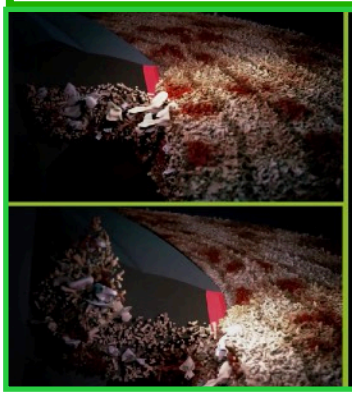
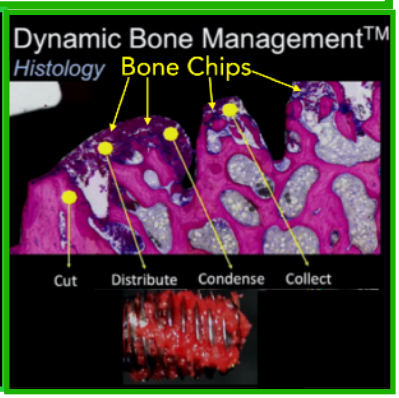
SHORTCOMINGS OF STRAUMANN'S BLX/TLX IMPLANT SYSTEM

Achieving initial stability in soft bone, needed for immediate loading, is best achieved by inserting a tapered implant into an undersized socket to compress soft bone.

Straumann claims BLX/TLX implants are "Fully Tapered". In fact, they are straight for the top 12 mm with an extremely tapered inner core that creates space for bone chips.

Spiral, bi-directional "claw like" grooves create bone chips > deposited at the recesses of the deep threads and sluiceways, rather than condense bone



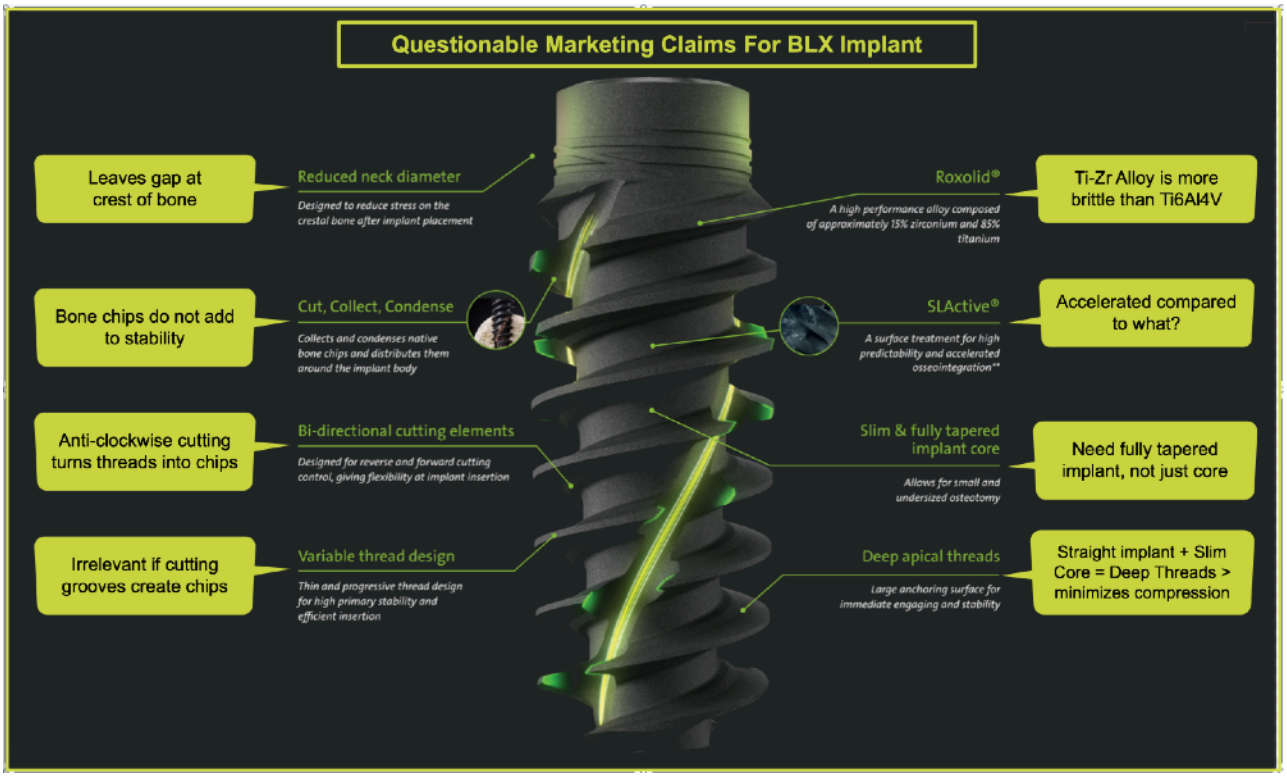


Straumann's flagship product line is now the BLX (Bone Level) and TLX (Tissue Level) implants with only 1-3 years of clinical documentation. Both have the same thread design and a 7 degree internal connection, called TorcFit. The BLX is a traditional bone-level implant with a blasted surface to the top, while the TLX has a 1.8 mm or 2.8 mm smooth neck. Both implants are straight for the first 12 mm with a tapered core so that the threads get deeper towards the apex. Both have spiral, bi-directional cutting grooves designed to "cut, distribute, collect and condense" the bone chips created by the "lion's claw like" cutting grooves. It is a well established principal that inserting a tapered implant into an undersized socket in soft bone increases stability.

1. Inserting a straight implant into an undersized socket risks fracture of the bone

2. Rather than condense bone for increased stability, these implants turn bone into chips, and collect these chips between the deep threads and cutting grooves. Condensing bone increases initial stability whereas turning cortical bone into bone chips does not.

3. Having a single diameter internal connection for 7 diameters of implants, limits the ability to create a natural emergence profile. Wider abutments that overlapping the shoulder of the implant are available for the 3 widest BLX implants. This defeats the advantages of the frictional retention of the implant's internal conical connection, thereby increasing the chance of screw loosening.



MISCONCEPTION #1: Straumann's SLActive surface treatment reduces healing time by 50% Straumann claims its SLActive Surface Technology "Accelerates Osseointegration [for] Reduced Healing Time….You can reduce your patients' healing time by 50%."
A review of the studies relied on by Straumann do not support its claim that SLActive surface "reduces healing time by 50%". On their face, these claims are suspect because they do not say 50% faster than what. These claim comes from studies by Straumann's paid opinion leaders over a decade ago, who merely loaded the SLActive implants at 4 weeks compared to the then recommenced 8 weeks. When the implants still achieved Osseointegration, they claimed the surface was responsible for cutting the healing time in half, when all the study did was cut the loading time

Straumann charges **$479** for the BLX implant with the SLA surface while charging **$535** for the same implant with its "hydrophic" SLActive surface. The difference in packaging the same implant in a sterile saline solution maybe cost a few dollars more in contrast to the **$56** more Straumann is charging for the more expensive packaging.

A 2021 study in JOI Vol. 47, Issue 2 concluded: *"The present study demonstrated that dental implants provided with a hydrophilic moderately roughed surface….did not show any significant improvement of pripimary or secondary stability compared with implants provided with a hydrophobic surface"*

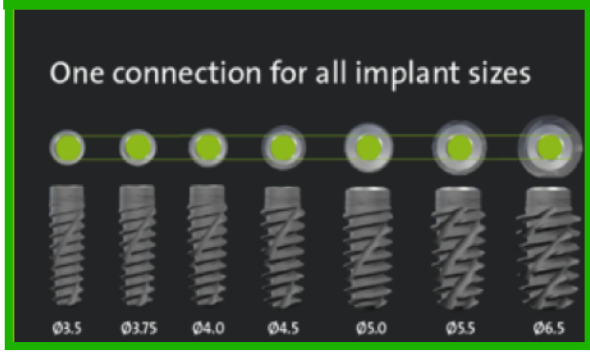
MISCONCEPTION #2: Roxolid is stronger than Ti6AL4V used by most manufactures.
Straumann's implants are made from an alloy of Titanium and Zirconium. Most other implant companies use Ti6Al4V which has a modulus of elasticity more than twice that of Ti16Zr and therefore, is less brittle.

"Young's modulus is ***a measure of the ability of a material to withstand changes in length when under lengthwise tension or compression****. Sometimes referred to as the modulus of elasticity, Young's modulus is equal to the longitudinal stress divided by the strain."*

Table 1. Mechanical properties of Ti and Ti-based alloys (adapted from [8,16,18,20]).

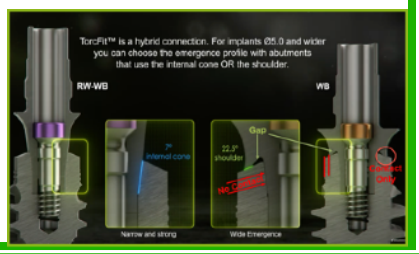
Material	Young's Modulus (GPa)	Tensile Strength (MPa)	Elongation (%)	Density (g/cm3)
cp-Ti	104	450	15	4.5
Ti6Al4V	113	860	10	4.4
Ti6Al7Nb	100	995	14	4.5
Roxolid Ti16Zr	54.5	953	12	4.75

MISCONCEPTION #3: Using only one connection "simplifies workflow".
Straumann claims that by using only one connection for all the diameters of BLX and TLX implants, they have "Simplified Workflow [and] Reduced inventory." While it is true that only having one connection would reduce the inventory of abutment and transfer components, this has nothing to do with a "Simplified Workflow." Color coded platforms and prosthetic components as well as All-in-1 packaging simplifies workflow.



MISCONCEPTION #4: Using only one connection to reduce inventory is worth the compromise of not being able to achieve and esthetic and hygienic emergence profile
The major shortcoming of having only one connection for 7 diameters is the unaesthetic and unhygienic emergence profile that is created when using abutments that fit into the conical connection of wider implants, leaving the implant's shoulder exposed.

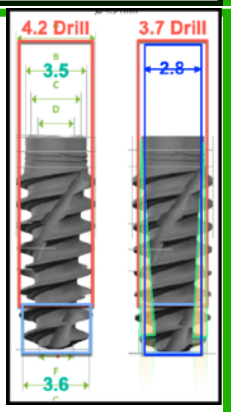
MISCONCEPTION #5: Straumann can overcome the BLX's emergence profile problem by offering abutments that seat on the shoulder of the implant.
Straumann offers a wider abutment option for the 3 widest implants, that seats on part of the implant's shoulder. Straumann claims its TorcFit is a hybrid connection that can interface with either the internal 7 degree cone or the shoulder of the implant. As shown below, the wider abutments only make contact on its periphery. Abutments that seat on the top of the implant cannot also engage the internal conical connection, sacrificing stability for a better emergence profile. Paragon's new conical connection includes a deeper Morse Taper connection for a friction-fit even when the abutment seats on the top of the implant.



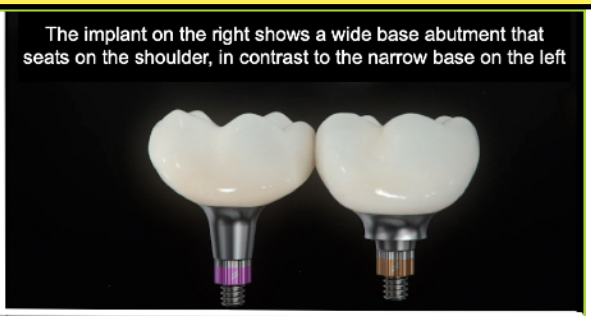
MISCONCEPTION #6: Having the neck of the implant narrower than the thread diameter reduces stress at the crest of the ridge.
The thread diameter of the wider implants are greater than the diameter of neck of the implant. That difference increases with the wider implants. Straumann claims the narrow neck reduces stress at the crest. What it does in actuality, is reduce stability because of lack of contact near the crest. It also leaves a gap at the crest of the ridge that could encourage soft tissue down growth.

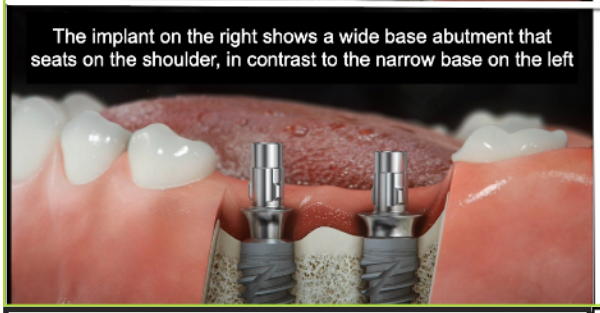
MISCONCEPTION #7: Straumann claims the BLX's fully tapered core "allows for insertion into a small and undersized osteotomy".
The BLX Implants are basically straight with only a slight reduction in diameter to the outside thread diameter below the top 12 mm. Forcing a wide apex of an implant into an undersized socket increases the risk of bone fracture and may cause the implant to not fully seat, even when using the widest drills recommended for dense bone. BLX's final seating in dense bone may require the reverse cutting grooves to enlarge the site by turning more bone into bone chips. This video shows that for a 4.5mmD implant, final sizing with a 4.2mmD drill may not be enough bone reduction to fully seat the implant. The concept of inserting a tapered implant into an undersized socket was first explained in a 1995 patent (Niznick U.S Pat #5,427,527) and documented in a 2000 Niznick Journal Article. This picture compares the apex of a 4.7mm X 13 mm tapered GEN5 to a 4.5 mm X 12 mm BLX. The GEN5's apex could start more easily into an undersized socket.

MISCONCEPTION #8 & 9: The BLX implant's deep threads provide "a large anchoring surface for immediate engaging & stability".
Straumann recommends different drill sequences for soft, medium and dense bone. For a 4.5 mmD Implant in soft bone, a 2.8 mmD drill is recommended for final sizing. Forcing an implant into a socket about half its diameter increases the risk of fracturing the bone. Even then, only about half the depth of the apical threads are engaging bone with bone chips filling the void. In medium bone, a 3.7 mmD final sizing drill is recommended. This results in only about 1/3 of the depth of the threads engaging bone initially. In dense bone, a 4.2 mmD final sizing drill is recommended. This results in only 4.5-4.2/2 = 0.15 mm of thread/bone engagement. BLX's surgical prodocol of going back and forth using the bi-diretional cutting grooves to to fully seat the implant will reduce stability.



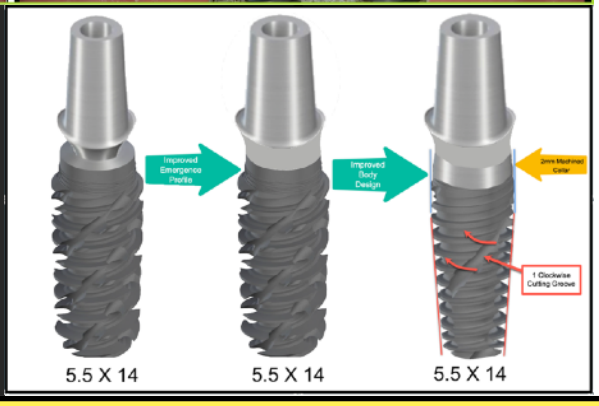
The series below shows the narrow and wide abutment options, neither of which achieve a natural emergence profile from the implant's diameter to the abutment and crown



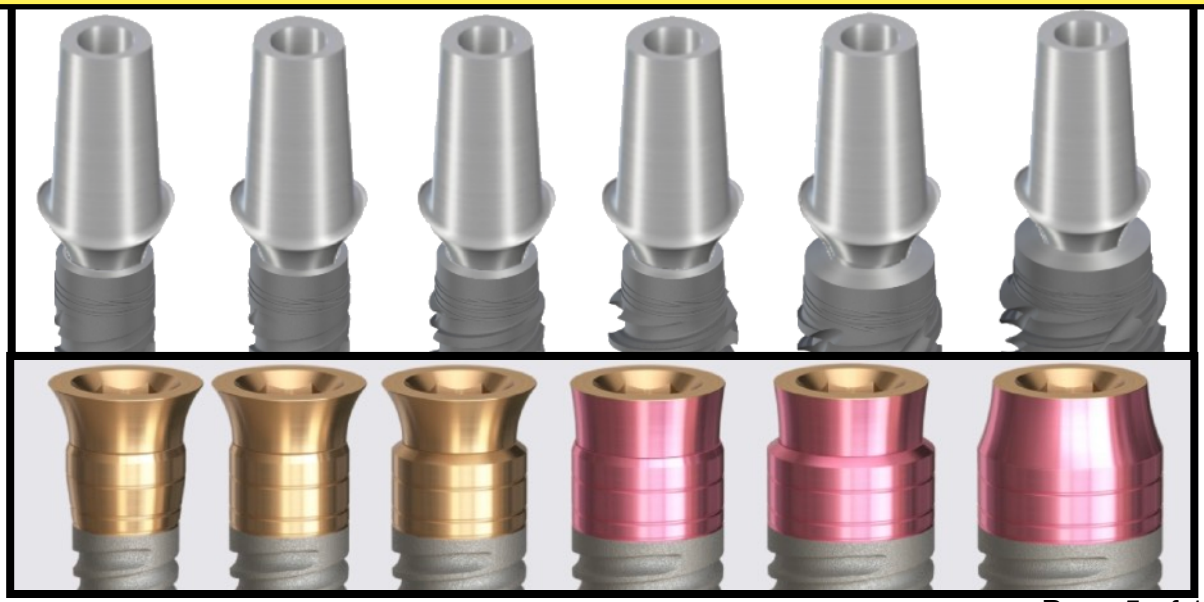


THE DESIGN OF STRAUMANN'S BLX IMPLANT COULD BE IMPROVED BY:

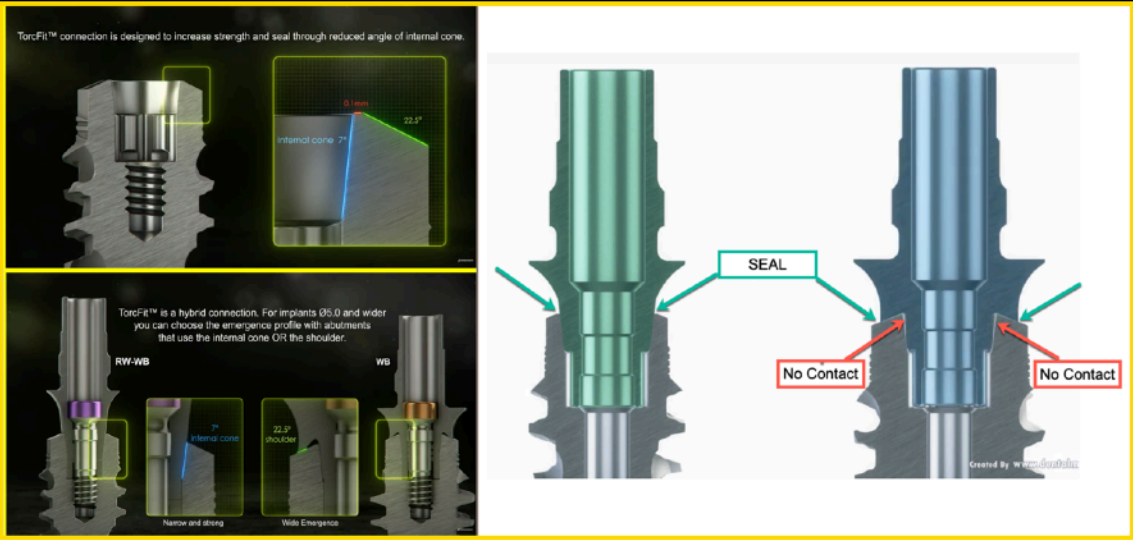
1. Tapering the outside threads about half as much as the taper of the core;
2. Reducing the number of spiral grooves and eliminating counter-clockwise cutting;
3. Adding a wider diameter connection to improve emergence profile on wide implants or incorporating GEN5 connection
4. Adding a machined collar between the top of the implant and the first thread;



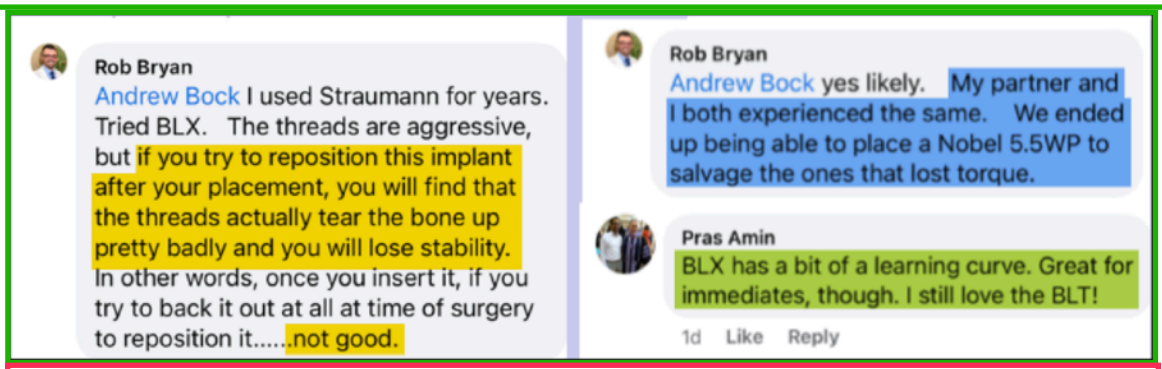
Below are BLX straight abutments in implants ranging from 3.5mmD to 5.5mmD, and below that are GEN5+ implants ranging in diameter from 3.3mmD to 5.7mmD with their 1.8mm high friction-fit extenders. NOTE the difference in emergence profile between the two systems.



Straumann acknowledges need for wider abutment but with just one diameter internal conical connection, they need to overlap the implant shoulder with a wider abutment. This sacrifices the stability achieved by engaging the internal conical connection.



The aggressive threads and cutting grooves of the BLX/TLX turn the soft bone into an autogenic bone graft which compromises initial stability. The claw-like effect of the bi-directional cutting grooves. The surgical protocol of using this feature to overcome high insertion torque and allow full seating will decrease initial stability. Below are comments on LinkedIn from Dentists who experienced this dramatic reduction in stability.



ZimVie's Torque Tests confirm increasing the depth of the threads actually decreases initial stability. Screw-Vent generated 29% more insertion torque than the NobelActive implant.
Niznick 1995 Patent #5,427,527: Dental Implant Method of Installation
Niznick G., Article, Oral Health, August 2000: Achieving Osseointegration in Soft Bone:

Video interview of Dr. Daniel Buser, Prof. Emeritus, University of Bern, explaining how Straumann's "Tissue Level" Implants are actually placed only 1mm supra-crestal.

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."

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

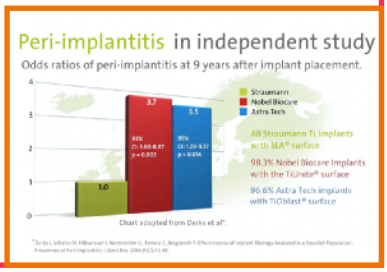
RESEARCH SUPPORTS REDUCTION OF PERI-IMPLANTITIS BY USING A HYBRID DESIGN SURFACE WITH THE IMPLANT-ABUTMENT JUNCTION SUPRA-CRESTAL
Applies to Straumann's TLX implant and Paragon's GEN5 implant BUT not the BLX

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 implant-abutment 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**



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.

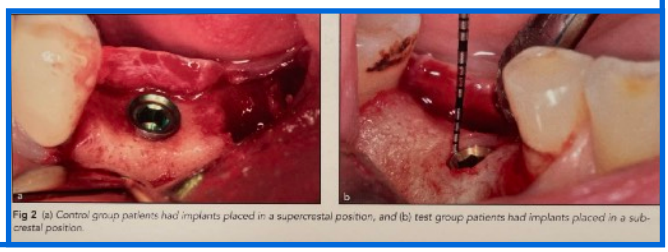


Fig 2 (a) Control group patients had implants placed in a supercrestal position, and (b) test group patients had implants placed in a sub-crestal position.

GEN5™

PARAGON
IMPLANT COMPANY

40 YEARS OF INNOVATION

NIZPLANT™

* Includes Overdenture Attachment Components

40 YEARS OF INNOVATION

37 PATENTS - 4 SPECIFIC TO GEN5

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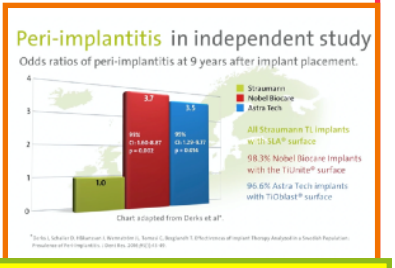

Video Lecture and interview of Dr. Daniel Buser, explaining importance of Hybrid Surface and how he partially submerges smooth neck of "Tissue Level" Implants

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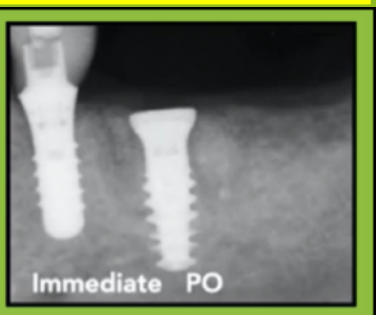

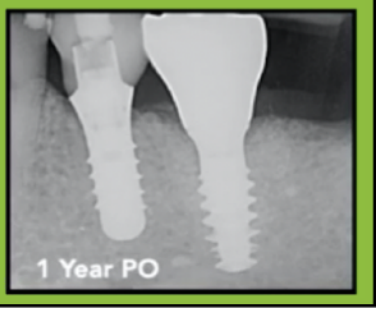

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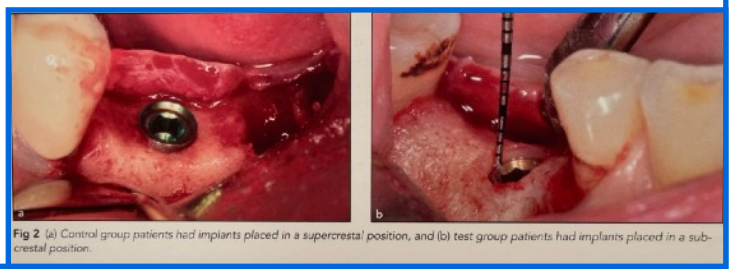
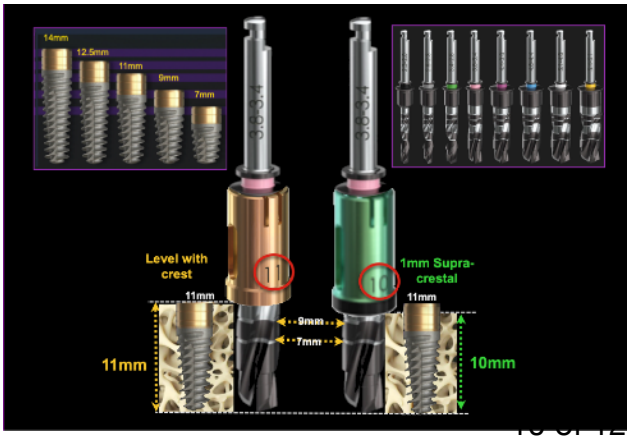
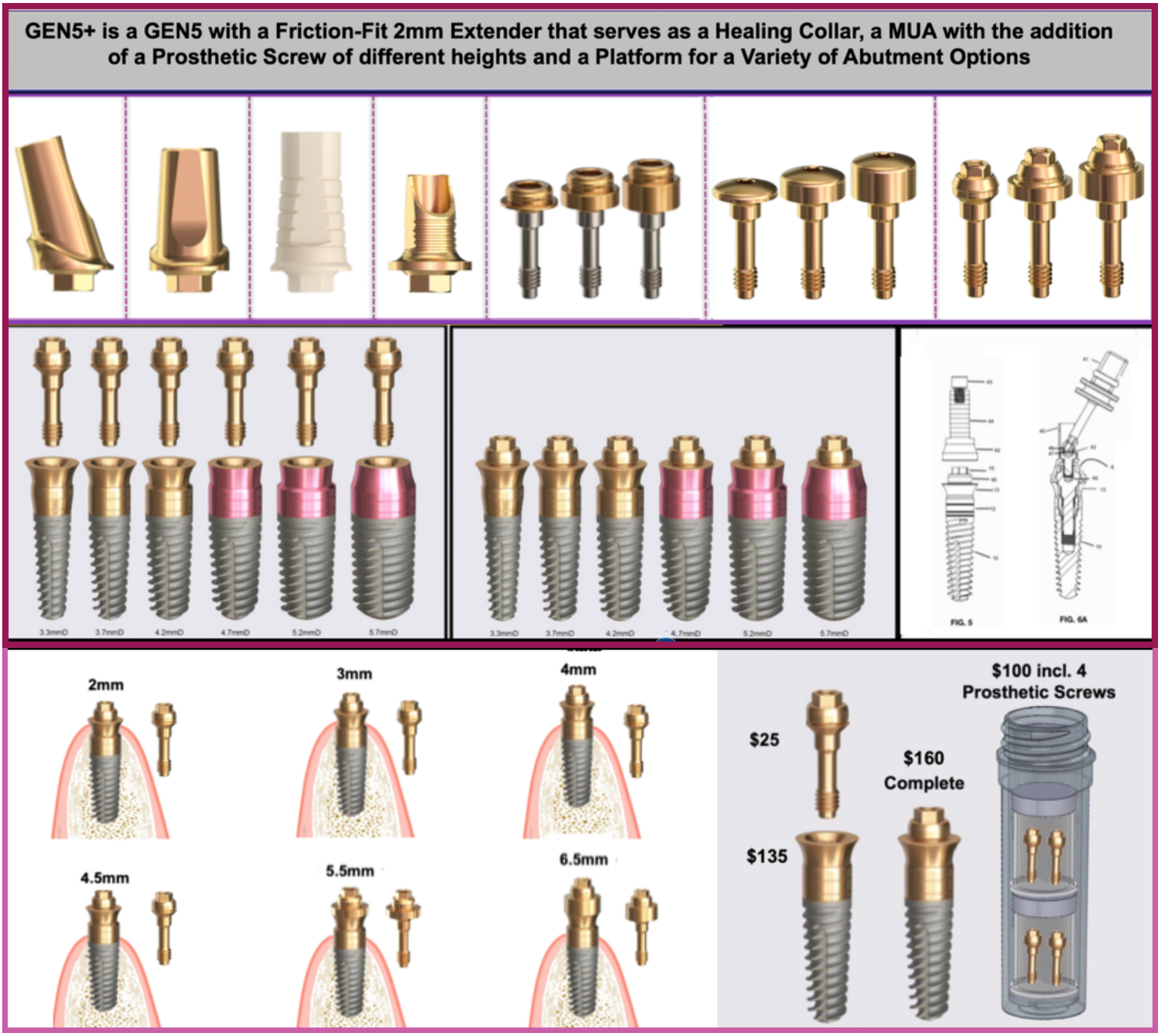


Fig 2 (a) Control group patients had implants placed in a supercrestal position, and (b) test group patients had implants placed in a sub-crestal position.

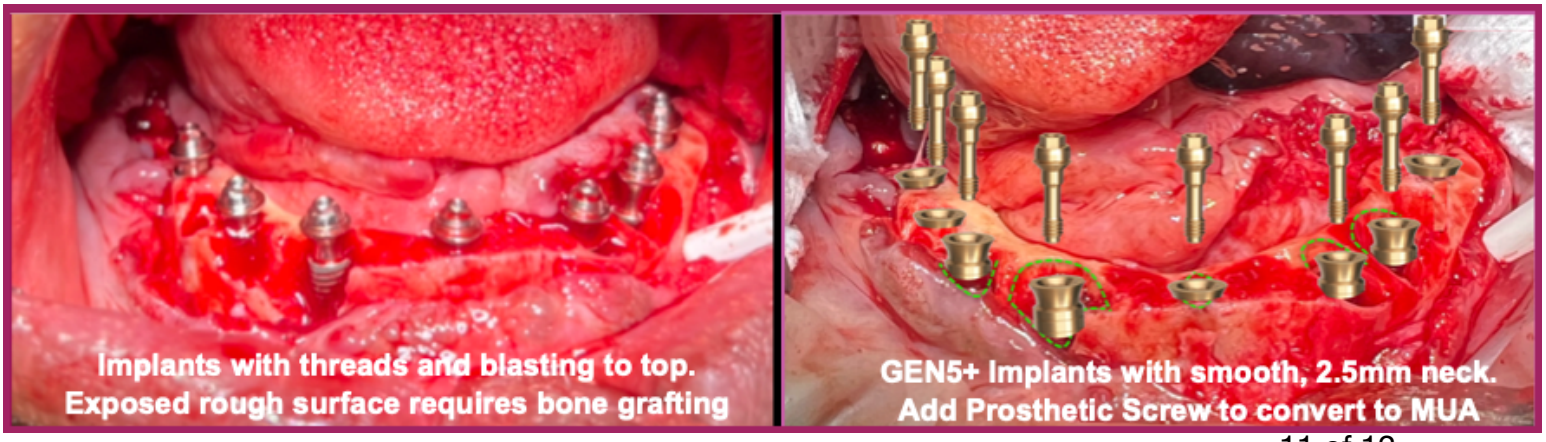
Paragon's GEN5™ , GEN5+ and NizPlant™ implants have the same implant body with a 2.5 mm machined, anodized neck. Depth gauge lines at 1 mm, 2 mm and 2.5 mm from the top (Pat. Pend.), along with 2 depths of drill stops, facilitate placement level with or 1mm above the crest of the ridge. The insertion 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.

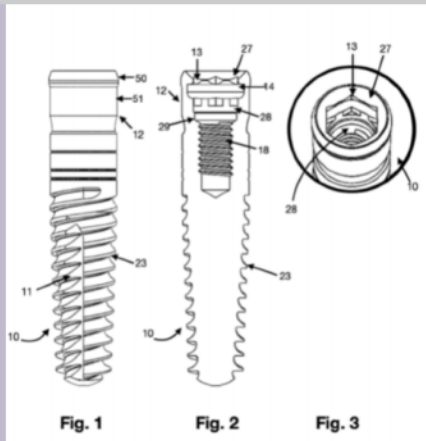


Patented Features of the 1-Piece NizPlant Implant with its Dual-Function Platform

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 under-cut/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.