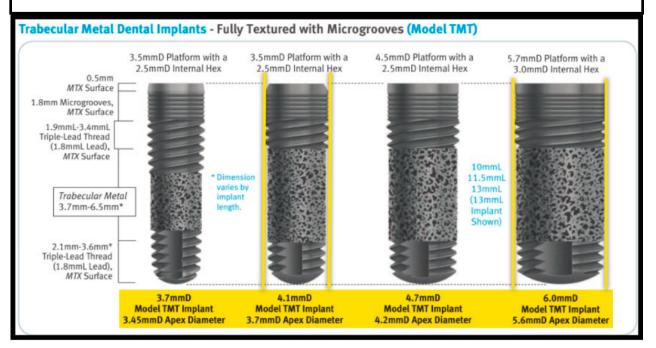
Analysis of the Shortcomings of ZimVie's Tapered Screw-Vent with Trabecular Metal

I sold Core-Vent/Paragon to Zimmer Dental (today ZimVie) in 2000 along with the patent on the conical connection and the patent on the friction-fit abutment. For the last 21 years the TSV with its friction-fit abutment has been ZimVie's flagship product with remarkable success. I formed Implant Direct in 2004 and in 2007, when the patent on the conical connection expired, I launched the next generation of TSV which I called the Legacy implant. Both the TSV and Legacy had the standard Branemark "V" shaped threads but to the Legacy, I added the patented quadruple lead micro-threads above the double lead body threads. In 2008 I designed Legacy2 with progressively deeper flat-based threads. My new implant company, Paragon, is developing the GEN5 implant with the same body and surface as the Legacy2 but with a 2.5mm machined, anodized neck to accommodate for uneven ridges and subsequent bone remodeling.

In 2010, ZimVie, to create a unique selling proposition, added a Trabecular Metal ("TM") insert to the TSV, which, by 2012, triggered an FDA Recall. The threaded end of the implant repeatedly separated from the body of the implant when it engaged bone on full seating. The solution was to prepare the socket with a straight rather than step drill to prevent the threaded apex from engaging bone. As can be seen from the picture below from the ZimVie catalog, the TM implants are basically straight with a slightly tapered apex. The 3.7mmD implant has only a short section of Trabecular Metal while the wider implants have longer sections. Initial stability is enhanced by thread engagement and a tapered body. The U.S. list prices are: TM @ \$550, TSX @ \$540, TSV @ \$507, Legacy2 @ \$200.



2 of 10

ZimVie's claims that the Trabecular Metal insertion on the Screw-Vent generates a "BioBoost Effect" that provides a "seemingly super natural multiplication of naturally occurring growth factors, delivering faster healing and earlier bone formation than traditional implants." This is at best unproven and at worst pure sophistry. (definition sophistry — "the use of fallacious arguments, especially with the intention of deceiving").



ZimVie Claims the following advantages of its TM Screw-Vent:

1. "Risk Management - Expanding treatment in poor bone."

The Tapered Screw-Vent's soft bone surgical protocol addressed the risk of placing an implant in poor quality bone by undersizing the socket.

2. "Rapid Recovery - Accelerating healing with a 2-week final loading protocol."

Implants that achieve 30+Ncm of initial torque can be loaded immediately. Replacing half the length of the threads with a porous titanium mesh and using a straight rather than tapered implant detracts from initial stability and limits immediate loading success. Research has shown that stability of an implant decreases by week 2-4 following insertion but by week 7-8 its initial level is re-established. High initial stability makes initial reduction in stability irrelevant.

3. "Revision therapy - Leveraging the healing advantages in implant replacement."

Replacement of a failed implant requires establishing initial stability which is facilitated by greater thread engagement. ZimVie offers the HA coated TSV which could leverage the healing advantage.

ZimVie's Encode Scanning Healing Collars were recently updated to improve the emergence profile. Today, most companies offer reasonable priced scan adaptors which accomplish the same thing. Healing collars are of limited use with the increased popularity of immediate loading of overdenture, multi-unit & cementable abutments.



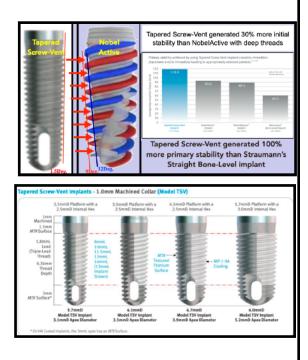
T3 PRO's platform is compatible with Encode® Emergence which further provides hard and soft Tissue maintenance

T3 PRO implants are available with a coronal platform-switching feature. In platform-switched T3 PRO, the outer edge of the implantabutment interface is repositioned inwardly and away from the outer edge of the implant platform.

Analysis of the Shortcomings of ZimVie's "Updated" Tapered Screw-Vent, Called TSX

ZimVie's website references a torque comparison study showing that the Tapered Screw-Vent ("TSV"), following <u>the soft-bone</u> <u>surgical protocol developed for that implant in</u> <u>1999</u>, already achieves extremely high primary stability — 30% higher than the NobelActive and 100% higher than the straight Straumann TL implant.

In 2023 ZimVie launched the TSX Implant, claiming its Unique Selling Proposition was: *"Going to the Xtreme for primary stability and peri-implant health."* The increased stability claim relates to adding progressively deeper threads. The initial stability is already extremely high with the TSV, created by inserting this tapered implant into an undersized socket. The claim of "peri-implant health" relates to the neck of the TSX implant being acid etched which is smoother than the rough, blasted surface BUT one option with the TSV is a 1mm machined neck which is smoother than an acid etched surface.



ZimVie's US list price for the TSX is \$540 vs \$507 for the TSV. The difference of \$33 is probably more than it cost to make either implant. Besides some cosmetic changes, the TSX adds bi-directional cutting grooves which can compromise stability by creating bone chips rather than compressing bone.

What is the difference between the TSX and TSV to justify the price increase?

With the TSX, ...

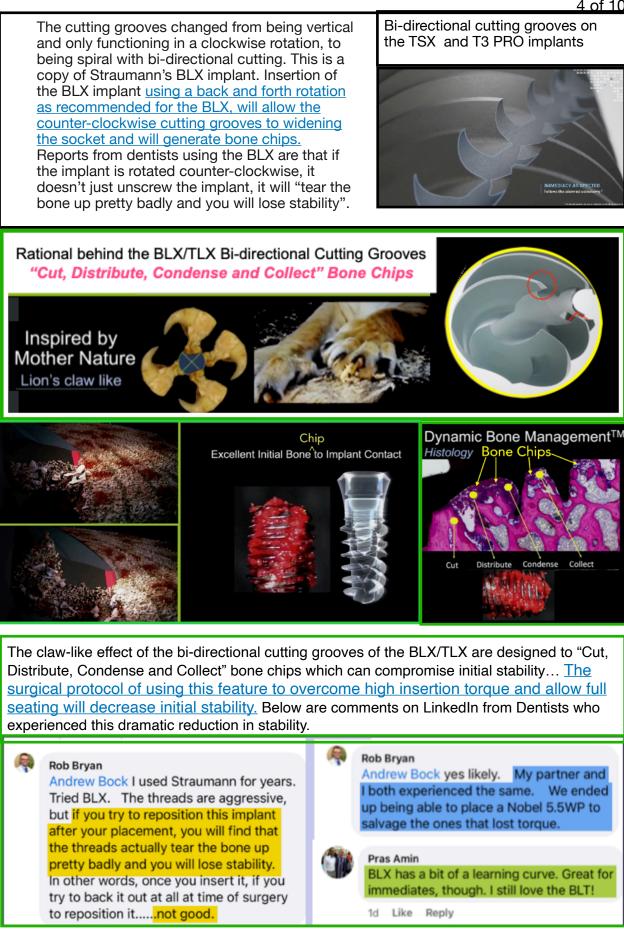
- (1) The threads get progressively deeper. Deep threads alone do not increase initial stability as shown by ZimVie's comparison study between the TSV and NobelActive.
- (2) The TSX replaces the smooth, machined neck of the TSV with an acid etched, textured surface that was on the body of the Certain 3i implant since 1996. ZimVie calls this surface Osseotite claiming it "has no higher risk of periimplantitis than machined titanium". 3i/Zimmer Biomet/ ZimVie offered the Certain internal connection and external hex implants with a hybrid surface i.e. with an acid etched Osseotite surface on the body claiming it was rougher than the machined surface on the neck.







4 of 10



Analysis of the Marketing Claims of ZimVie's Updated Certain Implant, Called T3 PRO

ZimVie claims that the T3 PRO is "Engineered with a laser focus on stability." ZimVie modified its Certain Implant by adding the same progressively deeper threads and spiral, bi-directional cutting grooves as with the TSX. Achieving high (35+Ncm) intial stability in soft bone is accomplished by inserting a tapered implant into an undersized socket. ZimVie has demonstrated that the TSV provides 30% higher initial stability than the NobelActive with its deep threads and spiral cutting groove.

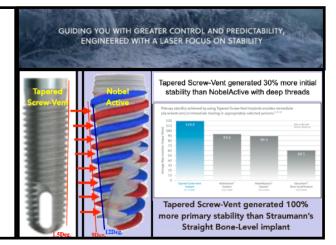
T3 PRO claims to have a "Contemporary hybrid surface." The Osseotite® micropitted, acid etched surface on the body of the Certain implant replaced the machined neck and a blasted surface replaced the Osseotite surface on the body. It is questionable whether the Osseotite on the neck is an advantage vs machined surface.

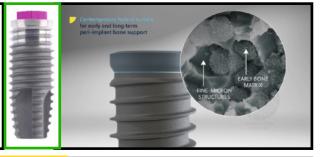
T3 PRO tapers the inside thread diameter greater than the outside in order to make the thread depth progressively deeper towards the apex. Implant Direct's Legacy implants made this change in 2008, 15 years ago. The implant In the yellow box is a GEN5 with 2 vertical cutting grooves and progressive, buttress threads.

T3 PRO has spiral, bi-directional grooves with chisel. This is the same design as the Straumann BLX implant introduced in 2019 that generates bone chips rather than compressing the bone. The implant in the yellow box is a BLX with bone chips between the threads and in the grooves.

ZimVie claims "the foundation of T3 Pro remains the unique Certain connection ... Better Seal Integrity than Conical and Other Flat-on-Flat Connections."

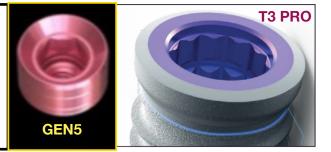
It is a widely accepted that conical connections provide greater stability and seal than flat-on-flat connections.

















40 YEARS OF INNOVATION 37 PATENTS - 4 SPECIFIC TO GEN5



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RESEARCH SUPPORTS REDUCTION OF PERI-IMPLANTITIS BY USING A HYBRID DESIGN SURFACE WITH THE IMPLANT-ABUTMENT JUNCTION SUPRA-CRESTAL

Applies to Straumann's TLX implant and Paragon's GEN5 implant BUT not the BLX

Dr. Niznick Article: AO News Vol.33 No. 2, 2022:

"Dr. Buser cites a Swedish 10-year study comparing three implants: Astra, NobelBiocare and Straumann's Tissue Level implant, claiming the latter exhibited

significantly less peri-implantitis. Assuming part of the smooth neck of the Straumann TL implant was inserted in bone, this would give it a hybrid bone interface. It also adds the variable that the implantabutment connection would be supra-crestal... [which] is at least as important a factor in minimizing peri-implantitis as a hybrid surface." **Dr. Michael Dard, Prof. NYU Interview:**

- 1. Explains peri-implantitis and
- 2. Discusses results of the Derks et al study

Video Lecture and interview of Dr. Daniel Buser, explaining importance of Hybrid Surface and how he partially submerges smooth neck of "Tissue Level" Implants

Dr. Daniel Buser explains insertion of Straumann's "Tissue Level" implant with 1.8mm of its 2.8mm smooth neck sub-crestal, leaving 1mm and the implant-abutment junction, supra-crestal.

Buser Quote on Straumann's Website: "The Future of Implant Dentistry is with neck designs combining a smooth surface in the trans-mucosal area with a micro-rough surface inside the bone. As the Derks study showed, moving the micro-gap away from the bone and having a smooth surface in the peri-implant sulcus reduces the risk of peri-implant complications." Derks 9 Year Comparative Study

PARAGON'S GEN5 IMPLANT HAS A 2.5mm ANODIZED, SMOOTH NECK, CONFIGERED TO BE 1mm SUPRA-CRESTAL



Peri-implantitis in independent study Odds ratios of peri-implantitis at 9 years after implant placement.

> Nobel Biscar Astra Tech



Influence of Implant Placement Depth and Soft tissue Thickness on Crestal bone Stability Around Implant with and Without Platform Switching

This case control study measured early crestal bone changes around sub-crestal placed platform-switched implants surrounded by thin soft tissue and compared them with regular, matching-platform implants placed in a supra-crestal position and surrounded by thick soft tissue. After 1 year, mean bone loss was 0.28 mm (SD:0.36 mm; range: 0.1-1.63 mm) in the

control group and -0.6 mm (SD:0.55 mm; range: 0.05-1.8 mm) in the test group. Platform-switched implants placed in a subcrestal position in vertically thin soft tissues showed statistically significantly more bone loss than non-platform-switched implants placed supra-crestal with vertically thick tissues.



Fig 2 (a) Control group patients had implants placed in a supercreastal position, and (b) test group patients had implants placed in a sub-

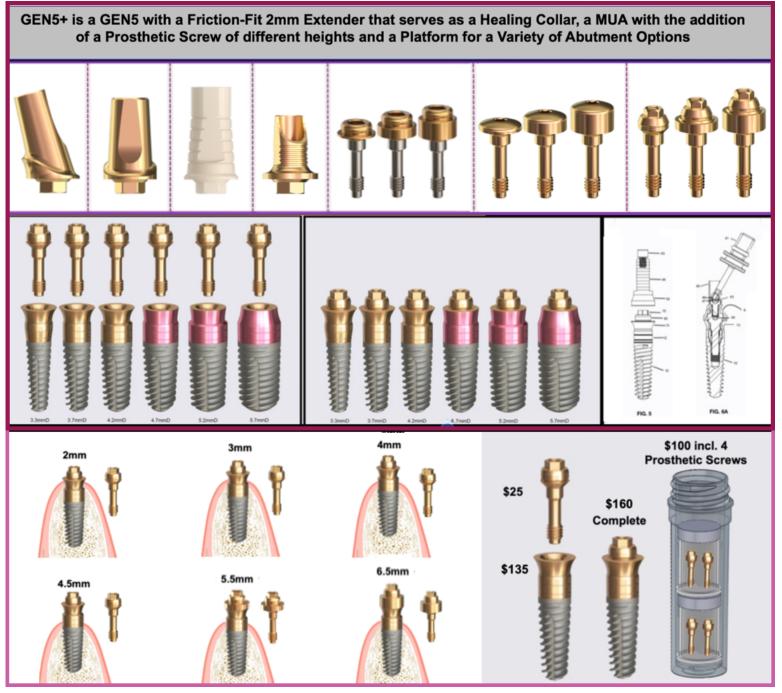
Paragon's GEN5[™], GEN5+ and NizPlant[™] implants have the same implant body with a 2.5 mm machined, anodized neck. Depth gauge lines at 1 mm, 2 mm and 2.5 mm from the top (Pat. Pend.), along with 2 depths of drill stops, facilitate placement level with or 1mm above the crest of the ridge. The insertion depth control, in conjunction with the ability to varying the height of the prosthetic screw, minimizes the need and cost of maintaining an inventory of abutment heights. The GEN5+ offers the additional flexibility of a 2 mm friction-fit collar that can serve as the trans-mucosal collar of an abutment or be removed for abutment connection directly to the top of the implant for unprecedented vertical flexibility.



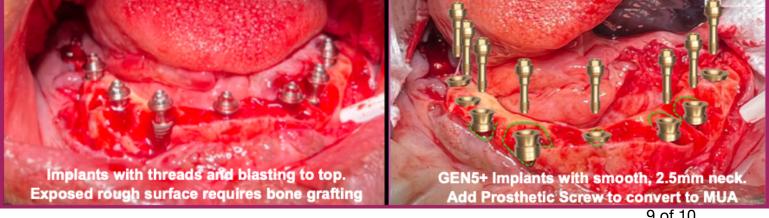
Each Paragon implant is 1 mm longer than the standard lengths of the respective Screw-Vent and Legacy implants. Paragon's surgical system includes two options of drill stops. One is for placement 1mm supra-crestal, which moves the implant-abutment junction away from the bone and and creates a 1mm supra-crestal zone of titanium for undisturbed soft tissue attachment when prosthetic components are attached and removed from the implant. The other drill stop positions the implant level with the highest point on the the ridge, usually on the lingual, leaving the smooth neck exposed if there is bone recession on the labial/buccal. The diameters of the drill stops and the freedom of rotation of the drills within the drill stops allow there use through surgical guide without the need for keys.







Simulated case (right) shows 8 GEN5+ implants replacing exposed implants (left). Little or no bone grafting needed because only smooth surfaces exposed. Attaching a Prosthetic Screw converts platform to standard MUA.



Patented Features of the 1-Piece NizPlant Implant with its Dual-Function Platform

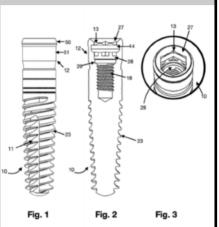


NIZPLANT 1-PIECE IMPLANT WITH DUAL FUNCTION PLATFORM FUNCTION AS OVERDENTURE AND MULTI-UNIT ABUTMENT

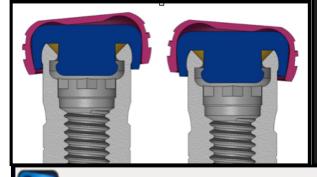
NizPlant 1-Piece Locator Compatible Implant with Internal Threads

ABSTRACT:

A screw-type endosseous dental implant includes, near the top on the implant's external surface, a ridge projecting laterally, and an internally-threaded shaft with a lead-in, beveled opening, an internal wrench-engaging surface located below said lead-in, beveled opening, and, below said internal wrench-engaging surface and above said internal threads, an internal undercut/groove forming a chamber configured to receive a snap attachment for retention of an over-denture.



NizLoc Attachments Engage both outside and inside of the NizPlant implant. The male projection can be removed to reduce the degree of retention.





Zest LODI 2-Piece Implant with Over-denture Attachment @\$220, Includes Cap Attachment Components

NizPlant 1-Piece Implant with Dual Function Platform @ \$150, Includes Cap Attachment Components

