Key Technological Features of the BioHorizons Tapered Pro Conical System: Surgical and Prosthetic Insights

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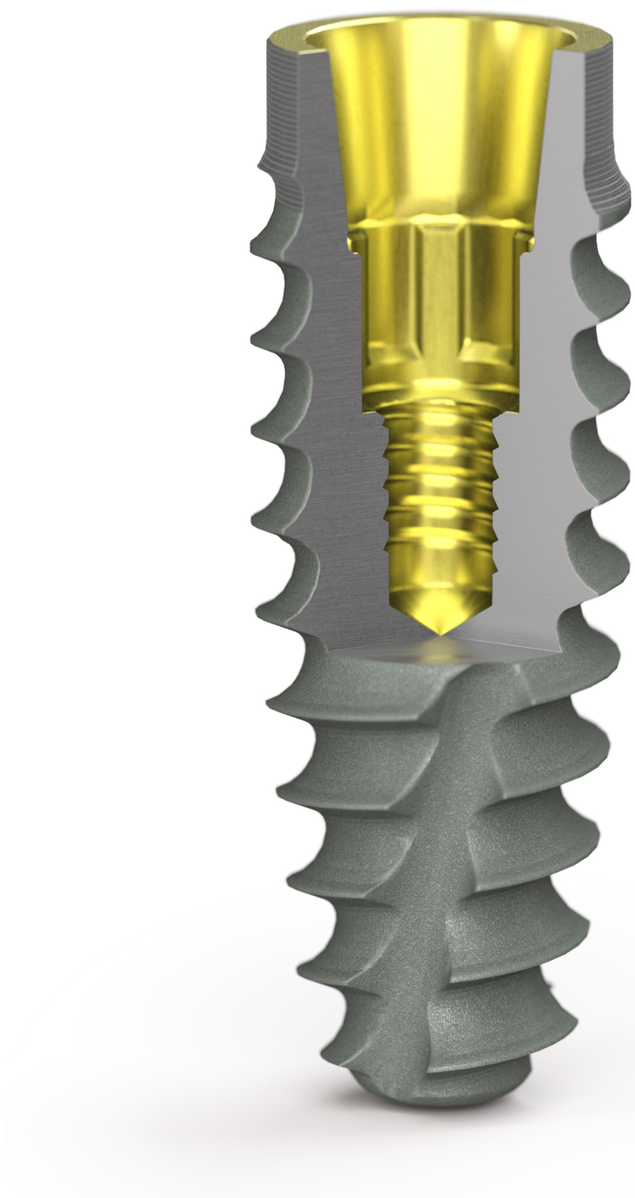

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1. Introduction

BioHorizons Implant Systems Inc. launched the Tapered Pro Conical (TPC) system in June 2024, entering the deep conical connection market. In line with the company's mission to produce innovative yet evidence-based medical devices, TPC combines the design of the Tapered Pro implant line with the proven CONELOG® connection. Key technological features from BioHorizons® and Camlog® were merged with patented innovations for surgical drill designs used in guided and freehand workflows to present a comprehensive solution for clinicians and patients. This paper examines the unique benefits of the PRO Guided Surgical Kit (PRO5000), Freehand Surgical Kit (FSK5000), Tapered Pro Conical and Tapered Short Conical (TSC) implants, and SmartShape® Healers.

2. Surgical Workflow

Implant surgical site preparation is performed either by a guided (digital) protocol using 3D printed surgical guides to ensure optimal implant orientation or via a freehand (analog) procedure. Both guided and freehand approaches are supported by BioHorizons surgical kits, PRO5000 and FSK5000, respectively. Both kits are thoughtfully designed to:

- Simplify the procedures through their organized, color-coded layout and corresponding instruments
- Increase flexibility and efficiency with new instrumentation and surgical approaches
- Allow for personalization of the kit with provided spare slots for specialized instruments

2.1. Guided Surgical Protocol (PRO5000)

The PRO5000 Guided Surgical Kit streamlines the implant placement protocol by offering a comprehensive, keyless guided solution that ensures accuracy and efficiency.[1] Central to its design is the guide adapter, which eliminates the need for bulky keys (Figure 1a) and the need to utilize two hands for one drilling step, i.e., drilling with the PRO5000 guide adapter can be completed with one hand. A single guide adapter, which corresponds to the diameter of the implant, is connected to the handpiece through an ISO shank for the entire drilling sequence (Figure 1b). The guide adapter directly aligns with the master cylinder in the surgical guide, reducing the risk of stacked tolerances between various components (e.g., added drill guides).

(a) (b)

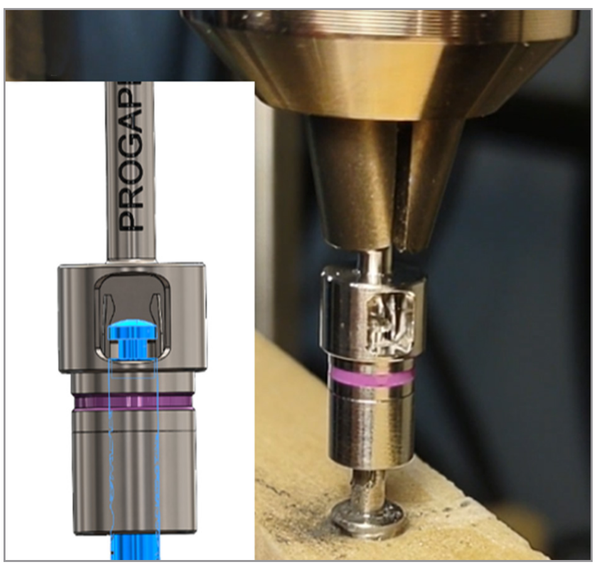
Figure 1: (a) Traditional drill guide setup; (b) optimized guide adapter eliminates the need for additional drill guides, thus (1) reducing the number of stacked components within the master cylinder and (2) minimizing the risk of binding between sharp drills and drill guides.

Reusability and endurance of the guide adapter's snap-in retention feature (Figure 2) was exhaustively tested with the heaviest drill for over 790 cycles, an estimated 100 guided surgeries.[2] A total of 22 samples were included based on a 90% confidence interval. Testing aimed to verify that the retention of the drill to the guide adapter is sufficient to prevent any unintentional disconnection, due to gravity, when used clinically and repeatedly. All samples not only passed the test, but exceeded the minimal force established by BioHorizons via Equation 1:

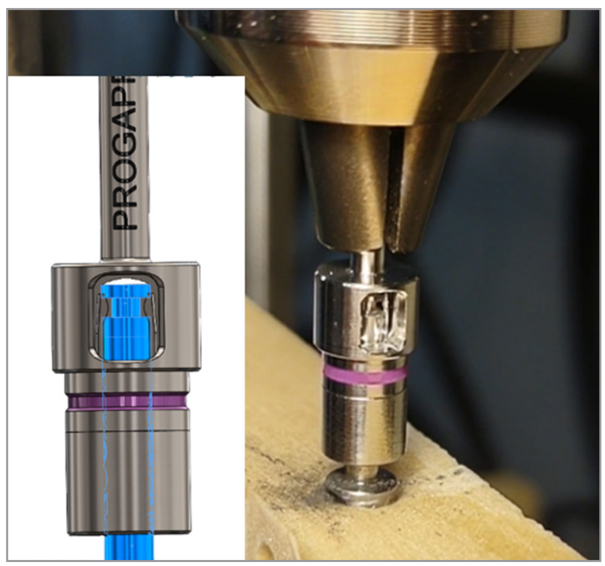
Equation 1

$$\text{Force} = m \times g \times \text{S.F.}$$

Where: m = mass of the heaviest drill, g = gravitational acceleration, and S.F. = safety factor of 2



(a)



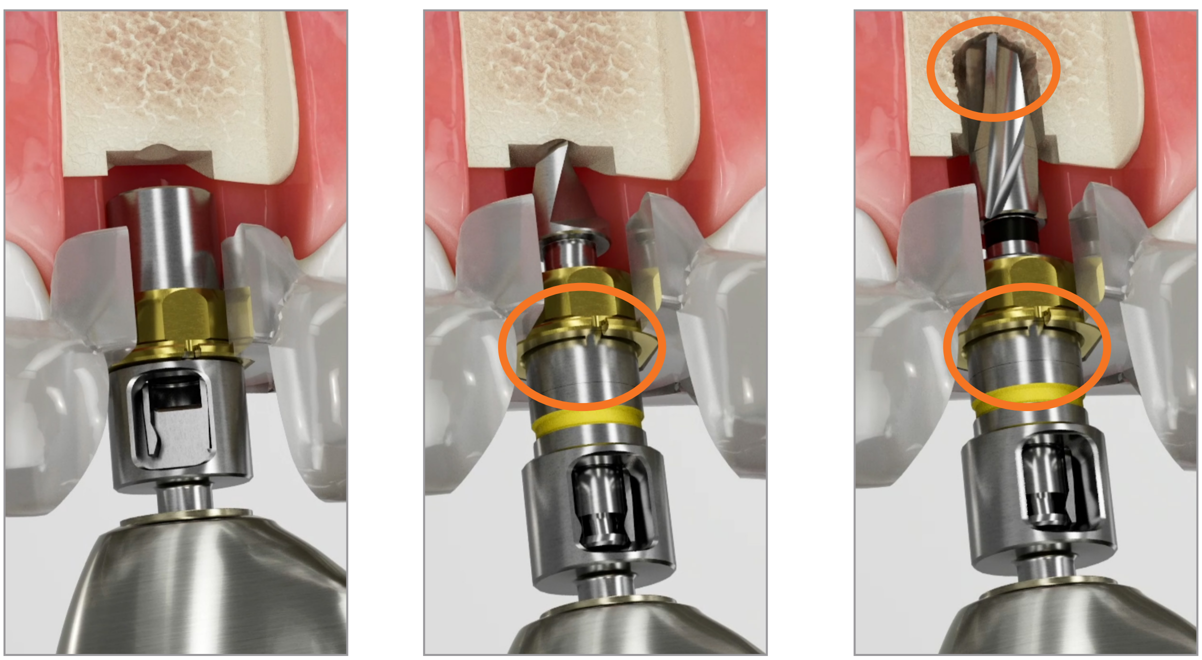
(b)

Figure 2: Representative test set up with superimposed CAD models depicting a drill ISO shank (a) disengaged and (b) engaged into the guide adapter.

Extrapolating the trendline to 4,000 cycles, which represents approximately 5 years of clinical use, retention values still exceeded the minimal force deemed clinically acceptable for the retention of the drills to the guide adapters, ensuring component retention and vastly reducing the risk of aspiration or ingestion of sharp surgical devices during operation.[2]

Progressing through the surgical procedure in a depth increasing manner, the guide adapter offers the option to prepare an undersized osteotomy, a technique especially useful when working with softer bone. Here, using a drill with a reduced diameter and preplanned length minimizes the amount of native bone removed when creating the osteotomy and subsequently fosters a more favorable environment for osseointegration.[3] This protocol is especially advantageous in cases with insufficient bone quantity or quality as it enhances primary stability by compressing the bone around the implant during insertion.[4,5] By incorporating the option of a reduced osteotomy, the PRO5000 kit allows for versatility, where chairside modifications can be made to optimize outcomes in challenging anatomical scenarios.

Once the gingival tissue is removed (traditional flap procedure or flapless using a tissue punch) the osteotomy is initiated with a bone leveler to flatten the ridge. This is followed by a short pre-drill allowing for early engagement of the guide adapter with the master cylinder for guidance (Figure 3b). As the length of the drill increases to create a depth-increasing osteotomy, two points of engagement become available: 1) the tip of the drill nesting into the existing osteotomy and 2) the guide adapter nesting into the surgical guide (Figure 3c). This dual guidance reduces the potential for drill deviation.



(a) (b) (c)

Figure 3: (a) The guide adapter is inserted into the master cylinder to ensure there is proper clearance with soft tissue and bone. (b) The guide adapter is engaged into the master cylinder prior to osteotomy initiation with pre-drill. (c) Two points of engagement with subsequent drills in the osteotomy and the master cylinder.

Accuracy is a key technical benefit of digitally planned, prosthetically driven guided surgery. As such, the PRO5000 kit allows for a guided osteotomy preparation and guided implant placement. An accuracy verification test was completed on a 3.0 x 15mm implant, considered a worst case with small diameter and long length, usually more prone to positional deviation.[6] Vertical angulation of implants placed and orientation of the indexing feature using the PRO5000 were measured. Implant insertion angles measured with respect to the vertical axis, deviated by an average of 3.13°. Clinically acceptable angular deviation averages 3.5°, and may go up to 5.0°, varying based on the degree of edentulism and technique used, as reported by a systematic review on over 2,000 implants placed via guided surgery.[7] The PRO5000 kit and instrumentation support clinically accurate implant placement.

Digital guided workflows streamline dental procedures, from planning, customization, clinic-to-lab communication to final placement and restoration. Guided workflows can also provide a less invasive surgical approach (via the use of tissue punches) by reducing the need for open-flap surgeries to visualize bone which can improve patient experience and reduce recovery time.[8,9] Additionally, this workflow can significantly reduce the time required for each surgical step, reducing patient chair time and allowing clinicians to complete more cases during a clinic workday.[8,10] Yet, prior to the PRO5000 launch, clinicians had limited ability to switch from guided to freehand at the time of surgery if the case required it. The PRO5000 kit is loaded with a drill bank that supports freehand osteotomy and implant placement within the same guided kit, offering full surgical flexibility (Figure 4 and Figure 5).

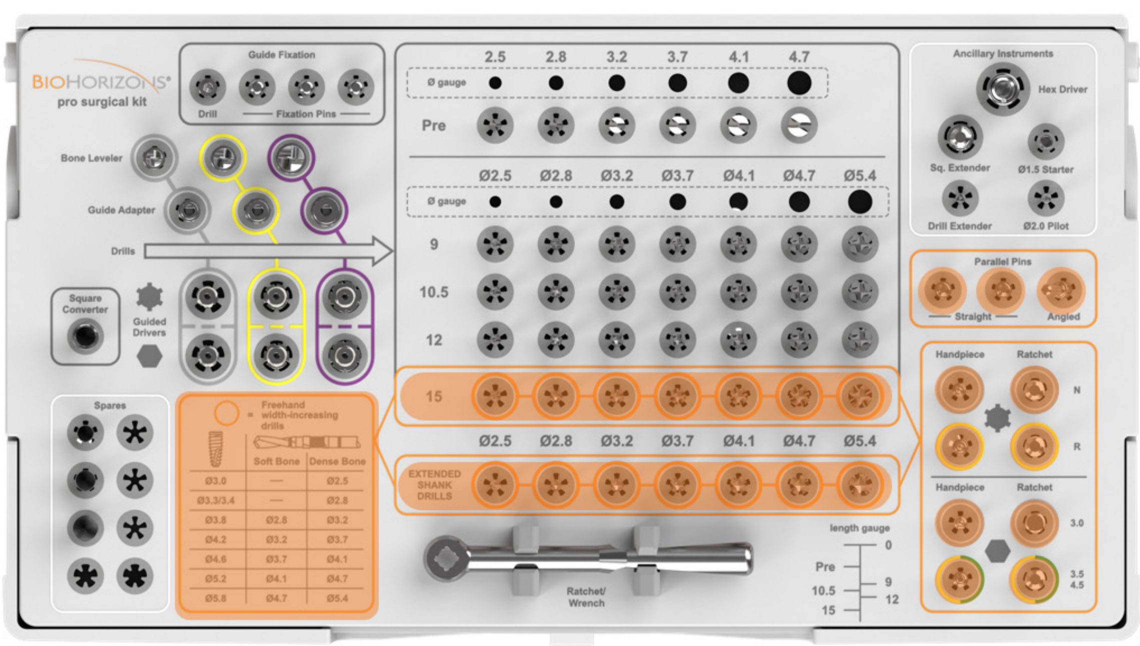


Figure 4: Instruments used for freehand placement within the PRO5000 are outlined in orange.

The PRO5000 kit streamlines guided surgeries and simplifies digital workflows, offering many benefits including:

- **Customization:**
  Digital planning allows for the customization of the surgical protocol and final dental restoration to match the patient's unique anatomy.

- **Improved patient experience:**
  Patients benefit from less invasive procedures and shorter chair times.

- **Enhanced communication:**
  Digital files can be easily shared, facilitating communication between dental clinics and labs.

- **Predictable outcomes:**
  Use of digital planning tools and guided surgery leads to more predictable and consistent results.

- **Surgical flexibility:**
  Clinicians may perform both guided *and* freehand surgery with a single PRO5000 kit.

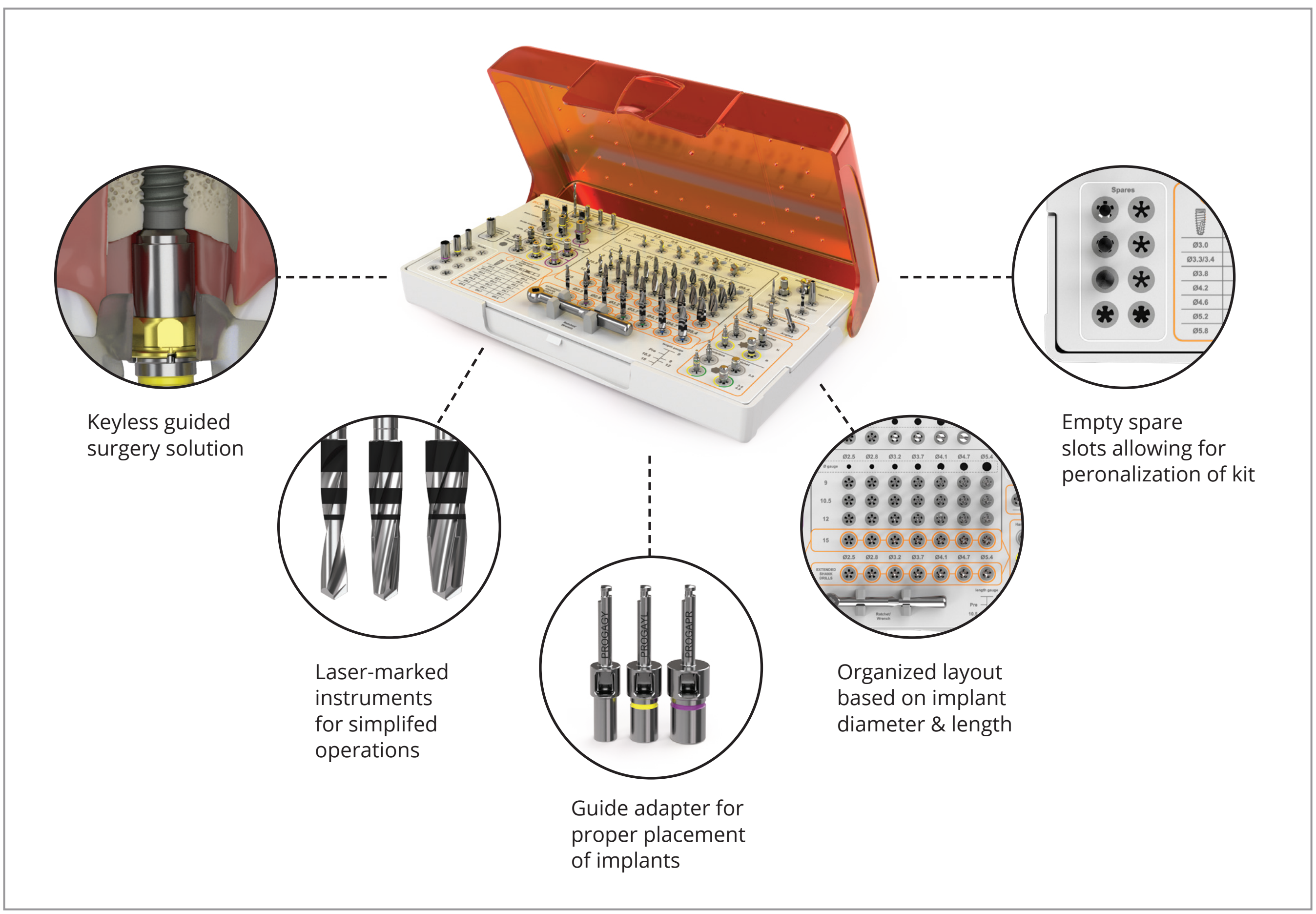


Figure 5: Summary of the PRO5000 features.

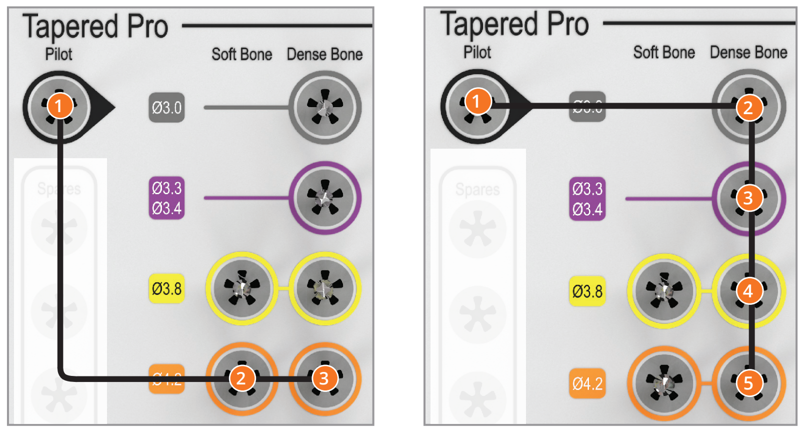
2.2. Freehand Surgical Protocol (FSK5000)

Clinicians who prefer conventional freehand workflows have the option of BioHorizons' Pro Freehand Surgical Kit, FSK5000. The FSK5000 kit is designed to simplify freehand implant protocols by offering reduced and conventional width-increasing drilling sequences for the placement of all BioHorizons implant systems.

The new reduced sequence leverages a patented parabolic technology for the drill body, intended to capture and disperse bone chips throughout the helix, increasing cutting efficiency compared to the traditional twist drill design (Figure 6).

(a) (b)

Figure 6: (a) Proprietary parabolic drill design and (b) traditional twist drill design.



(a) (b)

Figure 7: Representative image of the (a) reduced and (b) conventional drilling sequences for the placement of a 4.2mm diameter implant in dense bone.[11]

The innovative parabolic design of the soft bone drills enables clinicians to accelerate their freehand procedure. The reduced sequence offers a soft bone protocol using two (2) drills only and a dense bone protocol using three (3) drills total (Figure 7a). The osteotomy is initiated by a pilot drill, followed by a parabolic soft bone drill. After using the soft bone drill, clinicians determine, based on bone density, whether the wider diameter twist dense bone drill is needed to complete the osteotomy.

Alternatively, the conventional drilling sequence with standard twist drills may be followed. This sequence allows for the gradual preparation of the osteotomy, using up to eight (8) drills to place the largest diameter, 5.8mm, implant. For example, placing a 4.2mm diameter implant requires up to 3 drills using the reduced sequence (Figure 7a) and 5 drills using the conventional sequence (Figure 7b).

The parabolic cutting flute geometry incorporates larger empty space within the drill envelope allowing for better transport of debris outside of the cut site. The cutting efficiency of a drill, or its ability to remove material from an osteotomy with minimal force, is extremely important for preserving bone and promoting osseointegration.[12] High quality, sharp instruments are more efficient and minimize friction, limiting heat generation and potential osteonecrosis.[12] The insertion force of a drill is a good indicator of its cutting efficiency, as higher insertion forces often correlate with increased friction and resistance encountered during drilling.

The cutting efficiency of the new parabolic design was assessed by measuring the maximum load required to insert a drill in simulated cortical dense bone using a Mini Bionix® MTS Testing System with a controlled vertical displacement.[13-15] The average maximum load generated by the parabolic drills was significantly lower compared to the average maximum load for currently marketed twist and step drills (Figure 8).

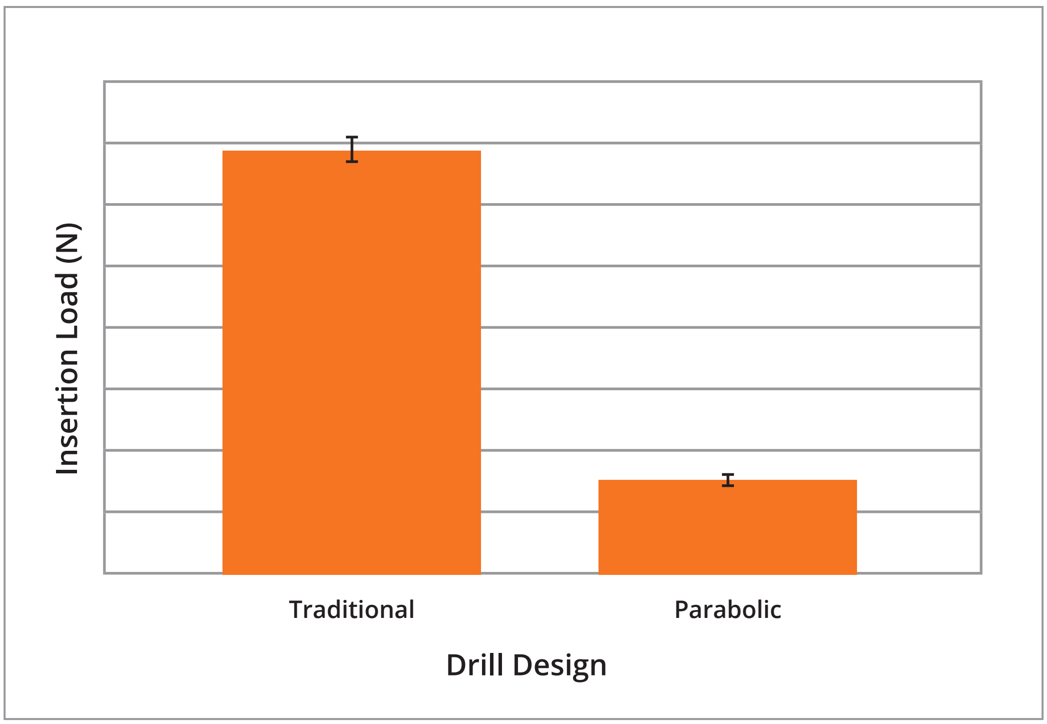


Figure 8. Parabolic drills showed ~ 75% decrease in insertion load of the drills into dense bone in a controlled simulated test. Error bars = standard deviation.[14, 15]

The insertion torque, crucial for achieving primary stability, is heavily influenced by factors such as implant macrogeometry, implant-to-osteotomy relationship, and clinical situation at hand. Excessively high insertion torques may negatively affect osseointegration.[16] BioHorizons assessed the implant insertion torque into an osteotomy prepared using a 2-drill reduced soft bone sequence to ensure it did not exceed the maximum acceptable implant insertion torque value (Figure 9). The results of both the insertion load and insertion torque tests demonstrate the high levels of safety and performance that BioHorizons drills are able to meet.

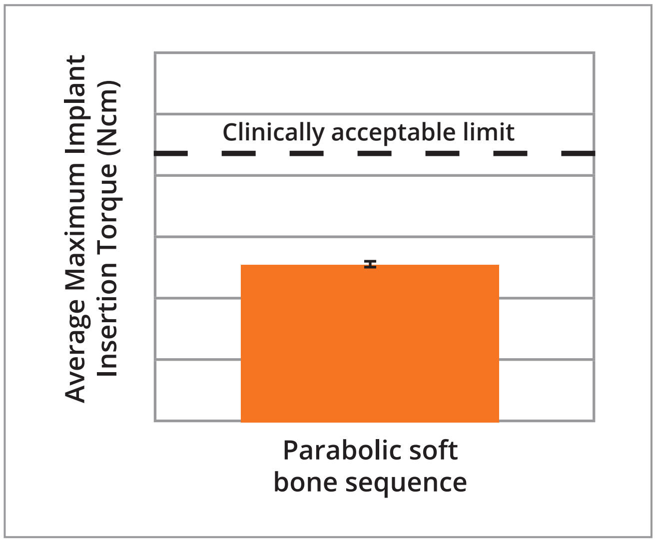


Figure 9. Average maximum torque value of implants with the FSK5000 soft bone sequence was ~40% less than the maximum clinically acceptable limit for BioHorizons implants. Error bar = standard deviation.[15]

Freehand surgical workflows, used for years in implant dentistry, provide dependable solutions for implant placement. The FSK5000 kit adds the advantage of an accelerated surgical workflow by reducing the number of drills required to complete osteotomy prep. The reduced drilling sequence requires significantly fewer instruments, providing a cost-effective kit and drill replacement plan (Figure 10).

- **Surgical Flexibility**:
  The reduced and conventional drilling sequences allow clinicians to adapt their surgical approach based on their experience and the patient's need.

- **Cost-effectiveness**:
  FSK5000 is an economical solution for clinicians looking to simplify their freehand surgeries.

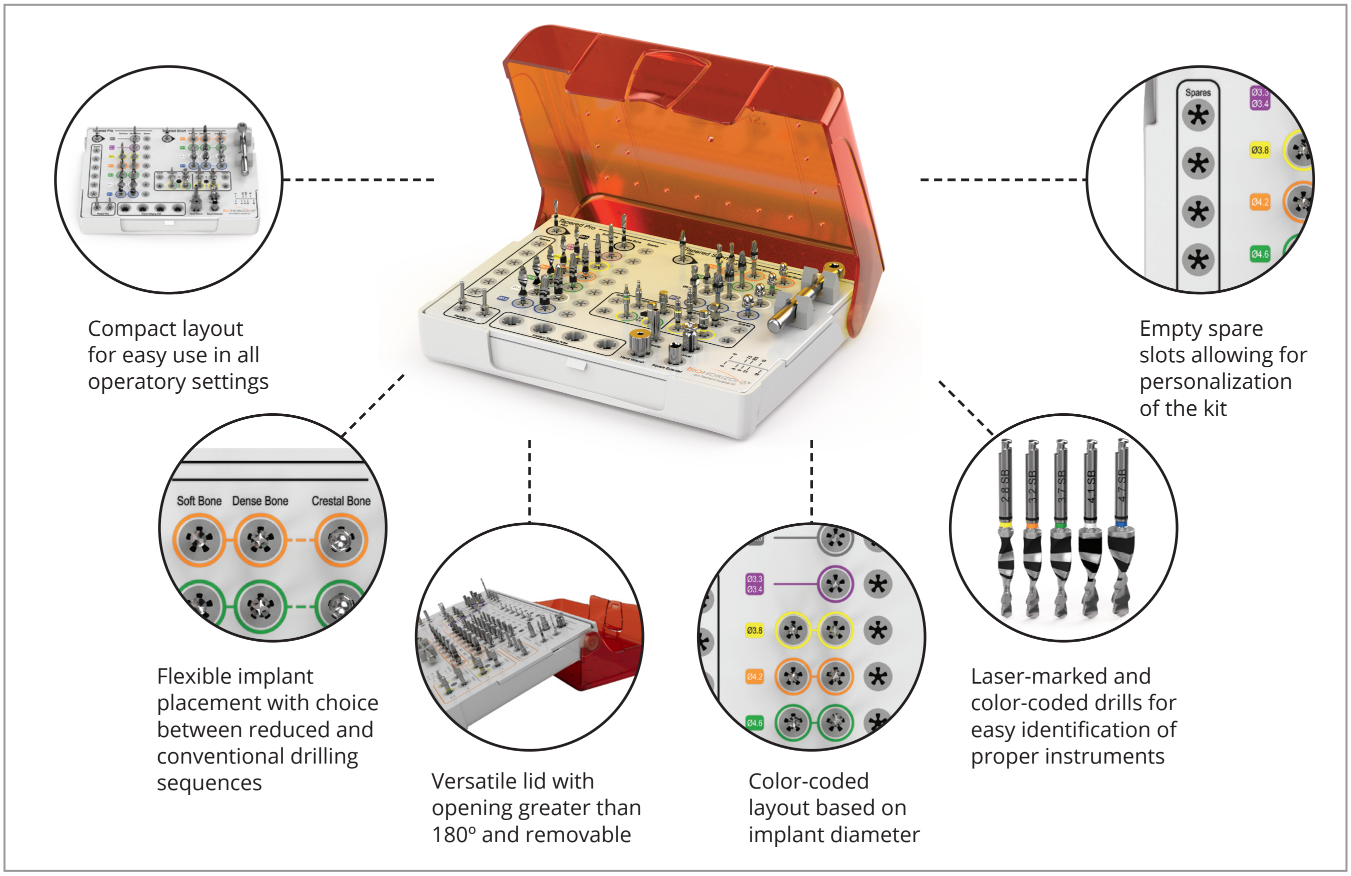
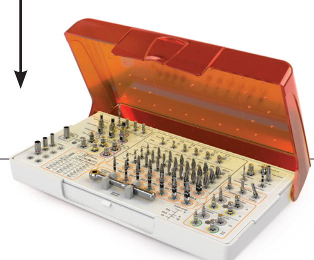


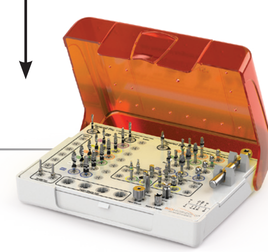
Figure 10: Summary of the FSK5000 features.

Surgical Kit Selection



PRO5000

- Guided & freehand workflows
- Premium comprehensive solution
- Full size kit
- Conventional flap & flapless procedures (*with tissue punches and bone levelers*)
- Twist drill design
- Soft to dense bone protocols

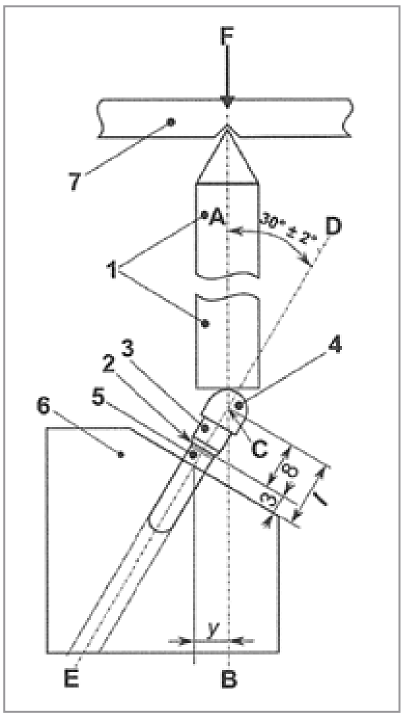


FSK5000

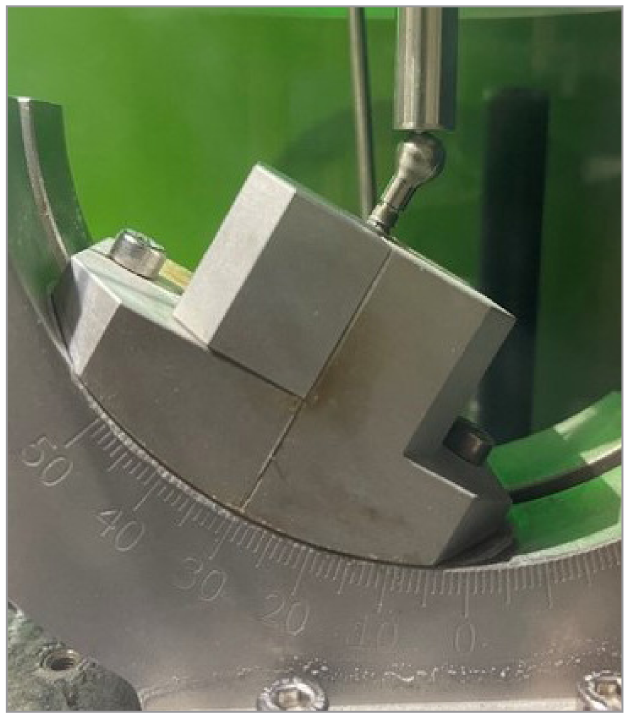
- Freehand workflow
- Cost-effective solution
- Reduced & compact kit
- Conventional flap procedures
- Parabolic & twist drill designs
- Soft to dense bone protocols

3. Tapered Pro Conical and Tapered Short Conical Implants

The surgical workflow lays the foundation for a successful dental implant procedure, with precise osteotomy preparation being critical to achieve primary stability and long-term outcomes. Equally important to osteotomy preparation is the selection of the dental implant, as the implant's design and technological features must ensure optimal osseointegration and durability. While infrequent, published studies reported incidences of dental implant fracture between 0.2 to 5%.[17,18] Those fractures are often the result of fatigue failure caused by repetitive loading and unloading of the dental implant during chewing over an extended period. Fatigue failures, in general, account for approximately 90% of metal mechanical failures.[19] As such, the fatigue limit of an implant system must be thoroughly assessed to ensure durability and maximize patient safety (Figure 11).



(a)



(b)

Figure 11: (a) Required setup for dynamic testing of an endosseous dental implant connected to a straight abutment, per BS EN ISO 14801:2016.[20] (b) Representation of a dynamic test setup.[21]

In October 2024, the U.S. Food and Drug Administration (FDA) issued a guidance on the performance criteria for endosseous dental implants and abutments.[22] This guidance identified the acceptable maximum endured load for the worst-case construct based on the major thread diameter of the implant body. The device's indications for use and warnings should then be formulated based on the load at which the system passed the fatigue test and should be communicated to the intended user in the instructions for use.

Tapered Pro Conical's smallest implant, with a diameter of 3.3mm, successfully exceeded the maximum load established by the FDA guidance for the largest major thread diameter group (Table 1).[21] The implants within the TPC and TSC portfolios are indicated for use in the mandible and maxilla with no limitation for the region in the mouth.*

Table 1: FDA's guidance on the maximum endured load based on implant major thread diameter.

Major thread diameter (mm)	Maximum endured load (N)
3.0 – 3.3	150
3.4 – 3.5	170
3.6	180
Greater than 3.6	200

BioHorizons' Tapered Pro Conical implant system was also compared to established and commercialized systems based on their fatigue performance after dynamic loading (Table 2).

Table 2: Implant systems evaluated for fatigue strength using dynamic testing.

Implant Type	Material	Diameter	Connection Type
BioHorizons Tapered Pro Conical	Ti-6Al-4V ELI	3.3mm	Deep conical with 6 cams
Commercialized Implant A	Commercially Pure Titanium (CP4 Ti)	5.0mm	Deep conical with hex
Commercialized Implant B	CP4 Ti	3.3mm	Deep conical with 3 cams
BioHorizons Tapered Internal	Ti-6Al-4V ELI	3.0mm	Internal hex

*Refer to L01087 for full instructions for use.

To pass the test, three (3) consecutive implants must successfully reach the required number of cycles without failing, per BS EN ISO 14801:2016.[20] The TPC system demonstrated superior fatigue limits under dynamic test conditions, outperforming competitors in the following scenarios (Figure 12):

- **Different Connection, Larger Diameter, Different Material (TPC > Implant A)**:
  Larger diameter implants with increased wall thickness typically provide greater strength. However, in challenging sites like anterior esthetic zones or areas with limited bone width, using larger implants may not be feasible. To compensate, enhancements in material selection and connection design are essential. TPC's titanium alloy and deep conical connection provided superior strength, even with smaller diameter implants.

- **Same Connection, Same Size, Different Material (TPC > Implant B)**:
  TPC outperformed systems with similar design manufactured of CP4Ti, highlighting the importance of implant material selection in durability.

- **Different Connection, Similar Size, Same Material (TPC > Tapered Internal)**:
  Compared to Tapered Internal implants with similar diameter, TPC with a deeper conical connection achieved higher fatigue strength.

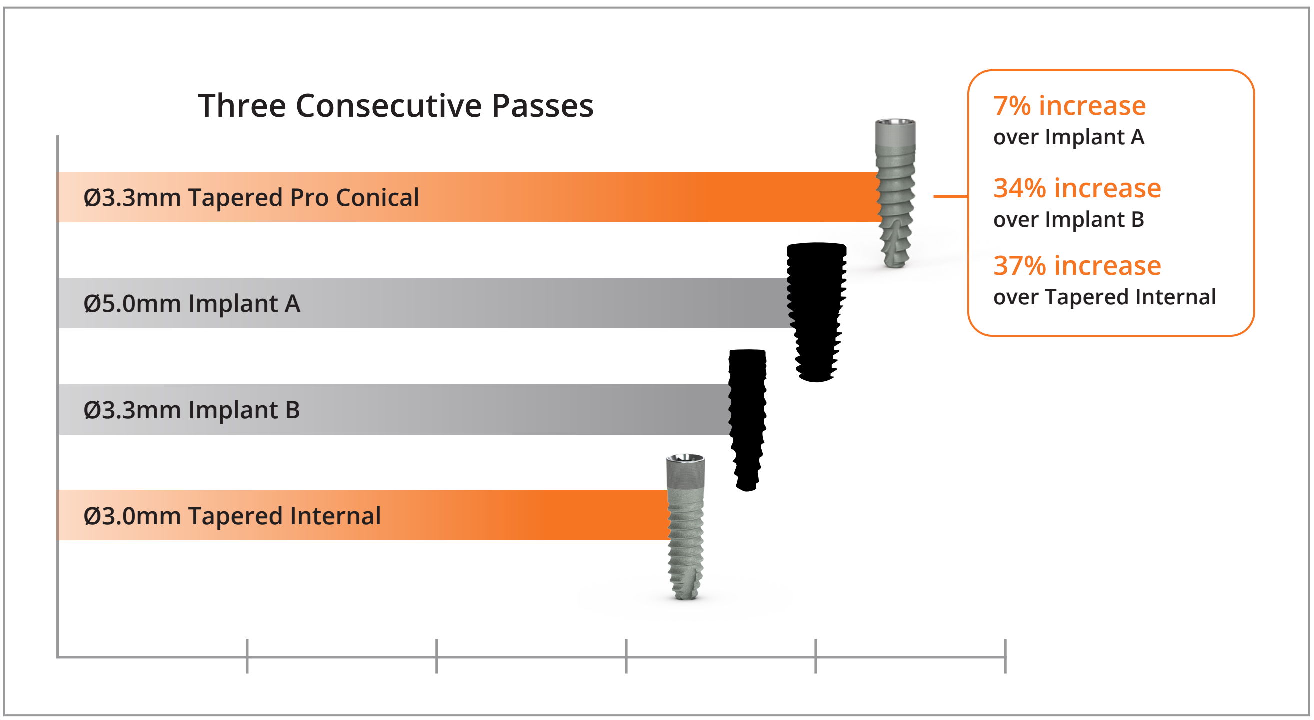


Figure 12: Dynamic fatigue testing results for TPC versus other commercialized systems.[21, 23-26]

An implant's design has a considerable influence on its long-term success and on the patient's health. Features crucial to an implant's success include:

- **Material:**
  The material of an implant influences its strength, durability, and biocompatibility.

- **Connection:**
  The implant-abutment connection (IAC) affects the lateral and rotational stability of implant-supported prostheses.

- **Macrogeometry:**
  The design of an implant influences bone-to-implant contact area, primary stability, and stress distribution capabilities.

- **Surface Treatment:**
  The surface modifications on an implant enhance its ability to osseointegrate.

3.1. Implant Material

Implant material plays a significant role in increasing the strength and fatigue limits of implants. All BioHorizons titanium implants and prosthetic components are manufactured of Ti-6Al-4V ELI (Grade 23). Grade 23 is one of the strongest titanium alloys on the market and is frequently used in dental and orthopedic implants (Table 3).[27] Ti-6Al-4V ELI is composed of approximately 90% titanium (Ti), 6% aluminum (Al), and 4% vanadium (V) with "Extra Low Interstitial" elements. This designation indicates a higher purity version of the alloy, with reduced levels of interstitial elements like oxygen, nitrogen, and carbon.[28] These reduced levels of interstitial elements improve the material's ductility and fracture toughness, increasing its ability to resist breaking under large masticatory forces.

Table 3: Comparison of the strength behaviors of various dental implant materials.

	grade 1 CP titanium	grade 2 CP titanium	grade 3 CP titanium	grade 4 CP titanium	Roxolid® Ti-15Zr**	Ti-6Al-4V titanium alloy	Ti-6Al-4V ELI titanium alloy
yield strength (MPa)*	240	345	450	550	785	860	860
strength comparison ratio	28%	40%	52%	64%	91%	100%	100%
fatigue strength (MPa)	175	250	300	360	500	530	530
		Dentsply®	Keystone (Restore®)	Nobel™ Astra® Biomet 3i™	Straumann®	Zimmer® (Orthopedics)	BioHorizons

* Source: MatWeb Material Property Data. MPa = Megapascals
** Properties published in Medvedev et al. *J Mecha Behav Biomed Mater*, Vol 62, 2016

The ability of titanium to resist corrosion makes it an excellent material for use in medical applications where metals may be subjected to corrosion-inducing environments. The corrosion resistance of titanium is due to the formation of an insoluble and continuous titanium oxide (TiO_2) layer on its surface (Figure 13). The TiO_2 layer inhibits the ingress of oxygen, protects the material from degradation, and allows a layer of biomolecules to attach.[29] The excellent biocompatibility of titanium and titanium alloys is a direct result of this surface layer.

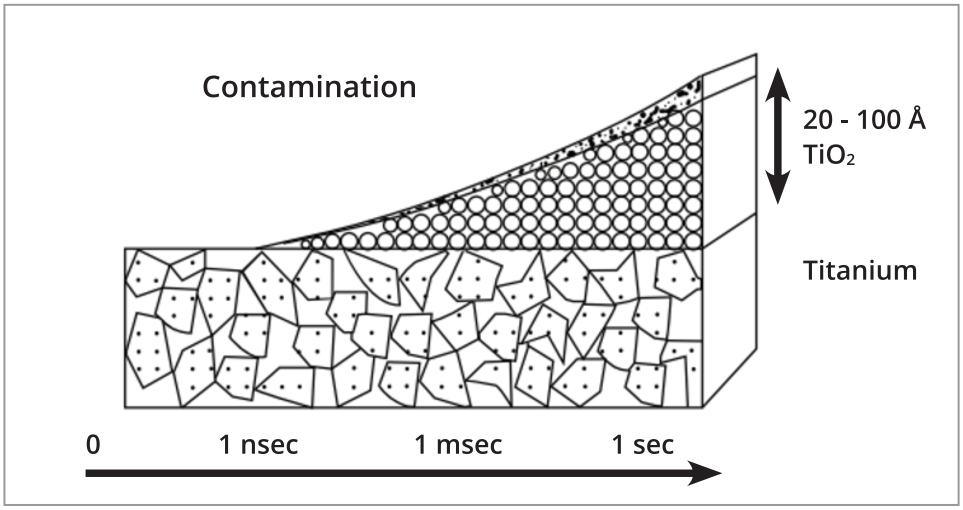


Figure 13: Formation of an insoluble TiO_2 layer on the surface of titanium.[29]

3.2. Connection

The implant-abutment connection (IAC) determines the strength and stability of single- and multi-unit implant-supported restorations. Tapered Pro Conical and Tapered Short Conical feature the BioHorizons-Camlog internal 7.5° deep, conical connection (Figure 14). This connection offers a long 4.2mm cone and cam from the implant shoulder to the start of the abutment screw thread, and a total length of 6.3mm from the implant shoulder to the bottom of the thread (Figure 15). Camlog first introduced this connection in 2010, and since then, consistently proved its superior positional stability and ability to maintain peri-implant tissue in long term clinical studies, reporting on data for more than 7 years.[30-33]

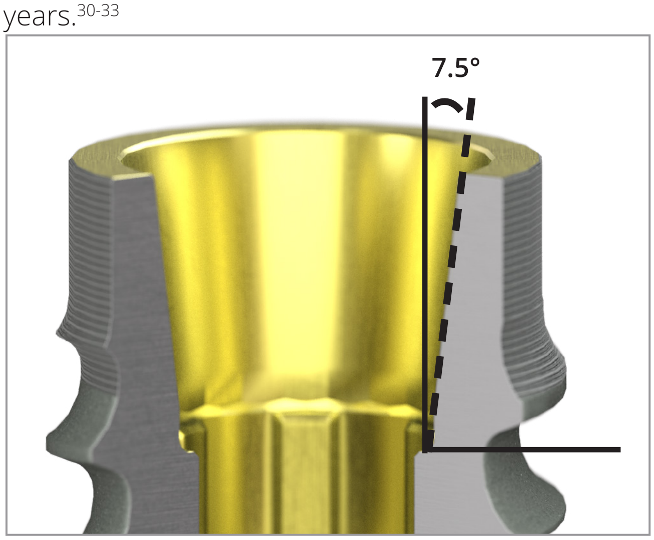


Figure 14: Representative image of the BioHorizons-Camlog connection's 7.5° cone.

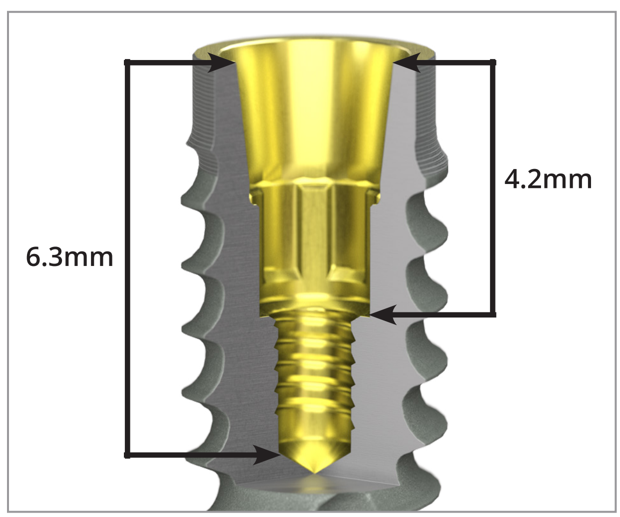


Figure 15: Depth of the BioHorizons-Camlog conical connection.

The 7.5° conical connection offers a gradual emergence from the implant to the prosthetic abutment. This vertical transition of the prothesis allows for subcrestal placement of the implant, where clinically appropriate, without the need to profile peri-implant bone for full abutment seating (Figure 16). Publications have documented the effect of both hard and soft tissues on the management and prevention of complications in implant dentistry.[34, 35] Peri-implant bone maintenance supports peri-implant soft tissue maintenance and subsequently, the predictability of surgical interventions and oral health.

The original 3-cam conical connection allows a 120° rotation of the prosthetic component. To compensate for the large rotation, angled prosthetics are offered in 2 types (A and B) with a cam offset of 60°. BioHorizons' conical implants include a 6-cam connection designed for flexible abutment orientation (60° instead of 120°) without the need for 2 abutment types (Figure 17). Furthermore, all TPC and TSC implants can be restored using 2 prosthetic connections: Narrow (Gray) or Regular (Yellow).

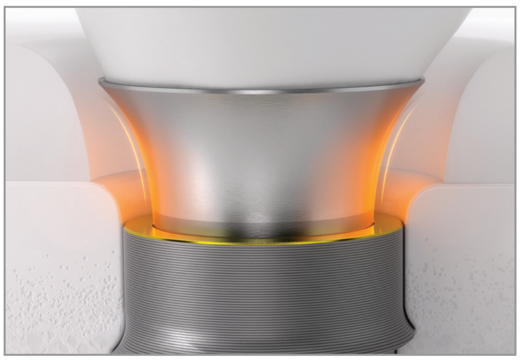


Figure 16: Vertical emergence of the implant-abutment platform allowing subcrestal placement without the need for bone profiling.

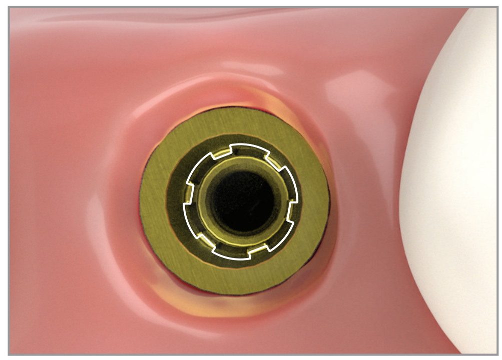


Figure 17: Representative image of the 6-cam connection on TPC and TSC implants.

The drive towards a single platform for all implant diameters is an oversimplification that does not account for the long-term success of the dental implant. BioHorizons has previously reported on the impact to the mechanical strength of a single prosthetic connection on implants ranging in diameter from 3.5mm to 7.0mm.[36] A large difference between the implant diameter and abutment diameter results in higher stresses on the smaller abutment connection, especially when the load is not co-axial to the system. BioHorizons' TPC and TSC systems offer a Narrow connection for implants ranging from 3.3 to 3.8mm in diameter and a Regular connection for implants ranging from 3.8 to 5.2mm in diameter (Figure 18). With this, a full arch restoration may leverage a single connection for various implant diameters without compromising the mechanical integrity of the implant-abutment construct. Dental implant systems are subjected to higher occlusal forces in the posterior region, where literature reported increased prosthetic complications.[37] As such, offering two (2) prosthetic sizes, as opposed to one, provides structural stability where needed.

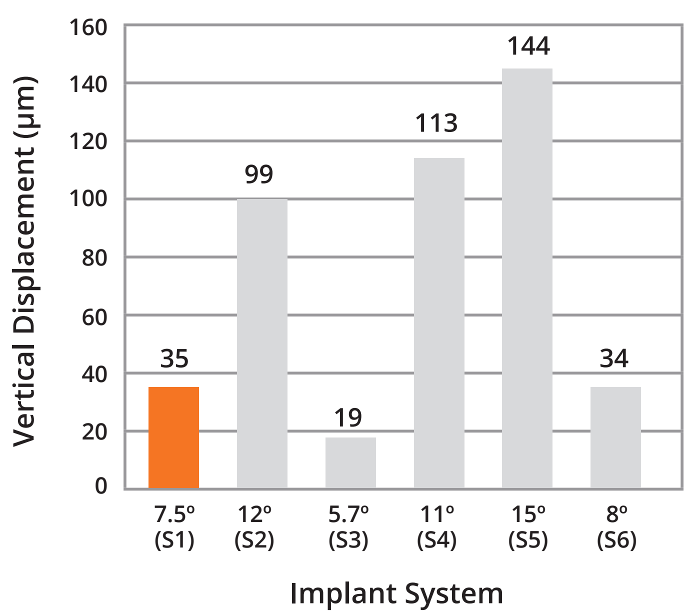
Body diameter	3.3mm	3.8mm	4.2mm	4.6mm	5.2mm
Prosthetic connection	Narrow	Narrow Regular	Regular	Regular	Regular

Figure 18: Connection size for the different implant diameters.

A 2015 extensive benchtop study evaluated the impact of torque tightening on abutment position stability in implant systems with conical connections of various cone angles and different positional index designs (Table 4).[32] To assess the stability after repeated torque tightening, the following endpoints were evaluated: degree of rotation, vertical displacement and canting moment (Figure 19). Each implant system was tightened per the manufacturer's instructions for a total of 20 times.[32]

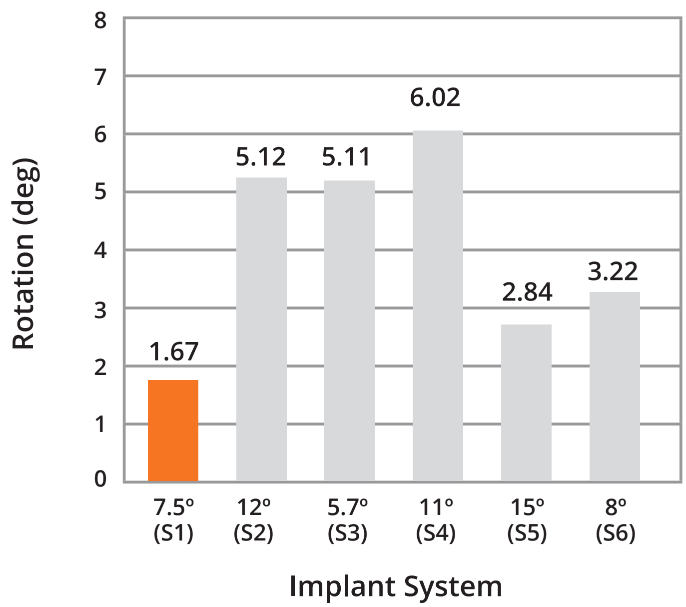
Table 4: Specifications of the connections evaluated.

System	Cone Angle	Positional index design	Manufacturer's torque recommendation
S1	7.5°	Cam-groove	20 Ncm
S2	12°	Hexagon	35 Ncm
S3	5.7°	Cam-groove	15 Ncm
S4	11°	Dodecagram	25 Ncm
S5	15°	Cam-groove	35 Ncm
S6	8°	Octagon	35 Ncm



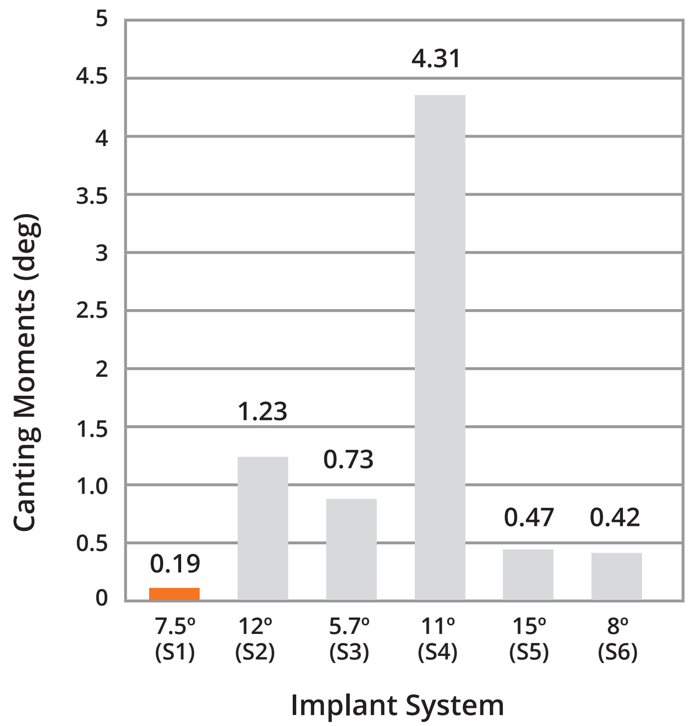
Statistical analysis (P < .05)					
S1 vs S2	S2 vs S1	S3 vs S1	S4 vs S1	S5 vs S1	S6 vs S2
S1 vs S3	S2 vs S3	S3 vs S2	S4 vs S3	S5 vs S2	S6 vs S3
S1 vs S4	S2 vs S5	S3 vs S4	S4 vs S6	S5 vs S3	S6 vs S4
S1 vs S5	S2 vs S6	S3 vs S5	-	S5 vs S6	S6 vs S5
-	-	S3 vs S6	-	-	-

Figure 19a: The BioHorizons-Camlog connection showed competitive results in vertical displacement.[32]



Statistical analysis (P < .05)					
S1 vs S2	S2 vs S1	S3 vs S1	S4 vs S1	S5 vs S4	S6 vs S2
S1 vs S3	S2 vs S4	S3 vs S6	S4 vs S2	-	S6 vs S3
S1 vs S4	S2 vs S6	-	S4 vs S5	-	S6 vs S4
-	-	-	S4 vs S6	-	-

Figure 19b: The BioHorizons-Camlog connection showed superior results in the degree of rotation.[32]



Statistical analysis (P < .05)					
S1 vs S2	S2 vs S1	S3 vs S2	S4 vs S1	S5 vs S1	S6 vs S1
S1 vs S4	S2 vs S3	-	-	-	S6 vs S2
S1 vs S5	S2 vs S6	-	-	-	-
S1 vs S6	-	-	-	-	-

Figure 19c: The BioHorizons-Camlog connection showed superior results in canting moments.[32]

The results indicate that the BioHorizons conical connection:

- **Optimizes restorative fit:**
  The cam-groove indexing design reduces the degree of abutment rotation with respect to the implant, and the 7.5^{o} cone angle reduces the vertical displacement. While some vertical discrepancy is expected in a conical connection as part of the friction fit design, a large difference affects the accuracy of the restoration and the passivity of the fit. The positional stability of the IAC is essential as the clinician repeatedly connects the prosthesis onto the implant during the entirety of the restorative process.[30] BioHorizons' conical connection optimizes the restorative fit through tested designs, tight manufacturing tolerances, and verified torque recommendation.

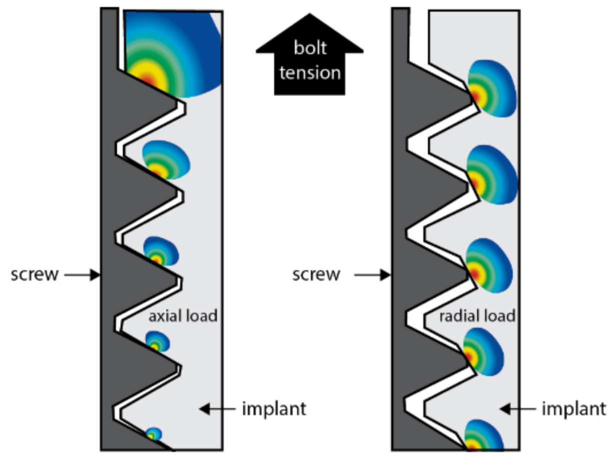
- **Reduces risk of mechanical failure:**
  BioHorizons maintains tight manufacturing tolerances on all devices, reducing the chance of micromovements and stress accumulation at the connection. Minimizing canting moments decreases the likelihood of screw loosening, abutment tilting, and fracture.

- **Enhances biologic stability:**
  A stable IAC exhibits decreased micromovements which then reduces the risk of bacterial ingress, and peri-implant inflammation.

These results highlight the benefits of the BioHorizons deep conical connection. The accuracy of the fit between components directly impacts stability, load distribution, and long-term performance and durability of dental implant systems.

Another key feature of *all* BioHorizons implants is the Spiralock® thread technology, an advanced internal thread design integrated to enhance the mechanical stability of the IAC. First designed for NASA with applications in the aerospace industry, this internal thread form is ideally suited for threaded joint applications subjected to heavy shock and vibration, long hours of strenuous operation, and millions of loading cycles.[38]

Unlike traditional V-threads, Spiralock incorporates a 30-degree wedge ramp at the root of the thread that locks the abutment screw securely to the implant and helps distribute forces more evenly across the entire thread profile, reducing stress concentration and preventing loosening under cyclic loading. Standard abutment screw V-threads are axially loaded, causing the first thread to bare the majority of all masticatory forces (Figure 20). Over time, this thread loses its integrity and will fracture inside the IAC. The clinical impact of a gradual preload loss is more pronounced towards the posterior/molar region of the mouth with increased chewing forces. Spiralock's wedge ramp distributes forces radially, allowing every thread to share loads more evenly, reducing the loss of torque pre-load and the risk of screw fracture (Figure 20).[39]



Standard
A Conventional thread is axially loaded, increasing probability of shear, especially in soft metals.

Spiralock
A spiralock thread form distributes the load radially beyond the threads, significantly increasing the strength of a connection.

Figure 20: Comparison of the load distribution between a conventional V-thread and Spiralock. The dark gray component represents the abutment screw and the light gray component the implant.[38]

3.3. Macrogeometry

The TPC and TSC implant portfolios offer a range of diameter and length options to accommodate various clinical scenarios and bone conditions. Tapered Pro Conical implants are available in diameters from 3.3mm to 5.2mm and lengths from 9.0mm to 18mm, providing versatility for cases requiring high primary stability and optimized load distribution. Tapered Short Conical implants, designed for cases with limited vertical bone, are available in diameters from 4.2mm to 5.2mm with a length of 7.5mm, ensuring a stable foundation while preserving critical anatomical structures. These dimensional options are combined with BioHorizons' proven Tapered Pro and Tapered Short implants' macrogeometries. The macrogeometry of an implant plays a pivotal role in its clinical performance and long-term success. The implant's features should be carefully designed to provide controlled placement into the osteotomy, preserve crestal bone, enhance primary stability, and optimize load distribution.

Implants within the Tapered Pro Conical system have a tapered apical portion, a parallel coronal portion and a single-lead thread. This model has been very well documented in literature with clinical studies exceeding 10 years of follow-up.[40-42] A tapered design mimics natural oral anatomy and provides more engagement and stability of the implant within the site. The single-lead thread extends continuously from the apex of the TPC implant to the platform with a consistent pitch. While multi-lead threads may provide a faster insertion, in clinical applications, the accurate placement of an implant near critical anatomy (sinus, nerves, etc.) is a complex challenge. The single-lead thread design provides clinicians with more control and predictability as they drive the implant into the osteotomy.

TPC implants include a reduced collar and platform switch design, which shifts the implant-abutment junction inward, toward the implant's center (Figure 21). TSC implants are also designed with the platform switch concept (Figure 22). Platform switch implants have been shown to minimize bone resorption at the implant-abutment junction, preserving vital hard and soft tissues for long term stability and esthetics.[43-45] By maintaining peri-implant bone and gingiva, clinicians can better meet patients' expectations for natural and esthetic outcomes.

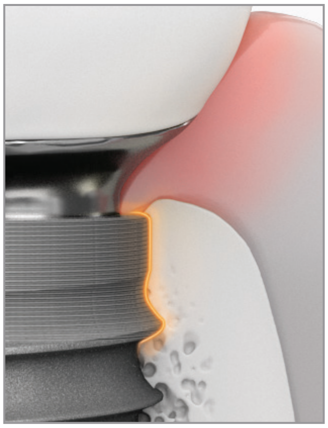


Figure 21: TPC implants have a reduced collar and platform switch design.

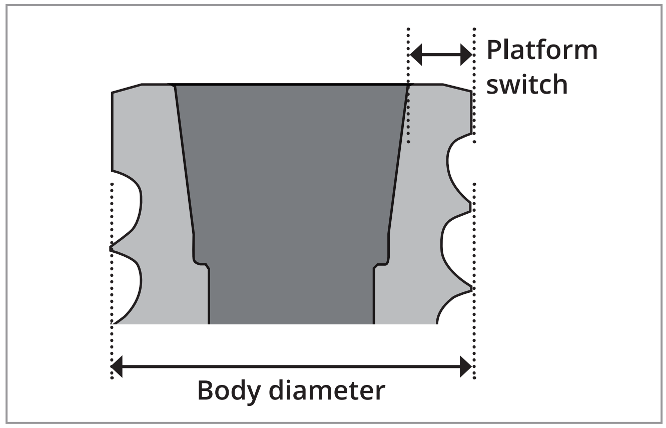


Figure 22: TSC implants feature a beveled platform switch collar.

The thread design of an implant heavily influences the force distribution from the implant to the surrounding bone. BioHorizons TPC and TSC feature moderately aggressive, reverse buttress threads. Reverse buttress threads convert occlusal forces primarily into compressive loads while minimizing shear stress (Figure 23), unlike traditional V-threads that tend to produce high shear forces on surrounding bone (Figure 24).[46]

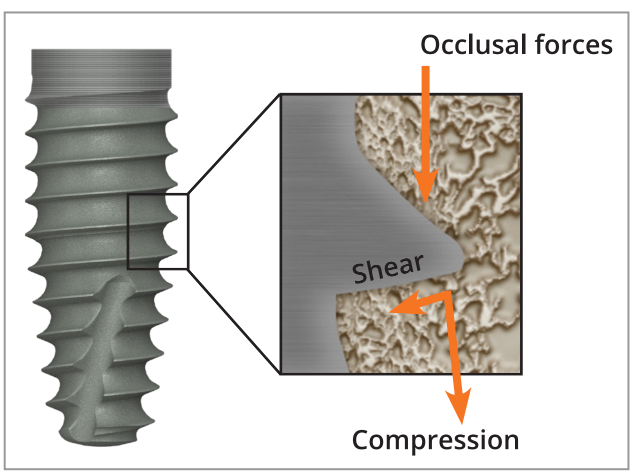


Figure 23: BioHorizons' deep reverse buttress threads have a bottom surface face designed to provide compressive rather than shear force.

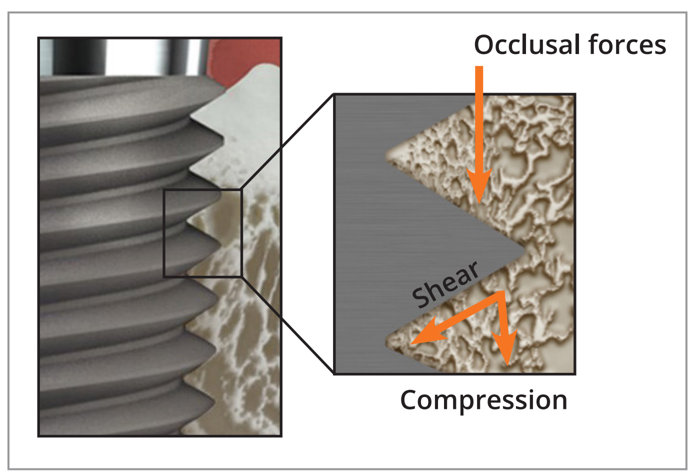


Figure 24: In compression, traditional V-threads' angled interfaces produce significant shear stress which can cause instability and bone resorption at the interface.

Bone is approximately 65% weaker under shear loads compared to compressive loads. The reverse buttress thread design is advantageous and promotes osseointegration by reducing the risk of bone resorption caused by prolonged shear loading.[47] This performance is beneficial for maintaining bone integrity and implant stability across all clinical applications, from single-unit to full-arch.

Additionally, deep reverse buttress threads increase the surface area of the implant in contact with bone compared to standard threads (Figure 25). There is a direct correlation between bone-to-implant contact (BIC) and primary stability of an implant; by increasing the BIC, clinicians are able to achieve higher implant primary stability. This increased primary stability allows implant placement in soft/low-density bone and/or provides an opportunity for immediate implant loading.

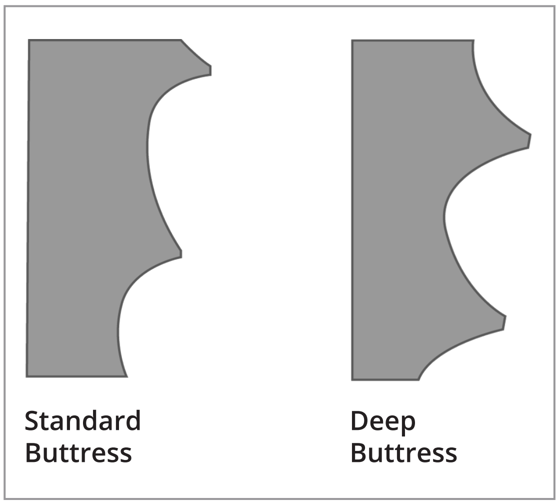


Figure 25: Comparison of buttress thread designs.

The TPC and TSC systems include self-tapping, helical flutes on the apical end of the implants (Figure 26), designed to ease the implants' insertion into osteotomy sites. This design reduces the need for excessive pre-drilling by removing bone fragments upward and away from the osteotomy during insertion. This feature reduces the amount of friction during implant insertion, limiting excessive heat generation and insertion torque, both of which are known to negatively affect osseointegration.[16]

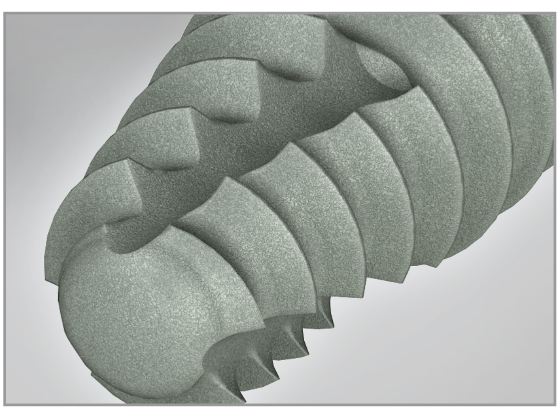


Figure 26: Helical cutting flute featured on BioHorizons' self-tapping TPC and TSC implants.

3.4. Surface Treatment

Dental implants with roughened surfaces are the gold standard in implant dentistry, promoting superior hard tissue attachment by increasing the surface area onto which the tissues adhere.[48, 49] The body of BioHorizons dental implants is grit blasted with resorbable hydroxyapatite (HA), designed to roughen the surface, in a process known as resorbable blast texturing (RBT) (Figure 27). The blasted HA is then cleaned from the implant surface to remove the risk of any imbedded particles. BioHorizons RBT *only* implants clinically demonstrated survival rates between 93% and 100% after 3 to 5 years, 88% to 92% after 10 years, and have exhibited success rates of 88.6% after 7-10 years of follow-up.[40, 50-52] Additionally, BioHorizons RBT implants have produced higher biomechanical fixation compared to other blasted or acid etched surfaces.[53]

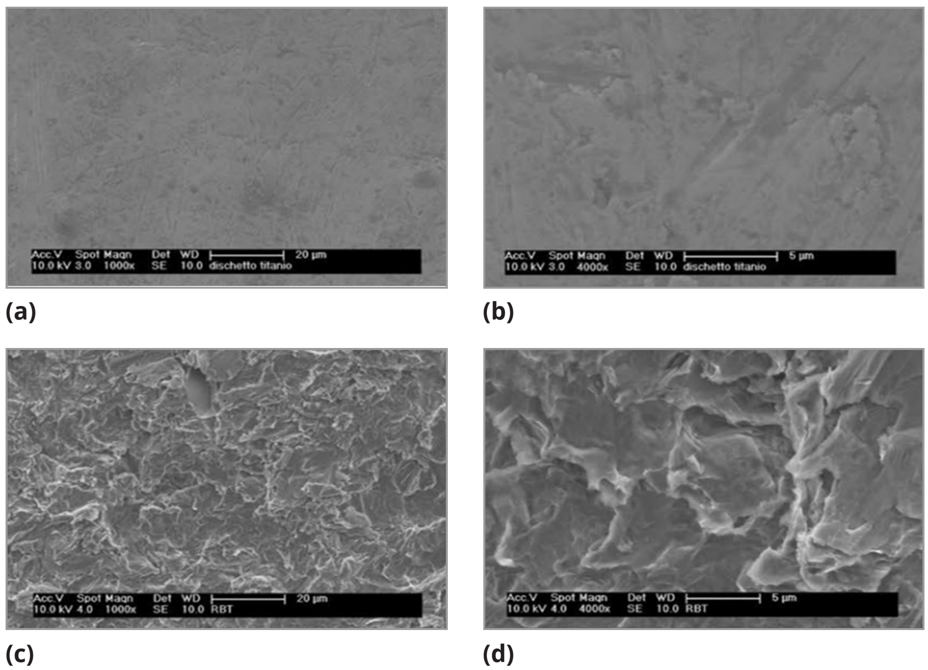


Figure 27: BioHorizons machined surface at (a) 100X and (b) 400X magnifications and RBT treated surface at (c) 100X and (d) 400X magnification.[54]

In addition to the RBT surface treatment, BioHorizons TPC and TSC implants are also offered with Laser-Lok®. This proprietary surface treatment consists of a series of precision engineered, cell-sized (8 µm) microchannels that are laser ablated onto the collar of the implants (Figure 28).

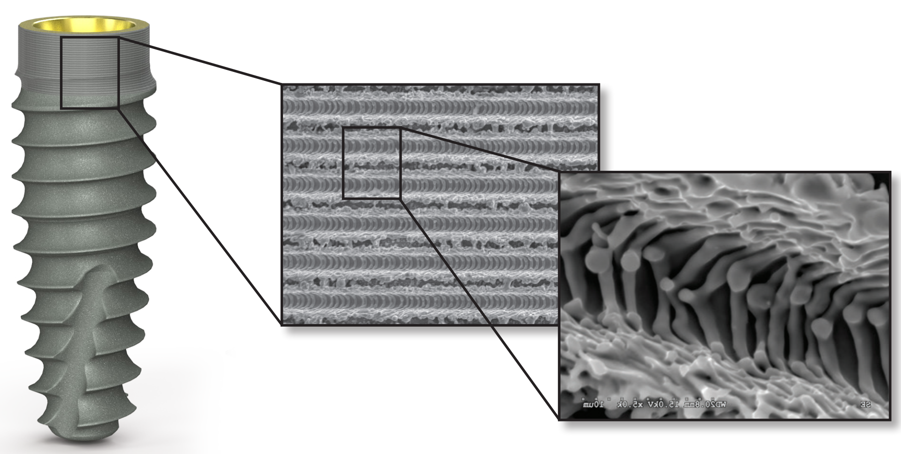
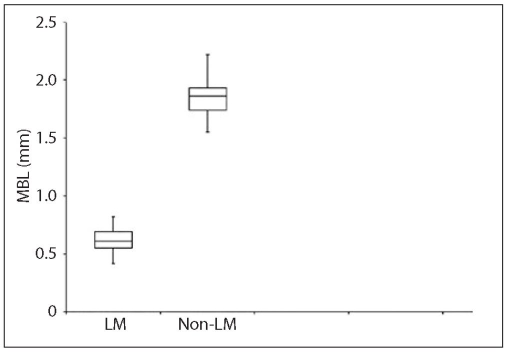
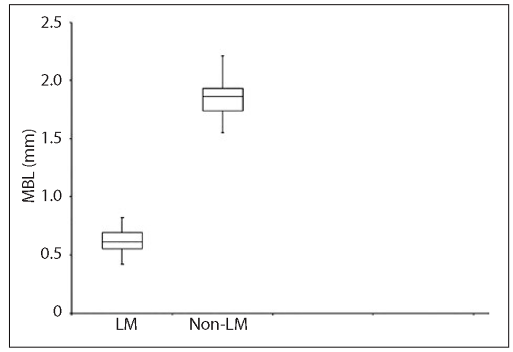


Figure 28: Magnifications of Laser-Lok microchannels show their uniformity and nanostructure.

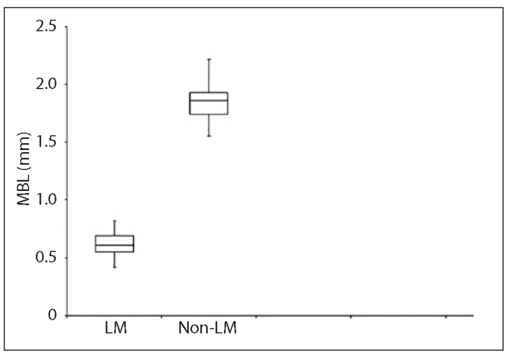
Laser-Lok has over 25 years of documented clinical research and is shown to elicit cellular responses that inhibit epithelial downgrowth and create connective tissue attachment, protecting and maintaining crestal bone levels long-term (Figure 29).[52, 55, 56]



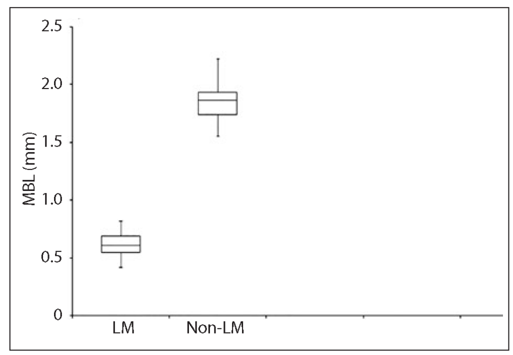
(a)



(b)



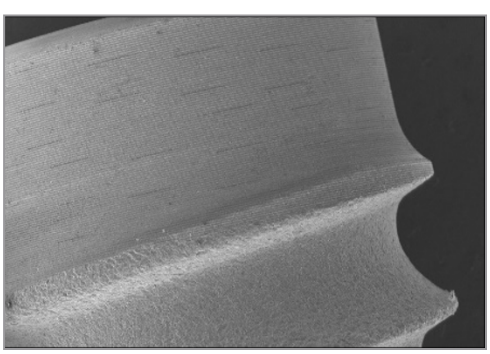
(c)



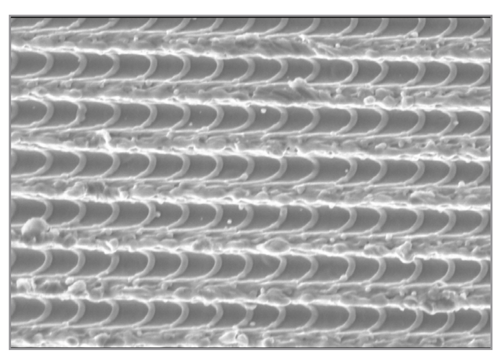
(d)

Figure 29: Comparative results of marginal bone loss (MBL) between Laser-Lok (LM) and non-Laser-Lok (Non-LM) implants after 7-10 years of follow-up according to protocols for (a) immediate placement/immediate loading, (b) immediate placement/delayed loading, (c) delayed placement/immediate loading, and (d) delayed placement/delayed loading.[52]

The transmucosal nature of dental implants requires interaction, and ideally integration, with both hard and soft tissues. Laser-Lok is the *only* dual affinity surface technology that allows for this phenomenon. While micro-threads are designed to engage cortical bone for additional mechanical anchorage, Laser-Lok microchannels are engineered to facilitate specific hard and soft tissue responses at the implant surface (Figure 30). The biologic responses caused by Laser-Lok lead to enhanced osseointegration and peri-implant health.[57-60]



(a)

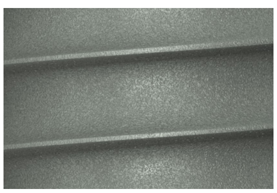
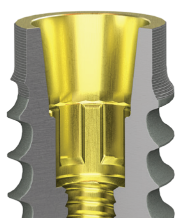
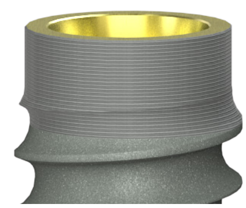


(b)

Figure 30: Laser-Lok microchannels at (a) 15X and (b) 500X magnifications.

A controlled case study on microbial colonization around Laser-Lok versus machined surfaces at the implant-abutment junction reported reduced plaque scores around Laser-Lok. The results were attributed to better connective tissue attachment with Laser-Lok, which led to reduced amount of plaque accumulation.[61] Similarly, a randomized trial compared the microbiologic differences between implants with and without Laser-Lok collars in partially edentulous patients, with and without a history of periodontal disease. A statistically significant difference was noted in periodontally compromised patients after 1 year, with Laser-Lok implants displaying less periodontal pathogens. The authors suggested that Laser-Lok seems to promote the formation of higher soft tissue support in the transmucosal area.[42]

Choosing the right dental implant is critical for ensuring long-term clinical success, predictable mechanical stability, and increased patient satisfaction. BioHorizons' conical implants are an ideal solution because of the extensive benefits stemming from their technological features.

Summary of Key Features for BioHorizons TPC and TSC Implants			
Implant Material	**Connection**	**Macrogeometry**	**Surface Treatment**
			
Ti-6Al-4V ELI	**7.5° deep conical connection with 6-cam locking system**	**Reduced collar, platform switch, reverse buttress threads and helical cutting flute**	**RBT body & Laser-Lok collar**
• Proven biocompatibility for osseointegration • High yield strength for years of masticatory function • TiO_2 layer to prevent corrosion • Higher purity material	• Precise abutment position with tactile feel • Reduced rotational and vertical discrepancies • 6-cam indexing system reducing abutment stock • Spiralock screw technology to prevent screw loosening	• Vertical and esthetic emergenge • No bone profiling, allowing for preservation of vital bone • Compressive distribution of load • Increase bone-to-implant contact area • Self-tapping, apical cutting flutes	• Higher biomechanical fixation • Dual affinity Laser-Lok collar for both soft and hard tissue attachment • Laser-Lok preserves crestal bone long-term and promotes peri-implant health

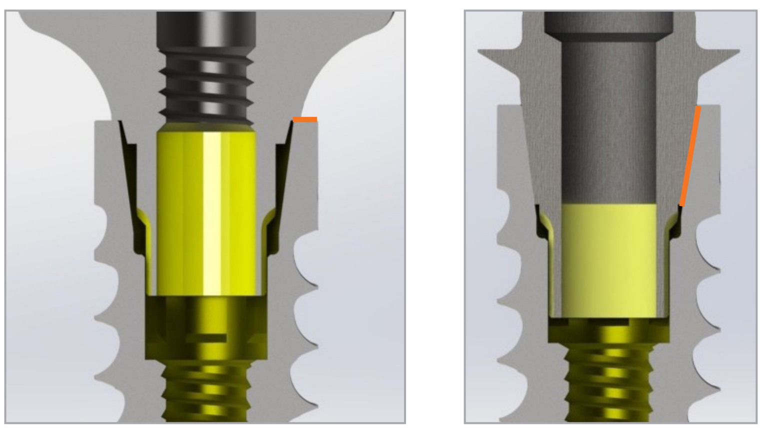
4. Conical Prosthetics and SmartShape Healers

With the dental implant securely placed, the next critical step is the selection of the prosthetic abutment. Just as implant design affects osseointegration and stability, the choice of prosthetics influences soft tissue health and the long-term success of the final restoration. BioHorizons' prosthetic portfolio for the conical systems includes a comprehensive offering from healing and temporary abutments to esthetic, Computer Aided Design/Computer Aided Manufacturing (CAD/CAM), Gold, multi-units and OD Secure™ abutments. The entire range of prosthetics uses only two platforms (narrow and regular) for a streamlined and simplified inventory (Figure 31).

Prosthetic platform	
Narrow	Regular

Figure 31: BioHorizons' full range of prosthetics are offered in two connection sizes: narrow (gray) and regular (yellow).

The conical cover caps, healing abutments, scan bodies, and impression components are designed to be seated onto the implant shoulder and do not lock into the cone of the implant (Figure 32). This design reduces the vertical offset during impression and preserves the implant's cone for the final abutment. The anti-rotational mechanism is maintained via the geometry of engaged cams. Additionally, the healing abutments do not cover the entirety of the implant shoulder allowing for soft tissue adaptation.



(a) **(b)**

Figure 32: (a) Healing and impression components sit on the shoulder of the implant and do not lock into the cone, leaving it intact for (b) final abutment engagement.

Straight, angled, engaging and non-engaging, single-unit, bridged, fixed multi-unit, and detachable restorations are all possible with the conical prosthetics. Digital workflows using Ti-bases or custom abutments are supported with digital libraries for design and milling at validated centers. CEREC® compatible Ti-bases may be used with the Sirona CAD/CAM system to fabricate an abutment with an angle up to 20°.*

*Refer to L02092 for applicable markets.

4.1. SmartShape Healers

In October 2024, BioHorizons launched its most innovative prosthetic component, SmartShape Healers. SmartShape Healers are titanium alloy, anatomically shaped scannable healing abutments, designed to:

- Promote a more natural emergence profile through distinct anatomical designs
- Allow for abutment seating verification through the use of radiographs
- Aid in both traditional and digital impression taking
- Streamline restorative workflows by reducing the need for additional impression components

Anatomical designs: The anatomical designs of SmartShape Healers were developed after extensive analysis of emergence profiles from real world custom milled abutments through BioHorizons' subsidiary, Vulcan Custom Dental. Published literature has greatly emphasized the importance of soft tissue profile management to support prosthetic emergence and long-term peri-implant health.[62-67] Upon review of Vulcan cases and literature, two designs for each of the anterior (A1 & A2), middle (M1 & M2), and posterior (P1 & P2) regions of the mouth were developed to optimize gingival contouring (Figure 33).

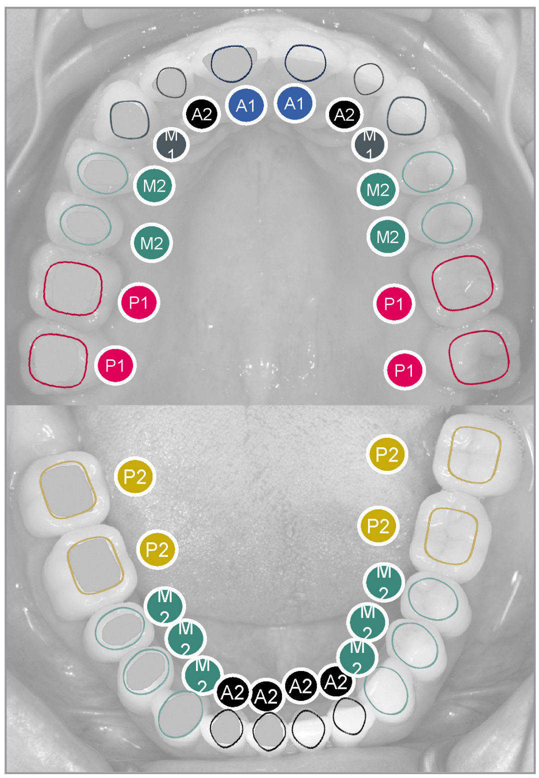
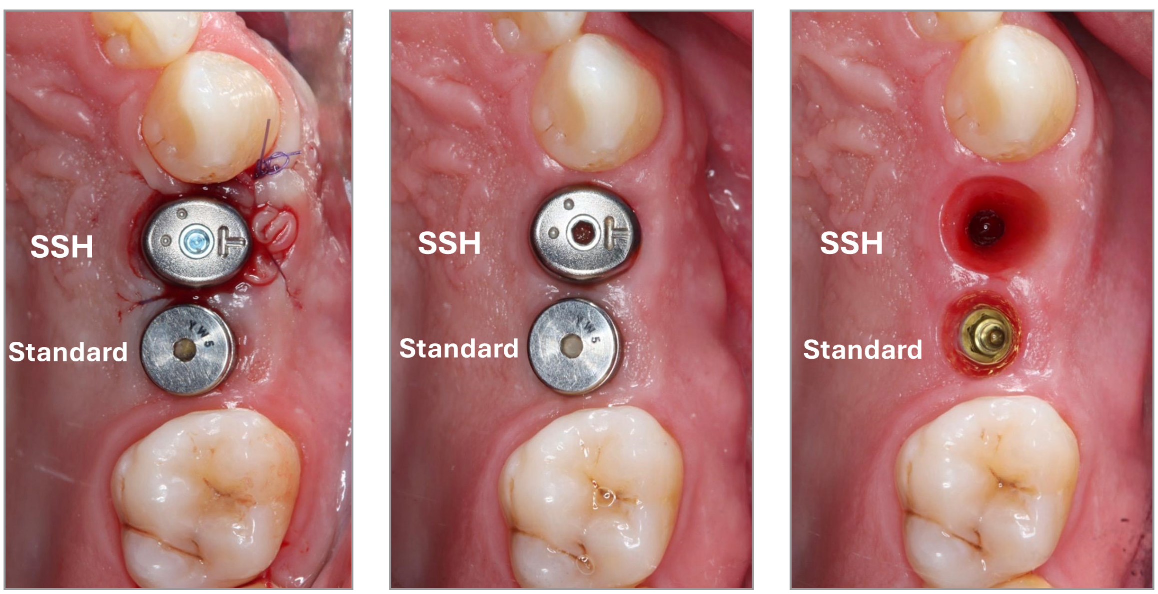


Figure 33: Clinical image from Bishara, et al. (2020) with annotations depicting the profile of SmartShape Healers.[62]

Standard healing abutments, usually circular in design (Figure 34a), do not suit the natural shape of the gingival tissue around teeth. They often necessitate additional soft tissue manipulation to properly seat final restorative components. Discrepancies in the emergence profile among components may increase pain to the patient and add time to the restorative process.[68, 69] SmartShape Healers' site specific designs promote contouring that replicates the natural profile of the soft tissue (Figure 35).

(a) (b)

Figure 34: (a) Standard circular healing abutment compared to (b) six (6) anatomically shaped SmartShape Healers.



(a) (b) (c)

Figure 35: Clinical comparison of a SmartShape Healer and a standard healing abutment (a) immediately after placement and (b) 2.5 months post-op. (c) At 2.5 months post-op, the soft tissue around SmartShape Healers forms a more natural shape compared to tissue around standard healing abutments. *Images are courtesy of Dr. Shaun Young, DMD.*

The SmartShape Healers emerge out of the implant with a concave profile. A concave emergence minimizes pressure on peri-implant tissue, potentially reducing the risk of recession and marginal bone loss and promoting healthier tissue and esthetics (Figure 36).[70, 71] A meta-analysis comparing the prevalence of peri-implantitis for bone level implants between concave and convex abutment emergence profiles, showed a statistical significance favoring a concave design.[72] The same analysis further suggested that repeated disconnection/reconnection of restorative components to the implant increases marginal bone loss.

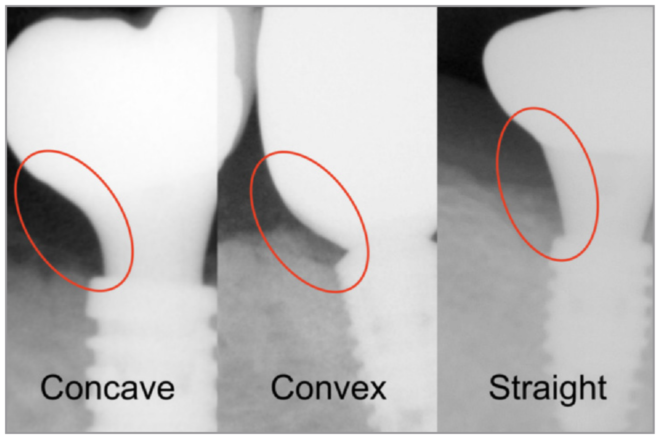


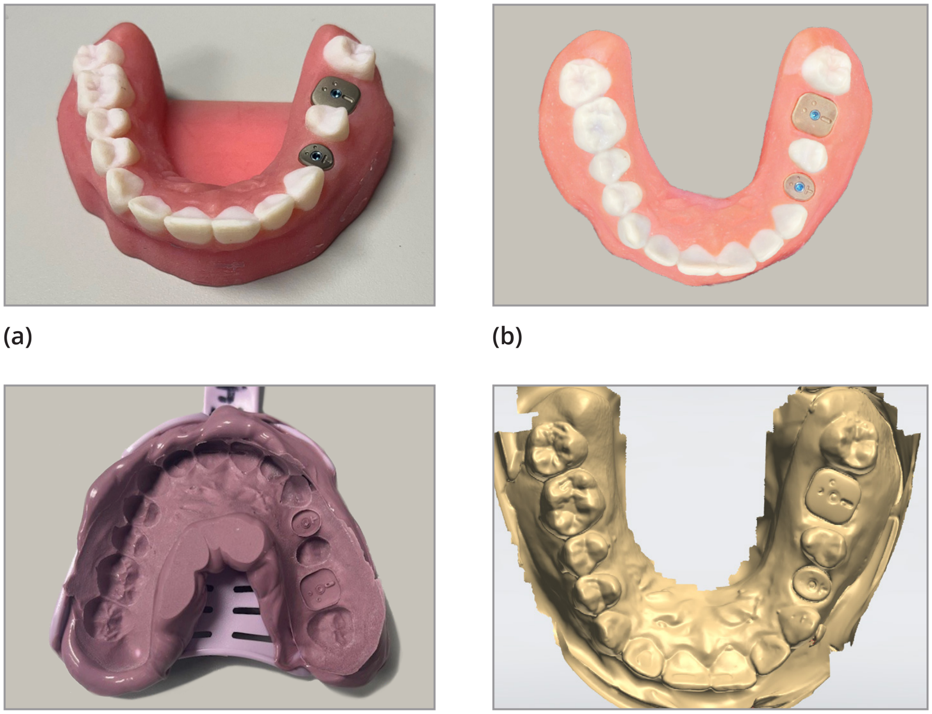
Figure 36: Depiction of concave, convex, and straight emergence profiles.[71]

Seating verification: To develop a final restoration that fits properly within the patient's mouth, impression components need to be accurately seated at all times during the impression process. SmartShape Healers are radio-opaque on radiographs allowing clinicians to verify the seat at the time of placement. This verification step offers two benefits:

- Proper seating reduces microleakage into the system.
- Accurate seating identifies correct implant location and reduces vertical displacement and incorrect restorative fit.

Traditional and digital impressions: BioHorizons' SmartShape Healers can be used for both traditional and digital impression taking. The markings on the occlusal surface, created for easy identification of the abutment, allow for closed-tray impression, while the matte surface finish allows for intraoral digital scanning.

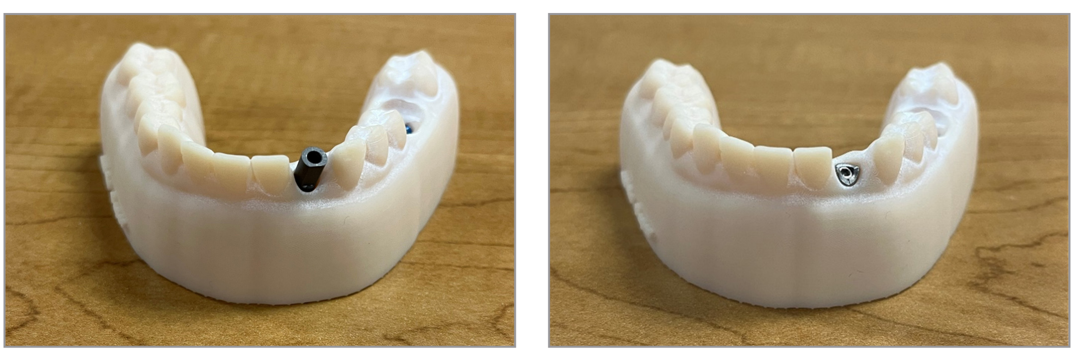
Internal testing established the extent of supragingival profile exposure required to produce an accurate impression (Figure 37).[73] Three hundred and twenty-four (324) total alignments were completed across the test scans, for intra-oral scanning and closed-tray impressions with 100% of the scans meeting the acceptance criteria. This test verified that *0.5mm* of emergence above the gingiva is needed for the accurate pick-up of SmartShape Healers.[73] To meet the minimum required emergence, Regular and Tall SmartShape Healers are available for all anatomical shapes.



(a) (b) (c) (d)

Figure 37: (a) Representative model loaded with M2 and P1 SmartShape Healers, its (b) intraoral scan (3DISC Heron IOS), (c) closed-tray impression and (d) desktop scan (Shining3D Lab Scanner) obtained with 0.5mm of emergence above the model.

Currently, titanium scan bodies are considered state-of-the-art digital impression components for picking up implant positions. As such, SmartShape Healers were tested against titanium scan bodies to verify their accuracy.[74] A model was prepared with missing dentition and appropriate implant analogs inserted. The model was loaded with BioHorizons titanium scan bodies and 3Shape® E4 Dental Lab Desktop Scanner was used to generate a master scan (Figure 38a). A total of twenty-two (22) intraoral scans, using 3Shape's TRIOS® 5 Wireless Intraoral Scanner, were captured for titanium scan bodies and 22 scans were captured for SmartShape Healers (Figure 38).



(a) (b)

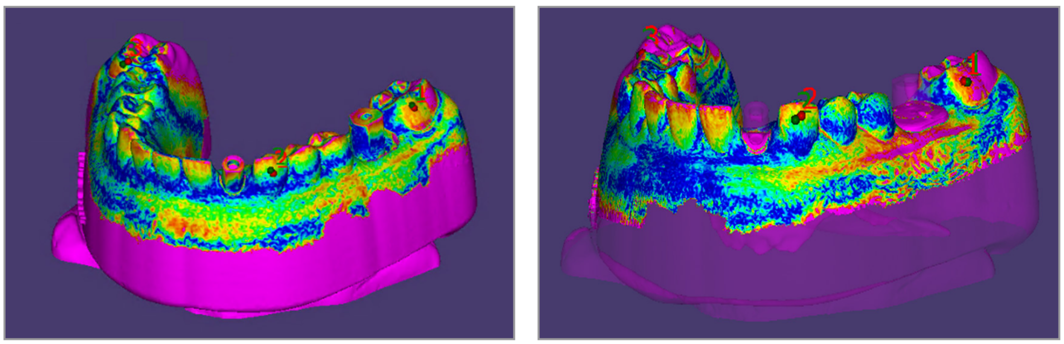
Figure 38: Model with (a) titanium scan bodies and (b) SmartShape Healers.

The IOS scans were superimposed onto the desktop master scan using exocad® alignment tool and the coordinate systems were assigned via 3Shape Abutment Designer (Figure 39 and Figure 40). The vector distance from the master scan was measured for each group using Equation 2 to determine its accuracy.

Equation 2

$$D_i = \sqrt{(x_i^2+y_i^2+z_i^2)}$$

Where: D = vector distance, x = x-coordinate, y = y-coordinate, and z = z-coordinate for scan *i*



(a) (b)

Figure 39: Example of exocad alignment of IOS scan and desktop master scan with (a) titanium scan bodies and with (b) SmartShape Healers.

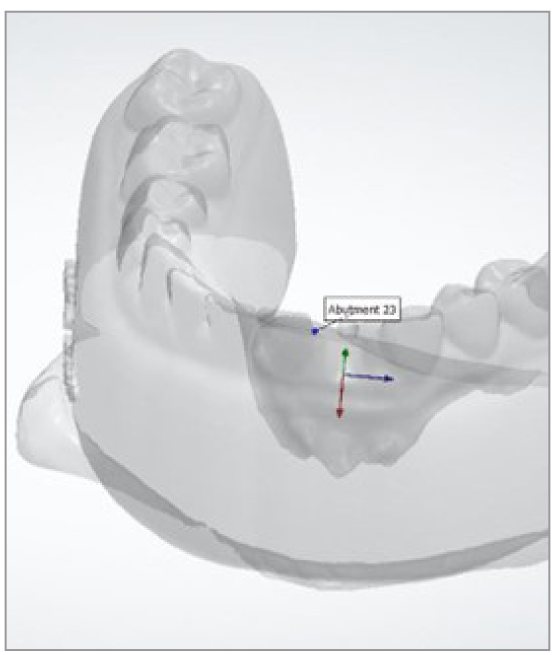


Figure 40: Example of coordinate system for the desktop scan.

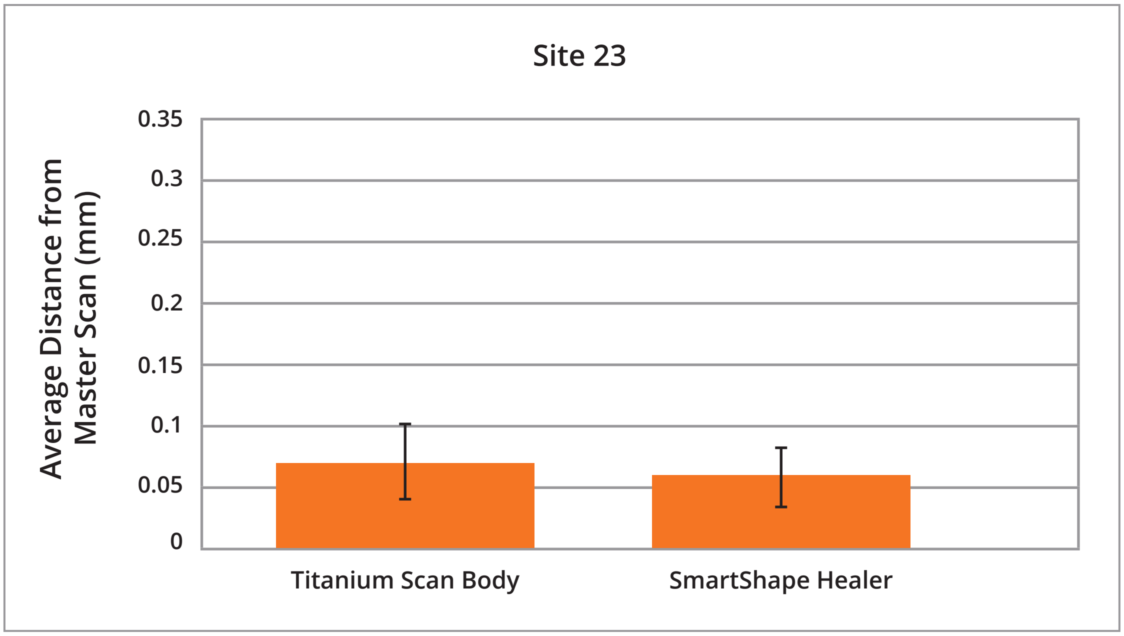


Figure 41. Average difference between IOS scans and the master scan for a representative site 23. Error bars = standard deviation.[74]

The digital scans generated using the SmartShape Healer were as accurate in identifying the implant position as the ones using a Titanium Scan Body, without the need for additional disconnection and reconnection of components.

Streamlined workflow: The integration of anatomical healing, and impression-taking functions into a single component with SmartShape Healers simplifies the restorative workflow and reduces the number of components required. The implant process timeline can span 7-11 months from the time of tooth extraction to the placement of the final crown if following delayed placement and delayed loading protocols (Figure 42).[75] With this approach, patients are required to make several trips to a dentist's office.

SmartShape Healers provide the opportunity for a streamlined workflow using the following steps:

- **Place:**
  After implant placement, the SmartShape Healer can be immediately situated into the implant-abutment connection, if the clinician deems it appropriate.

- **Impress:**
  Once the SmartShape Healer is placed, impression taking can be done at any point, i.e., an impression can be made on the same day as implant placement (surgical step), or the impression can be done later (restorative step).

- **Design:**
  Upon performing the impression, and digitizing as needed, clinicians can either work with a lab or with Vulcan Custom Dental to create their custom final restoration. Vulcan Custom Dental provides digital libraries that help clinicians design a custom milled abutment that is identical to the subgingival contouring of SmartShape Healers.

- **Deliver:**
  After milling, staining, and polishing, the clinician will have a restoration that directly matches the anatomical profile left by the SmartShape Healer, minimizing the amount of tissue remodeling during final abutment placement and maintaining the anatomical esthetics achieved by the SmartShape Healer.

The use of SmartShape Healers provides patients with a final crown within a few short months, reducing the number of visits, the chair time during the impression visit, and increases overall patient satisfaction.

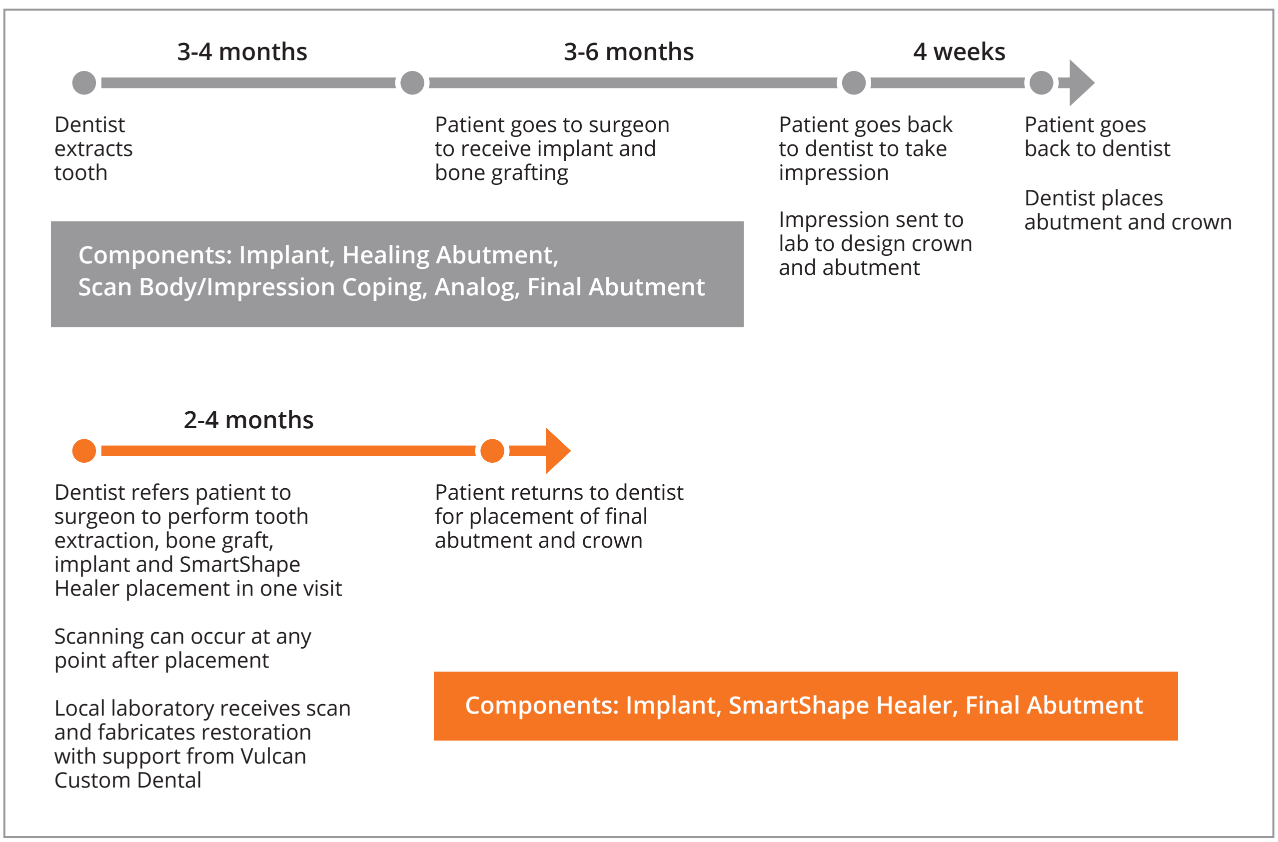


Figure 42: BioHorizons implant referral timeline.

5. Conclusion

BioHorizons' latest innovations- the PRO5000 Guided Surgery Kit, FSK5000 Freehand Surgical Kit, Tapered Pro Conical implants, Tapered Short Conical implants, and SmartShape Healers- demonstrate a continued commitment to advancing implant dentistry through precision, versatility, and clinical efficiency. Each of these solutions is designed to enhance surgical workflows, optimize prosthetic outcomes, and improve patient care by addressing key challenges in implant placement and restoration.

- The PRO5000 and FSK5000 surgical kits provide clinicians with the surgical flexibility to perform both guided and freehand procedures with confidence.
- Tapered Pro Conical and Tapered Short Conical implants offer a stable, biologically-driven foundation for long-term success.
- SmartShape Healers refine the restorative process by providing accurate impressions and improving soft tissue management.

BioHorizons remains dedicated to developing evidence-based solutions that push the boundaries of implant dentistry, supporting clinicians with scientifically backed, performance-driven products that elevate the standard of dental care.

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