implants without a smooth collar, like Astra, Nobel, Straumann, Zimmer Biomet, and Implant Direct, all with documented high success rates. I was offended by the arrogance of these two well respected opinion leaders in taking such a know-it-all attitude and wrote a detailed response in a Letter to the Editor. I have posted it on **www.niznick.com** with 12 links and 12 pictures. When I sent Dr. Buser a copy of my critique of his article he responded: "You will understand, that in my age and private situation as young emeritus [Professor) and young grandfather, I will not even read this reply, since it is 5 pages long." Dr. Tarnow did not respond when I sent him a copy of my Letter to the Editor. Perhaps he will use this forum to clarify or modify his opinion on HD surfaces. Since this is such a critical discussion related to implant design, I hope that dentists using implants with textured surfaces to the top of bone-level implants and manufactures selling such products will take the time to understand the issues rather than be unduly influenced by two academics who have their own agenda. **Having a smooth collar on an implant is a personal preference, not an imperative for success.**

Historical prototype implants as basis of HD implants

Current HD implants from major implant companies

1960's Original Brånemark implant machined

1970's 1st Generation Straumann implants TPS

1986 2nd Generation Straumann implants machined + TPS

1993 Dennis Tarnows Hybrid Design implant machined + TPS

Late 1990's 3rd Generation Straumann implants machined + SLA

Late 1990's 3i Hybrid implant sandblasted + Osseotite

2000's Nobel Replace Select machined + TiUnite

2000's Thommen Medical SPI implants machined + Inicell

2000's 3i Hybrid machined + DAE

2010 Straumann TLX Implant machined + SLA

Fig. 1: This shows on the left the prototype implants which lead to the development of HD implants. On the right side, you see current HD implants, which are on the market.

Hybrid Design Implants: Is this the future in implant dentistry?

By Daniel Buser, DMD, Dr. med.dent., Professor emeritus, University of Bern, Academy News *Guest Contributor*

Dental implant surfaces have been a hot topic in the mid 1990s, when a paradigm shift from the machined to micro-rough implant surfaces took place (Buser et al., 2017).

The original implants tested by Prof. **Per-Ingvar Brånemark** at the University of Gothenburg in the late 1960s (Fig. 1), had a smooth, machined surface. The clinical examination showed several short comings, such as long healing periods, increased early failure rates, increased late failure rates in the maxilla, and the need for rather long implants up to 18 mm of length. On the other hand, these implants had a very low prevalence of peri-implant infections.

The second implant surface in the mid 1970s was the TPS surface used for the first generation Straumann implants and tested by the group around Prof. **André Schroeder** at the University of Bern. This was a rather rough, coated implant surface. These implants showed excellent osseointegration in preclinical and clinical studies, but also a new form of peri-implant infection, called peri-implantitis, which was first described by Mombelli et al. (1987). It was obvious that the rough TPS surface, being present in the transmucosal part of these one-piece implants, was a causative factor for the observed infections.

In 1986, the second-generation Straumann implants were two-piece implants with two implant surfaces, later called *Tissue Level* implants, with the TPS surface in the endosseous portion for optimal bone anchorage, and a machined surface in the neck area for the supracrestal, transmucosal portion. In 1993, **Dennis P. Tarnow** also proposed to use both implant surfaces to benefit from the synergistic characteristics of both surfaces and created the new term *Hybrid Design (HD)* implant (Tarnow 1993).

In the late 1990s, several micro-rough implant surfaces were introduced to the dental market produced by sandblasting and acid-etching, or acid-etching alone, such as the SLA®, Osseotite®, and Osseospeed® implant surface. The main arguments were a better and faster bone integration allowing shorter healing periods and shorter implants, reduced early failure rates, and the same success rates in both jaws.

Heated debates followed at implant congresses, and prominent speakers of the Brånemark group strongly argued that these micro-rough implant surfaces would cause a high prevalence of peri-implantitis. Despite this warning, all implant companies made a paradigm shift within a few years, and today, all relevant implant systems sold on the market have a micro-rough implant surface for improved bone anchorage.

In the past 20 years, implant therapy has seen a wide expansion, and today more than 30 million dental implants are yearly inserted around the globe. Several hot topics have been debated at implant congresses such as implant esthetics, the timing of implant placement, the timing of implant restauration/loading, and digital implant dentistry. In these areas, implant therapy made a tremendous progress for the benefit of our patients.

Another hot topic has been, and still is, peri-implantitis, which is a negative issue since it deals with a potentially severe complication of implant therapy. For more than 25 years, peri-implantitis has been discussed at consensus conferences, and analyzed with countless systematic reviews and position papers. Depending on defined criteria, the prevalence of peri-implantitis seems to be between 10 and 50%, a major problem from a public health point of view.

Many risk factors for the development of peri-implantitis have been discussed, such as a history of periodontal disease, poor oral hygiene, smoking, the lack of keratinized mucosa, medical diseases such as diabetes and so on. One factor has been overlooked for years: the implant surface in the transcrestal area of the implant shoulder.

Today, I am convinced, that a micro-rough implant surface exposed to the peri-implant sulcus is an important risk factor for the development of peri-implantitis, in particular when it is combined with other co-factors. When an implant has a micro-rough implant surface at the crestal bone, the likelihood to get exposed during initial bone remodeling activities is high. Therefore, an HD implant with a machined implant surface in the crestal area has a reduced risk for peri-implantitis.

This assumption is supported by recent clinical studies. The most important one is the study by Derks et al. (2015, 2016) comparing one HD implant system with two non-HD implant systems in Swedish patients. HD implants showed significantly lower failure rates (odds ratio of 5 and 6), and the lowest prevalence of peri-implantitis (odds ratio of 3.5 and 3.7) after nine years of function.

A recent 10-year study on 407 patients with 1,482 non-HD implants by Windael et al. (2021) reported that early bone loss of >0.5mm during the first year of function was a predictor for peri-implantitis. This resulted in a much higher prevalence of peri-implantitis. At 10 years, the failure rate was 5.2%, and the prevalence of peri-implantitis 11.8%. This study can be well compared with a 10-year study on 304 patients with 511 HD implants at the University of Bern (Buser et al. 2012). This study showed a failure rate of 1.2%, and a prevalence of peri-implantitis of 1.8% after 10 years of function. The examined implants were tissue level implants of Straumann, the first HD implants used in the market since 1986.

It's time to realize that we have a pandemic of peri-implantitis around the globe. The problem is triggered by colleagues with a poor surgical education, a lack of surgical talent, and not enough surgical experience. When an implant surgery is conducted with a low quality, the implant often has an exposed micro-rough surface to the peri-implant sulcus at completion of healing, and the development of peri-implantitis within a few years is most likely.

The easiest way to reduce this risk is the utilization of HD implants as proposed by Dr. Tarnow 28 years ago. Most of the major implant companies do have HD implants in their product line, but the clear majority of sold implants are non-HD implants. It's time to convince these companies to change that. We need a second paradigm shift in the market towards HD implants to reduce the prevalence of peri-implantitis. This would not only be a benefit for our patients, but also in the interest of all dentists involved in implant dentistry, and all implant companies.

References in this article are available via scanning the QR code.

My 40 year history of developing and manufacturing dental implants with 33 US patents gives me a unique perspective in implant designs and surfaces. I feel compelled to respond to the two articles in Volume 33 Number 1, 2022 of the Academy of Osseointegration's Quarterly News by two very distinguished educators and clinicians, Dr. Dan Buser and Dr. Dennis Tarnow. Both articles advocate for a hybrid design implant surface ("HD") on dental implants as being a significant factor in preventing the incidence of peri-implantitis and assuring long-term clinical success. After a close review of these guest editorials which I will refer to as "Articles," I do not believe that the published research supports their opinions and conclusions.

In the first article, Dr. Dan Buser asks the question, "Are Hybrid Design [HD] implants the future in implant dentistry? His conclusion is "clearly yes," stating HD implants will help to reduce the prevalence of peri-implantitis." My answer to his question is also yes but not because it is the main, or even a significant factor in reducing the prevalence of peri-implantitis. Hybrid Design surfaces on the endosseous portion of bone-level and tissue-level implants will remain an option in implant dentistry because companies need to differentiate their products and marketing story from their competitors. Respected opinion leaders, like Drs. Tarnow and Buser, drive implant manufactures to fall in line with their thinking, while other dentists, interested in speaking on behalf of those manufacturer, often have their opinions fall in line with the manufactures' designs. This creates a momentum for certain design features to be perpetuated, regardless whether they actually provide any clinical benefits.

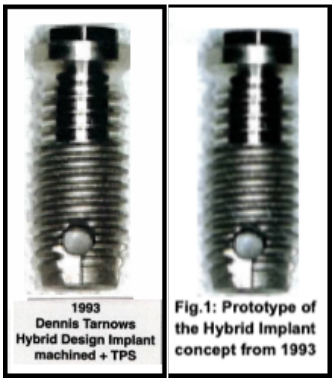
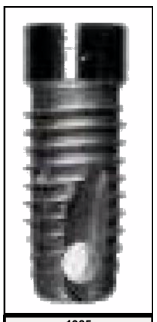


Fig.1: Prototype of the Hybrid Implant concept from 1993

To analyze the validity of their claims regarding HD implants, one needs to define what an HD implant is. The dictionary definition of "hybrid" is "a thing made by combining two different elements." Buser describes the first tissue level Straumann implant, introduced in 1986 as a hybrid design "with two implant surfaces…the TPS surface in the endosseous portion for optimal bone anchorage, and a machined surface in the neck area for the supra-gingival, trans-mucosal portion." The picture in Buser's article entitled "Current HD Implants from major implant companies" includes the original tissue-level Straumann implant (left) and its most recent one, the TLX (right) which was preceded in 2020 with the launch of the bone level BLX implant, both with the same connection and the SLA surface over the entire body of the implant intended to be imbedded in bone. Buser credits Tarnow for having "created the new term Hybrid Design [HD] implant" in 1993. He includes this picture (left) of an external hex HD implant mistakenly referring to the acid etched surface on the lower half as being TPS. Tarnow's article includes the same picture of the 1993 Prototype (from Implant Innovations) with a machined top half (10u grooves) and an even smoother bottom with an acid etched surface (2u pits). In 1997, I published a Technology Report discussing Controversies in Implant Surface Science (Pages. 17-24), demonstrating, the mischaracterization of this implant as being a HD design as Tarnow defines it in reference to his conception "28 years ago" (see below).

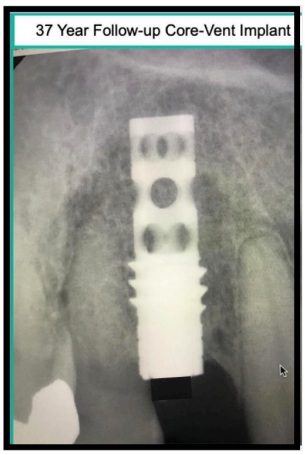

1985
Steri-Oss
Hybrid Design Implant
Machined & Etched

Dr. Tarnow's article, in discussing the "Origin and rational of the hybrid implant design 28 years ago" states: "it occurred to me [to] keep the top two or three millimeters of the implant machined ……and put the textured roughened surface in the middle and apical part of the implant." It also apparently occurred to Steri-Oss Implant company 8 years earlier, to design a HD implant as they launched this implant in 1985. Tarnow's definition of an HD implant would not include Straumann's Tissue Level implants with its TPS or SLA surfaces imbedded in bone and, according to Buser's article, its relatively smooth "machined surface in the neck area for the supra-crestal, trans-mucosal portion."

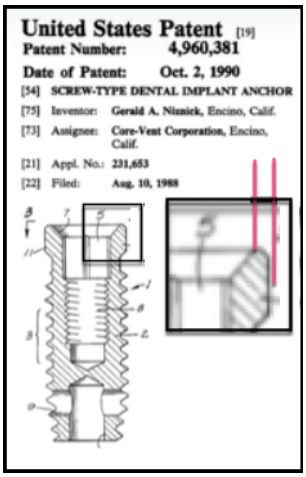
Dr. Buser cites three studies to support his contention that a HD surfaced implant reduces the incidence of peri-implantitis. Derks et al. (2015), referred to by Buser as "the most important one" compares one HD implant system [Straumann TL) with two non-HD implant systems [Astra and NobelBiocare] in Swedish patients. According to Buser, the "HD implants showed significantly lower failure rates and the lowest prevalence of peri-implantitis." This study reported only 1.4% early implant loss and only 2% late implant loss, so the differences between implants could not have been very significant. The study reported that the losses were higher in patients who smoked and those with a history of periodontitis. The Straumann TL implant, referred to by Buser as a HD implant, would not meet Tarnow's definition of a HD implant unless part or all of the machined neck was subcrestal. There is no indication that the Swedish dentists deviated from Straumann's 1-stage surgical protocol requiring the entire 2 mm of machined neck to be supra-crestal. Assuming there was a lower prevalence of peri-implantitis with Straumann's TL implants and assuming the machined neck was placed partially in bone, there are still many factors other than the hybrid surface that could account for any difference among the three implant systems. For example, the abutment junction on the Straumann TL implant would still be above the crest, whereas the two bone level implants would have this junction at or below the crest. There are also differences in surfaces among the 3 implants and differences in depth below the crest of the start of the threads that could effect bone recession. To conclude that a small difference in the incidence of failure or peri-implantitis relates only to the HD design is called "confirmation bias."

One of the studies Buser references is his own 2012 article using Straumann tissue level Implants. Buser reports the results of this "10-year study on 304 patients with 511 implants at the university of Bern [having] a failure rate of 1.2%, and a prevalence of peri-implantitis of 1.8% after 10 years of function. The examined implants were tissue level implants of Straumann." This disproves Buser's and Tarnow's contention that extending the rough surface to the crest of the ridge will result in an high incidence of peri-implantitis, and ultimately, compromise long-term success.

Tarnow states in his article "during the 1980s … most of us were using fully machined implants like the original Branemark implants. In the late 1980s and early 1990s…the desire to accelerate and increase bone to surface area contact evolved. This led to exploring different surface textures like SLA, TPS or HA coatings, which were believed to have a higher initial success rate in these softer bone areas."



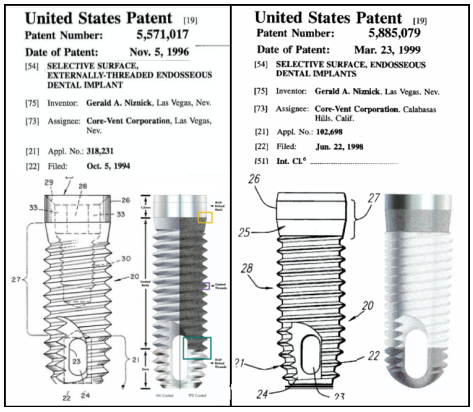
The Core-Vent implant was launched in 1982 with a SLA (sand blasted with large grit, followed by acid etching) surface extending to the top of the implant. The surgical protocol called for 1 mm to be placed supra-crestal to facilitate uncovering. Here is a 37 year follow-up x-ray of a 16 mm Core-Vent implant at a recall appointment to replace the abutment. Note the absence of bone loss around the 15 mm blasted surface that was initially imbedded in bone.


United States Patent [19]
Patent Number: 4,960,381
Date of Patent: Oct. 2, 1990
[54] SCREW-TYPE DENTAL IMPLANT ANCHOR
[75] Inventor: Gerald A. Niznick, Encino, Calif.
[73] Assignee: Core-Vent Corporation, Encino, Calif.
[21] Appl. No.: 231,653
[22] Filed: Aug. 10, 1988

By 1987, Core-Vent introduced the Screw-Vent Implant with its 45 degree lead-in bevel and internal hex, referred to today, regardless of the angle of the bevel, as an internal conical connection.This patented design (Niznick Pat. No. 4, 960,381 Issued 1990) is now the most widely used in the industry, effectively eliminated screw-loosening that plagued the external hex implants.The stability of the implant abutment junction cannot be underestimated when considering the causes of soft tissue complications, including peri-implantitis.

Tarnow has been a strong advocate for a platform switching interface developed with external hex connections. The internal, conical connection inherently provides platform switching, but it is the resistance to lateral forces and the protection provided to the fixation screw by the abutment's male hex, that significantly contributes to stability that maintains the seal.

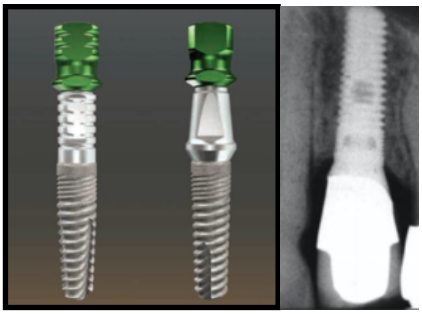
In 1987 Core-Vent introduced the Micro-Vent and Bio-Vent implants with a high crystalline Hydroxyl Apatite (HA) coating to the top of the implant. Core-Vent funded dentistry's largest multi-center, peer reviewed, prospective, implant study at 28 VA Hospitals and 4 Universities that included over 800 patients and almost 3000 implants. Dr. Tarnow may recall he served on the peer review committee for this study. The results were so significant that they were published in special issues of the Journal of Oral and Maxillofacial Surgery Volume 55 No. 12: 1997 and the Annalsof Periodontology Vol. 5 No. 1: 2000. The 3-5 years results were analyzed in an article by Drs. Harold Morris and Shigeru Ochi in J Oral Maxxilofac Surgery 56 1303-1311:1998. All the non-HA coated implants had a relatively smooth, acid etched surface. The results of this study lead Core-Vent to eliminate acid etching on its Screw-Vent by 1991, applying an SLA surface over the entire surface. The survival rate for HA coated implants was 97% in the posterior maxilla and 99% in the posterior mandible with 3-5 year follow-up.


United States Patent [19]
Patent Number: 5,571,017
Date of Patent: Nov. 5, 1996
[54] SELECTIVE SURFACE, EXTERNALLY-THREADED ENDOSSEOUS DENTAL IMPLANT
[75] Inventor: Gerald A. Niznick, Las Vegas, Nev.
[73] Assignee: Core-Vent Corporation, Las Vegas, Nev.
[21] Appl. No.: 318,231
[22] Filed: Oct. 5, 1994

United States Patent [19]
Patent Number: 5,885,079
Date of Patent: Mar. 23, 1999
[54] SELECTIVE SURFACE, ENDOSSEOUS DENTAL IMPLANTS
[75] Inventor: Gerald A. Niznick, Las Vegas, Nev.
[73] Assignee: Core-Vent Corporation, Calabasas Hills, Calif.
[21] Appl. No.: 102,698
[22] Filed: Jun. 22, 1998
[51] Int. Cl.[6]

In 1994 I filed a patent on what I termed Selective Surface, (Niznick U.S. Pat. # 5,571,617 Issued 1996). It had a smooth machined neck, a textured mid-section created by blasting with HA crystals (SBM) and a machined apical end to maintain a sharp self-tapping cutting groove. In 1998 I filed a patent on Dual Transition Surface,

By 2007 I had started a new company, called Implant Direct and launched the ScrewPlant, RePlant and Legacy Implant systems, all bone level implants with SBM textured surface treatment over the entire endosseous part of the implant. This decision was based on a number of studies that showed more bone recession with a smooth neck than one that had a textured surface. This was recently confirmed in A meta-analysis report by Qi Zhang & Xinxin Yue that assessed "8 manuscripts [2 randomized controlled trials and 6 controlled clinical trials from 6 clinical studies concluded 'rough threaded neck implants may be helpful in maintaining the amount of marginal bone around implants".



A 5 year clinical study of Implant Direct's Legacy Implants with a uniform SBM surface by Dr. Cavallaro from Columbia University documented 100% success with an average of 0.6 mm of bone loss: Implant Survival and Radiographic Analysis of Proximal Bone Levels Surrounding a Contemporary Dental Implant : Implant Dentistry Vol. 20, No.2:2011,

Buser concludes with the statement in the AO News, in reference to bone recession and subsequent peri-implantitis, "The problem is triggered by colleagues with a poor surgical education, lack of surgical talent, and not enough surgical experience." Furthermore, In a recent presentation at the Academy of Osseointegration 2022, Buser listed the surgical requirements to minimize or avoid early bone loss:

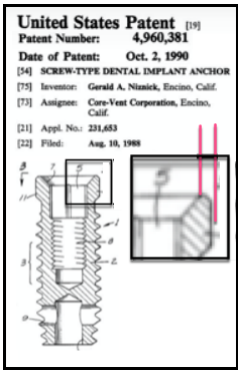
1. "The peri-implant bone walls must be at lest 1.5 mm at implant surgery"
2. "In case of a local bone deficiency > Contour Augmentation with GBR."

Buser's acknowledgement that such clinician related factors can lead to bone loss and subsequent peri-implantitis defeats his proposition that using a HD implant with a smooth machined or anodized neck will eliminate these complications.

Tarnow's article makes a number of unsubstantiated statements that require rebuttal:

1. **"As companies started to develop new surface characteristics, a new problem started to emerge from coating the entire implant to the top of the implant."**

   RESPONSE: This statement is refuted by the results of HA coated implants in the VA study. Furthermore, Buser's 10 year study of Straumann's tissue level implants with the entire endosseous portion being either TPS or SLA rough surfaces imbedded in bone, documented only 1.8% incidence of peri-implantitis.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[21] Appl. No.: 231,653
[22] Filed: Aug. 10, 1988

2. **"What was forgotten by the companies was that biologic response to abutment connections, which causes the biologic width on the implant to move down to the top of the implant on bone level implants after multiple disconnections. "**

   RESPONSE: Tarnow adds two additional factors other than just the lack of a smooth neck, that he claims will contribute to bone loss and could lead to exposure of a rough surface?
   1. "biological response to abutment connections" and

The internal conical connection provides stability and platform switching

2. "Multiple disconnections" of the healing collar and/or abutment.

3. RESPONSE 1: One of Tarnow's prior articles concluded "to reduce the effects of peri-implant bone resorption, a technique known as platform switching was recently developed….By shifting the implant-abutment interface medially, the deleterious impact of the implant-abutment micro gap on the peri-implant bone can be reduced." Tarnow fails to point out that this only applies to external hex implants as conical connections have an inherent platform switching interface. A recent prospective clinical study with a 1 year follow-up, concluded there was no difference in bone recession between platform switching and platform mating implants.[JOMI 36:5 2021 Page 945]

   RESPONSE 2: If Tarnow believes that multiple disconnections of the healing collar and/or abutment contribute to bone recession and possible exposure of a rough surface at the neck of the implant, then this can be avoided by using tissue-level implants, one-piece implants or healing collars that can remain attached to the implant and be utilized as the trans-mucosal neck of an abutment. This concept was first introduced in 1994 with Healing Collar Packaging (Niznick U.S. Pat. No. 5,622,500) and more recently popularized by NobelBiocare's "On-1" healing collar system.

3. **"In 1993, the concept was first published showing the prototype of a newly defined category of the hybrid implant. That was 28 years ago"**

   RESPONSE: The concept of a hybrid, two-stage implant was introduced in 1985 by Steri-Oss 37 years ago. Tarnow deserves credit for coining the term Hybrid Design ("HD"), but Selective Surface hybrid design (Niznick U.S. Pat. No. 5,571017 Filed 1994) and Dual Transition hybrid design (Niznick U.S. Pat. No. 5,885,079 Filed 1998) were incorporated into bone-level implants with SLA and/or HA coated implants sold by Core-Vent/Paragon in the 1990s.

4. **"It is amazing to me that it took so long for many companies to realize this concept makes sense for the short- and long-term success and survival of the implants ."**

   RESPONSE: It is amazing to me that Dr. Tarnow can reach such a conclusion in the face of the success reported with many systems that do not offer a HD surfaces on their bone level implants, Those include Implant Direct, BioHorizons and Astra, Straumann also has tissue level implants with a smooth neck that could be used as a HD since 1984 and bone level implants with a SLA surface to the top since 2015. Zimmer Biomet sells the Screw-Vent with and without a HD surface and its Screw-Vent with a Trabecular Metal insert, shown in Fig. 2 of Tarnow's article as a HD implant, has its SBM surface to the top.

5. **"Many companies who rejected the hybrid implant concept early on may have unintentionally contributed irreversible bone loss and implant failure,** "

   RESPONSE: Tarnow cannot cite to any study that proves a direct connection between the use of a HD bone-level implants and reduced bone loss. Many companies today have rejected the HD concept based on studies showing a smooth neck encourages bone recession. Tarnow needs to differentiate between porous surfaces like TPS and TiUnite, which may be a problem if exposed in the gingival sulcus and a textured surface, like SLA, (AlO2 blast) and SBM (Soluble HA Blast Media) that have been proven to reduce bone

recession

6. **"In my opinion, this may have also impacts some of the leading implant companies over the years going from being the most used implants to falling behind other companies who had the foresight to see this problem and make a change".**

   RESPONSE: Tarnow is obviously referring to NobelBiocare who lost its leadership position to Straumann in global sales. Recently, Nobel introduced a HD surface with a gold colored, anodized neck to distance its porous TiUnite from the top of the implant. Straumann converted from porous TPS to textured SLA 25 years ago. A 2012 published study by Buser using Straumann's tissue level implants with its SLA surface extending down from the crest of the ridge, demonstrated only 1.8% incidence of peri-implantitis after 10 years of follow-up. Some bone recession, given the number of implants in the study (512), must have had exposure of the SLA surface, yet this did not significantly contribute to peri-implantitis.

7. **"It is extremely encouraging to see today so many of the major implant companies have followed a hybrid implant and have a less rough surface at the coronal third of the implant, even if the top is not machined and that they put their highly textured surface in the middle and apical thirds of their implants. Bravo!"**

   RESPONSE: Some implant manufacturers may utilize a HD implant surface because they believe it is a benefit, or to differentiate from the competition. Some will use a HD design to conform with what opinion leaders of Tarnow's stature are advocating, regardless of their belief in the validity. A number of leading implant manufacturers have demonstrated long-term clinical success with their non-HD designed implants and will not see the need to change just to receive a "Bravo" from Dr. Tarnow.

8. **"This will hopefully bring us to a point where we minimize the bone loss around our implants over time and have a higher survival and success rate long term for our implants."**

   RESPONSE;
   If Tarnow had gotten on board with Core-Vent's internal hex, conical connection implants and our HA coated and SBM textured surface implants in the1980's and 1990s, instead of the Branemark and 3i external hex, smooth surface implants, he would have been at the point "where we minimize bone loss" and "have a higher survival and success rate" over two decades ago.