

Achieving Osseointegration in Soft Bone: *The Search for Improved Results*

by Gerald A. Niznick, DDS, MSD

Modern implantology represents a continuum of developments spanning more than a century. Most early implant restorations were relatively short-lived, due to a lack of fully biocompatible materials.¹ Increased predictability was finally achieved with Strock's² introduction of cobalt-chromium implants in 1939. The following year, Bothe *et al.*³ made the startling observation that living bone forms a biological bond to titanium and firmly roots the metal to the skeletal structure. Gottlieb and Leventhal⁴ (1951) and Clarke and Hickman⁵ (1953) first realized that titanium holds potential for medical applications, due to its superior strength, corrosion resistance, acceptance by bone and soft tissue, and tendency to increasingly "adhere to bone"⁴ over time. In 1965, after experimenting with a variety of titanium implant designs, Branemark *et al.*⁶ incorporated an external hexagon onto an internally threaded, submergible, machined screw developed by predecessors.⁷⁻⁸ The team's long-term study ultimately explained the biological processes underlying the earlier reports³⁻⁵ of titanium's behavior in vivo, which they termed "osseointegration."⁶

Despite impressive gains in long-term predictability with titanium dental implants, achieving immediate fixation in soft bone is a continuing challenge to implant dentistry. Studies of the Branemark® System over the last 20 years have shown a

10% higher implant failure rate in soft maxillary bone in comparison to the dense bone of the mandible (see table I).⁹⁻¹³ In one five-year study, an implant failure rate of 35% was documented for Branemark implants placed Type IV bone.¹⁴ This failure rate was 32% higher than the cumulative failure rate for all implants placed in Types I-III bone reported in the same study (see table II).¹⁴

The search for improved osseointegration in soft bone has helped propel more than 20 years of post-Branemark⁶ research in implant design, materials and surfaces. Much of the data drawn from these studies have influenced the continuing evolution of modern dental implants. This paper will review some of the recent research in the field, and show how their findings have influenced the development of the Tapered Screw-Vent® implant system (Paragon Implant Company, Encino, California, USA).

EARLY HISTORY

Core-Vent Corporation (now Paragon Implant Company, Encino, CA, and Core-Vent Bio-Engineering, Calabasas Hills, CA) was established in 1982 to market the Core-Vent® implant, a combination of a hollow basket design with external threads.¹⁵ In 1986, the company introduced the original Screw-Vent implant. The initial design was made of commercially pure titanium with a Branemark-style thread pattern and body diameter (3.75

mm). The Screw-Vent features an internal hex (U.S. Pat. #4,960,381) for insertion along with internal threads for attachment of screw-in abutments. As with other screw-type implants at the time, the original acid etched Screw-Vent's success rate diminished as the quality of the bone became less dense.¹⁶

The original Micro-Vent® implant (Core-Vent Corporation/Paragon Implant Company, Encino, CA) was introduced in 1986 to address the clinical need of a more stable implant for porous maxillary bone. It featured a unique tap-in/screw-in surgical protocol for initial stability, and was the first HA-coated implant with threads. This design was followed by the Bio-Vent® implant in 1989, an HA-coated cylinder implant with apical vents and vertical grooves designed for the mandibular jaw. In 1990, an implant selection protocol for the Core-Vent, Screw-Vent, Micro-Vent and Bio-Vent implants was developed based on jaw location and bone quality. The implants were standardized with internal, Hex-Thread® connections, packaged on fixture mounts in sterile vials, and the concept of varying the implant design and material was marketed as the Spectra-System®.

In 1991, the U.S. Department of Veterans Affairs (V.A.) launched a prospective, multi-center study to determine the influence of implant design and bone location on implant success. The Spectra-System



FIGURE 1 Tapered Screw-Vent implant. Triple lead threads are highlighted in three different colors for illustration purposes.

was selected for the study, due to its different design, material and surface options. The V.A. study comprised more than 800 patients and over 80 investigators at 30 V.A. medical centers and two university dental schools. A total of 2795 Spectra-System implants were placed. Based on the results of the V.A. study, the design, material, surface and surgical protocol of the Screw-Vent implant were subsequently changed to better address the differing requirements of hard and soft bone.

IMPLANT DESIGN

Development of small-diameter and tapered implant designs has expanded the benefits of osseointegration to patients previously excluded from implant therapy, due to narrow ridges or limited available bone. Unfortunately, diminishing the diameter of the implant results in a corresponding decrease in the implant's ability to withstand occlusal forces. Over time, there is a greater potential for fatigue fracture of small-diameter implants in high-

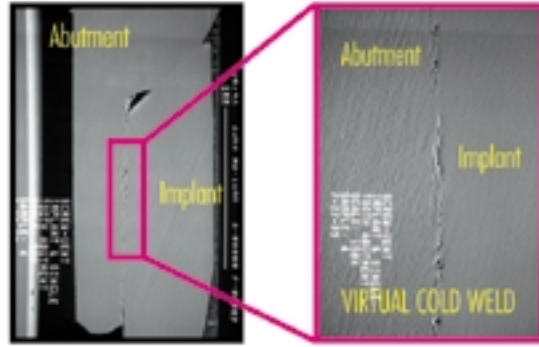


FIGURE 2 SEM cross-section reveals the "virtual cold weld" created between the implant and the abutment.

stress areas, such as the posterior mandible. Tapered screw implants have been able to restore ridges with labial undercuts and convergent tooth roots. Large-diameter tapered implants are also well suited for immediate extraction sites.

In 1999, a slight taper was added to the body design of the Screw-Vent implant. The Tapered Screw-Vent implant is available in 3.7 mm-, 4.7 mm- and 6.0 mm-diameter options. Each diameter option has its own platform diameter, 3.5 mm, 4.5 mm and 5.7 mm, respectively, designed to address the dimensional requirements for esthetics and immediate tooth replacement throughout the entire arch. The stability provided by the implant's patented insertion protocol (discussed below) has allowed for the elimination of the original Screw-Vent implant's narrow, 3.3 mmD implant option.

Tapered Screw-Vent implants feature three independent, external lead threads that spiral up the implant body at a steeper angle than conventional implant threads (Fig. 1). Each 360-degree turn seats the implant 1.8mm instead of the 0.6mm of standard threads. This triple lead thread pattern (U.S. Pat. #5,591,029) thus enables the implant to seat three times faster per 360-degree rotation than screw-type implants with the traditional single-thread pattern.

Multiple deep grooves on the apical ends of the implants are designed to accommodate for bone

chips generated during self-tapping insertion. An apical vent, which varies in size according to the length of the implant, is designed to initially function as a reservoir for the deposition of bone chips generated by the implant's self-tapping apical threads. After seating, the bone chips act as a graft to promote regeneration of bone into the vent for additional implant stability. A smooth, rounded bottom on the implant is designed to facilitate sinus elevation procedures.

Tapered Screw-Vent implants include the original Screw-Vent implant's patented internal hex connection and feature a variety of friction-fit restorative components. When fully assembled, the restorative component forms a "virtual cold weld" with the implant (Fig. 2). Forces are distributed deeper within the implant, which shields the abutment screw from excessive loading and eliminates all rotational and tipping micromovements, the leading causes of abutment screw loosening.¹⁷ This friction-fit connection is also designed to seal the internal chamber of the implant from the marginal leakage and internal bacterial colonization reported with some other implant systems.¹⁸ Once attached, a special tool is required to separate the abutment from the implant.

MATERIAL STRENGTH

Dental implants must be strong enough to resist deformation, metal fatigue and breakage during long-term functional loading. Tapered Screw-Vent implants are made from surgical grade titanium alloy (Grade 23 Ti-6Al-4V), which has a tensile strength of 150 ksi.¹⁹ In comparison, Grade 1 and Grade 3 commercially pure titanium implants have minimum tensile strengths of 35 ksi and 65 ksi, respectively.¹⁹ In corporate testing, the smallest diameter of Tapered Screw-Vent withstood 378 lbs of compressive force at 30 degrees and 24.6 in-lbs of torque (Fig. 3).

IMPLANT SURFACE

The higher failure rate of smooth

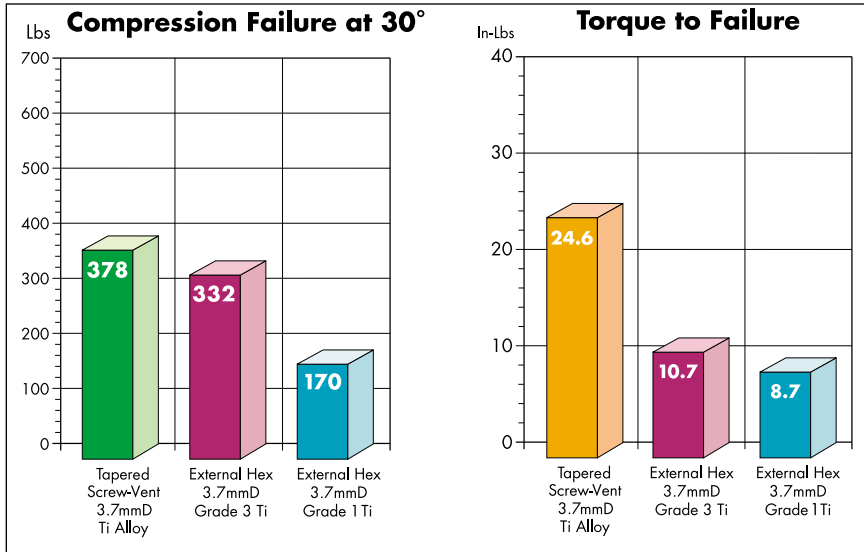


FIGURE 3 Compression failure at 30 degrees and torque to failure.

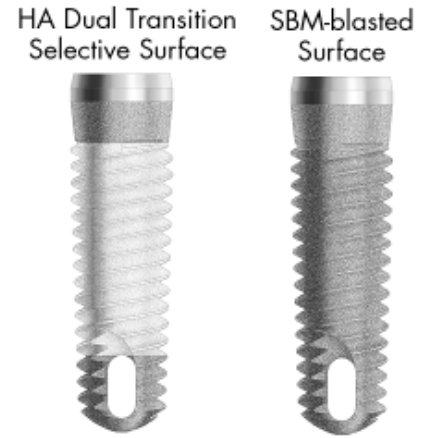


FIGURE 4 Tapered Screw-Vent with HA dual transition selective surface and SBM surface.

implant surfaces in soft bone⁹⁻¹³ and the need to optimize the load-carrying capacity of the implant have stimulated more than two decades of research in implant surface science. Roughening the machined implant surface through a variety of methods has been shown to increase the percentage of bone attachment to the implant,²⁰⁻³⁰ which is especially advantageous in soft bone. In 1976, Schroeder *et al.*²⁰ first introduced implant surfaces coated with Titanium Plasma Spray (TPS), which is the roughest implant surface on the market. Studies by Buser *et al.*,²² Carr *et al.*²⁷ and others have shown that TPS-coated surfaces achieve significantly more bone attachment than implants with machined surfaces. However, titanium particles have been reported in the soft and hard tissues adjacent to TPS-coated implants,³⁰ and soft tissue complications can arise if the rough-coated surface becomes exposed to the gingival crevice.

Hydroxyapatite Plasma Spray (HA) was developed as an implant surface coating by de Groot in 1980,³¹ but did not become commercially available in the United States until approximately 1985.³² Numerous studies have reported superior biocompatibility and long-term effectiveness of HA-coated

dental implants.³³⁻⁴² HA has been documented to bioactively stimulate a much more rapid attachment of bone than uncoated titanium surfaces of various textures,³³⁻³⁵ to form a stronger bond³⁶ and to achieve a greater percentage of bone contact than uncoated titanium surfaces.³⁶⁻³⁷

In the V.A. study, HA-coated implants were not only placed into soft bone, but also into challenging clinical conditions, patients with compromised medical histories and by dentists with different levels of training, skills and experience.³⁹ At every point in the treatment up to 36 months, HA-coated implants exhibited higher survival rates (Cumulative Success: HA 97% vs. Uncoated 86.5%) and less crestal bone loss than uncoated implants.³⁹

Despite numerous studies that affirm the long-term effectiveness of the HA surface,³⁹⁻⁴³ fears of soft tissue complications and subsequent coating resorption still persist among some clinicians. These are largely based on reports of early HA coatings that lacked the degree of crystallinity found in modern coatings. The HA-coated implants used in the V.A. study featured 0.5 mm-high metal collars, which resulted in the HA coating becoming routinely exposed in the short-term.⁴³ In spite

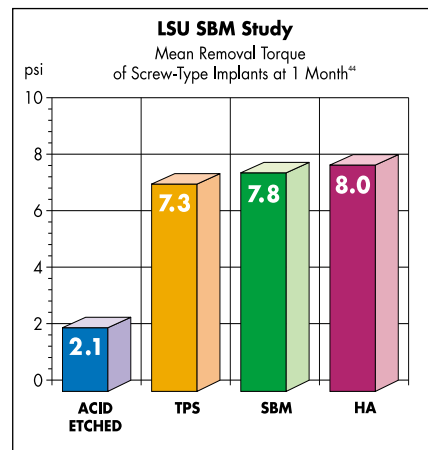


FIGURE 5 Louisiana State University SBM study.

of this, only 4% of the HA-coated implants and 2% of uncoated implants demonstrated any soft tissue complications (statistical significance of the difference = 0).⁴³

Roughening the implant surface by grit blasting has also been widely used in the industry to increase implant surface area. The original Core-Vent implant featured a moderately rough, titanium alloy (Ti-6Al-4V) surface created by grit blasting with aluminum oxide (Al₂O₃), followed by passivating in nitric and sulfuric acids.¹⁵ When blasted with a non-soluble material, such as Al₂O₃, particles of the blasting medium can become embedded in the metal and contaminate the implant surface. Blasting the implant surface with a soluble blasting medium (SBMTM)

provides the opportunity for dissolution of embedded particles during the washing cycles that follow the blasting procedure.

Tapered Screw-Vent implants feature two different surface options designed to enhance bone attachment (Fig. 4). The SBM surface option provides a 1.0 mm-high machined collar designed to minimize soft tissue complications, if exposed, and a body blasted with soluble tricalcium phosphate. Clinical studies of Tapered Screw-Vent's SBM surface have shown greater bone attachment with the SBM surface than with machined or acid-etched surfaces (Fig. 5).⁴⁴ The Dual Transition™ Selective Surface™ option (U.S. Pat. #5,571,017) features an HA-coated midsection (rough surface). Above the coating is a 1.5 mm-high SBM-blasted zone designed to help impede bone resorption and subsequent HA exposure (medium-rough surface). Above the blasted surface is a 1.0 mm-high machined neck (relatively smooth surface) designed for maintenance of soft tissue hygiene. The apical end of the HA coated implant remains uncoated with a SBM surface, to maintain thread sharpness for efficient, self-tapping insertion.

INSERTION PROTOCOLS FOR BONE DENSITY

Relative motion of the implant during the early stages of bone healing can prevent or destroy osseointegration.⁴⁵⁻⁵¹ Bidez⁵⁰ estimates that only 50-100 microns of implant micromovement may be sufficient to inhibit bone regeneration. According to researchers, the ideal implant design should mechanically interlock with the bone at the macro level to provide immediate stabilization.^{48,51} Thread engagement, friction fit or a combination of both are the methods used by root-form implants to achieve initial stabilization. For example, the porous coatings of cylinder implants and the concentric ribs of some finned implants press against the walls of the receptor site when the implant is tapped into place to create a friction fit. The importance of engaging dense, cortical bone as a stable base



FIGURE 6 Soft bone insertion of 4.7 mmD tapered Screw-Vent into an undersized straight osteotomy.

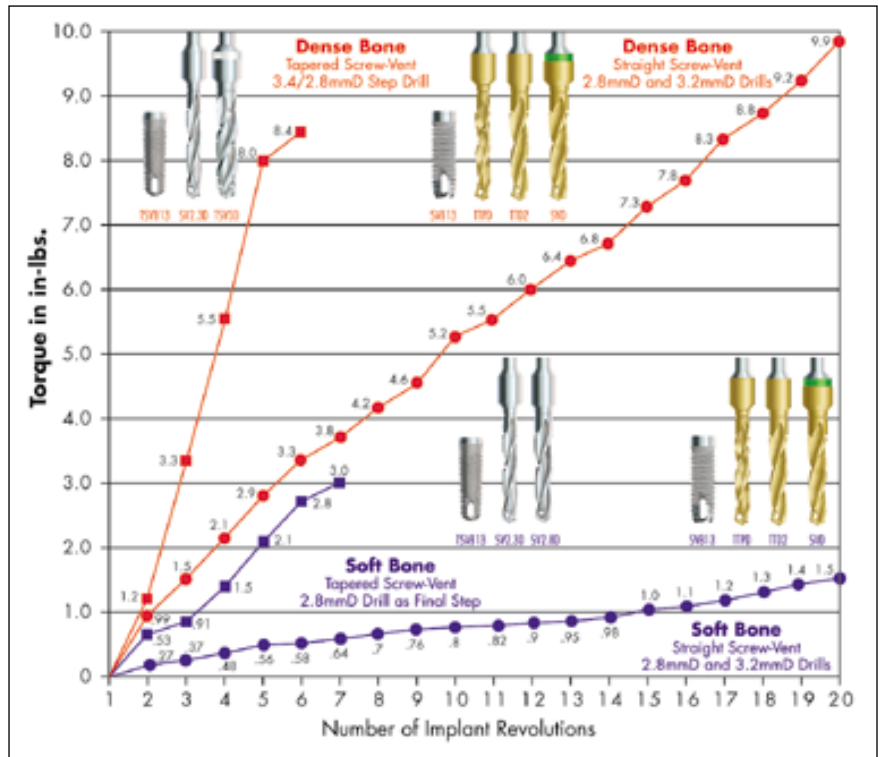


FIGURE 7 Torque comparison of insertion into simulated dense bone and soft bone.



FIGURE 8 Dense bone insertion of 4.7 mmD tapered Screw-Vent into a straight osteotomy.

for initial implant fixation is also well documented in the literature.⁵²⁻⁵⁷ A major challenge of placing implants into soft bone is that the tissue may only present with a thin

cortical shell that is insufficient for thread engagement, and may be too porous or spongy for the implant to achieve a frictional fit against the walls of the osteotomy.

Table I
Comparison of branemark system implant failures by jaw

STUDY	% FAILURE BY JAW			YEAR PUBLISHED/ STUDY PERIOD
	MANDIBLE	MAXILLA	DIFFERENCE	
Adell R, Lekholm U, Rockler B, Brånemark P-I ¹	9%	19%	10%	Published: 1981 5- to 9-Year Study
Mito RS, Lewis S, Beumer III J, Perri G, Moy PK ²	1%	11%	10%	Published: 1989 3-Year Study
Ahlqvist J, Borg K, Gunne J, Nilson H, Olsson M, Astrand P3	3%	11%	8%	Published: 1990 2-Year Study
Adell R, Eriksson B, Lekholm U, Branemark P-I, Jemt T4	14%	22%	8%	Published: 1990 15-Year Study (estimated)
Friberg B, Nilson H, Olsson M, Palmquist C5	0%	13%	13%	Published: 1997 5-Year Study

Table II
Comparison of Brånemark system implant failures by bone quality

STUDY	% FAILURE BY BONE TYPE			YEAR PUBLISHED/ STUDY PERIOD
	TYPES I-III	TYPE IV	DIFFERENCE	
Jaffin RA, Berman CL6	3%	35%	32%	Published: 1991 5-Year Study

The Tapered Screw-Vent is inserted into a straight socket (U.S. Pat. #5,427,527) that is prepared according to bone density. In soft bone, a straight, intermediate drill is used to prepare a socket slightly smaller in diameter than the implant body (Fig. 6). The tip of the tapered implant engages the walls of the osteotomy for insertion. As the implant gradually seats into the receptor site, the widening diameter of the implant body compresses the soft bone to increase mechanical retention for initial stability. In corporate tests of insertion torque into simulated dense bone and soft bone, placing the Tapered Screw-Vent into a straight socket greatly increased torque (Fig. 7). This technique is designed to increase mechanical stability at the crest of the ridge for improved stability in soft bone. It is also designed to provide a simple technique for expansion of narrow ridges.

In dense bone, double-cutting step drills are used to create an osteotomy that allows for thread engagement of the wider diameter implant top without bone expansion (Fig. 8). The bottom of the oste-

otomy is prepared at a smaller diameter for self-tapping by the 3mm-long, tapered, apical end of the implant.

OPTIONAL FEATURES

The Tapered Screw-Vent comes preattached to a color-coded fixture mount in double-vial, sterile packaging. After seating the implant into the osteotomy, the fixture mount can be used as a transfer for a stage-one impression. During the submerged healing period, this combination fixture mount/transfer can also be prepared for use as a temporary abutment. Making a stage-one impression allows for delivery of the provisional restoration at the stage-two uncovering. Alternatively, the fixture mount can be removed after seating the implants, then be used as a transfer at the stage-two uncovering appointment.

If a one-stage surgical protocol is desired, the clinician has the option of attaching the implant's healing collar or using Paragon's AdVent Implant with a 3mm high neck added to the Tapered Screw-Vent Implant body.

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Dr. Niznick is the President, Paragon Implant Company and Core-Vent Bio-Engineering and developer of the Paragon™ System of osseointegrated implants. He earned his DMD degree at the University of Manitoba in 1966, Certification in Prosthodontics from the University of Southern California in 1967 and an MSD degree in Prosthodontics from Indiana University in 1969.

Oral Health welcomes this original article. Complete references upon request.

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