Trabecular Metal™ Dental Implants: Overview of design and developmental research

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Abstract

Research in implant biomaterials and surface technologies over the past three decades has led to development of a porous tantalum biomaterial with a structure and elasticity similar to trabecular bone. This material has been used extensively in orthopedic reconstructions for over a decade. Recent advancements have led to the development of a new *Trabecular Metal* Dental Implant (Zimmer Dental Inc., Carlsbad, CA, USA). This article presents an overview of the implant design, and discusses some of the underlying research that led to its development.

Introduction

Attempts to replace missing teeth with implanted materials have been observed in ancient human remains,[1] and documented experimentally and clinically in the dental literature since the 19th century.[2-3] Over the past 3 decades, dental implant systems have been commercialized in a variety of materials, including tantalum,[2,4-5] vitreous carbon,[6-8] single-crystal sapphire,[9-10] stainless steel,[2-3] titanium,[3,11-14] and other substances. The era of modern implant dentistry, however, is primarily built on orthopedic titanium research subsequently adapted for dental implant applications. In 1940, orthopedic surgeons[15] first experimented with the surgical use of titanium and reported its extreme biocompatibility. In the 1950s, other orthopedic surgeons[16-17] documented titanium's superior ability to withstand corrosion and remain relatively inert in the body.[18-20] In 1977, orthopedic surgeon Per-Ingvar Brånemark and colleagues[11-14] published results of their monumental 10-year dental implant study. The Brånemark team documented[11-14] the processes and conditions in which ordered, living bone could form a direct structural and functional connection with a load-carrying titanium dental implant. The researchers[11] coined the term "osseointegration" to describe the natural phenomenon first reported more than three decades earlier by their predecessors.[15-17]

In the three decades since the seminal Brånemark study[11] was published, continuing dental and orthopedic research has focused on various techniques for enhancing bone apposition to implanted titanium surfaces. Despite differences in anatomical locations and bone structures, a variety of surface modification techniques developed in orthopedics have since been successfully adapted for dental implant use. Among these are hydroxylapatite (HA), titanium plasma spray (TPS), and porous surface coatings, such as porous bead surfaces and cancellous-structured titanium (CSTi™) Coating.

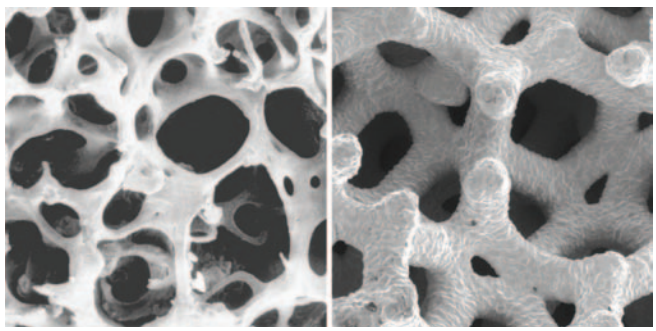

Figure 1. *SEM view of trabecular bone (left) and* Trabecular Metal *Material (right).*

Trabecular Metal Material (Zimmer Dental Inc., Carlsbad, CA, USA) is a porous biomaterial with a structure and stiffness similar to trabecular bone **(Figure 1)**.[21-26] It is fabricated by coating a vitreous carbon skeleton with tantalum **(Figure 2)** through a proprietary chemical vapor deposition coating process. The tantalum exhibits a crystallographic growth pattern[26-27] on the vitreous carbon surface of the interconnecting struts[23, 27-31] **(Figure 1)** that form the material. *Trabecular Metal* Technology significantly differs from sintered bead surfaces, titanium plasma-sprayed surfaces, titanium fiber mesh and titanium foam in the high degree of its interconnected porosity (up to 80%) and the regularity of its pore size and shape.[23, 27-28, 30-31] In contrast to conventional bone-to-implant contact achieved by non-porous surfaces, *Trabecular Metal* Technology's geometrical network of interconnected pores is designed for biological ingrowth through the pores.[20, 24-27, 30-32] This *Trabecular Metal* Material has been used extensively in orthopedic reconstructions for more than a decade.[23-25, 28, 31, 33-34] The present article will present an overview of a new *Trabecular Metal* Dental Implant and its developmental research.

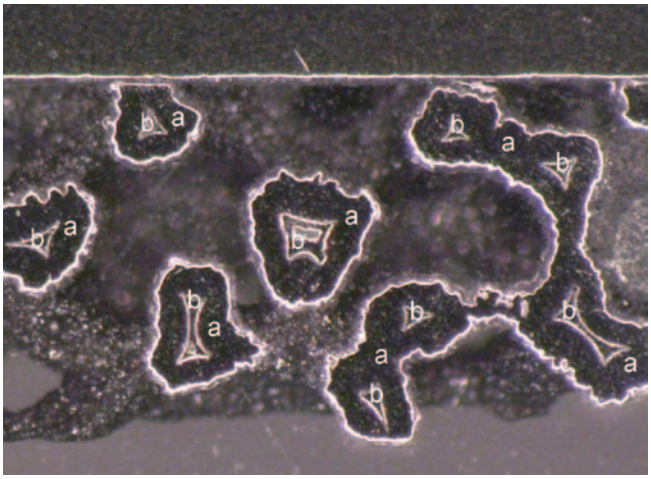

Figure 2. *SEM cross-section of* Trabecular Metal *Material struts shows the (a) tantalum coating over (b) the vitreous carbon skeleton.*

Preliminary experiments with Trabecular Metal Technology as a biomaterial

Trabecular Metal Technology was originally commercialized as *Hedrocel*® Material, and envisioned as a 3-dimensional bone augmentation material. Commencing in the early 1990s, a series of *in vivo* canine evaluations[30,35-37] in the canine model and mechanical testing[38] experimentally evaluated *Trabecular Metal* Material's 3-dimensional, open-cell structure as a potential implant for cancellous bone ingrowth and support of a dental implant in the alveolar ridge.

National Institutes of Health Research Grant (DE09781) Under a research grant from the National Institutes of Health, Kaplan et al.[30,35-37] created 18mm, full-thickness mandibular resections from the right hemi-mandibles of 6 dogs. A *Trabecular Metal* Implant was placed in the site and stabilized with a 10-hole reconstruction plate.[30,35-37] In the left (opposite) hemi-mandibles, a 17mm, full-thickness resection was made and then augmented with the bone resected from the right side of the jaw, and stabilized with a 10-hole reconstruction plate.[30,35-37] Animals were subjected to daily examination and monthly ventrodorsal radiographs for a period of 6 months to assess healing of the defect sites.[30,35-37]

Reconstruction plates were removed after 3 months in animals that exhibited mandibular stability in radiographic and physical examinations.[30,35-37] Animals that did not demonstrate stability after 3 months were allowed to continue healing and monthly evaluations until stability was confirmed and the plate could be removed.[30,35-37] After 6 months, all dogs were sacrificed and the entire mandible was harvested from each animal.[30,35-37] Any remaining compression plates were removed from the dogs at the time of sacrifice.[30,35-37] Each mandible was sectioned in left (control group) and right (test group) halves.[30,35-37] Mandible halves were then sectioned and prepared for histologic analysis.[30,35-37]

A total of 6 mandibles were obtained.[30,35-37] In 2 of these, the test implant had fallen out secondary to resorption of the adjacent bone caused by infection.[30,35-37] In all surviving samples, the *Trabecular Metal* Material side was compared with the contralateral control side.[30,35-37] All 4 surviving samples had osteoid crossing through the *Trabecular Metal* Implant, and 3 out of 4 samples had mineralized bone in the center of the material **(Figure 3)**.[30,35-37] One sample had mineralized bone at the edges, but the center was not yet mineralized **(Figures 4 and 5)**.[30,35-37] The majority of the mineralization appeared at the edges of the (osteotomy) cut.[30,35-37] There seemed to be more bone forming at the caudal, superior and the lingual aspects of the implants as opposed to the cranial, inferior and buccal sides.[30,35-37]

Most of the new bone was woven **(Figure 4)**, however small foci of lamellar bone were seen mostly at the edges of the implant bone interface.[30,35-37] Marrow elements were not seen in any sample.[36] Cellular elements (osteoblasts) were identified in the woven bone in the implant; however, these were quantitatively more prevalent at the edges.[30,35-37]

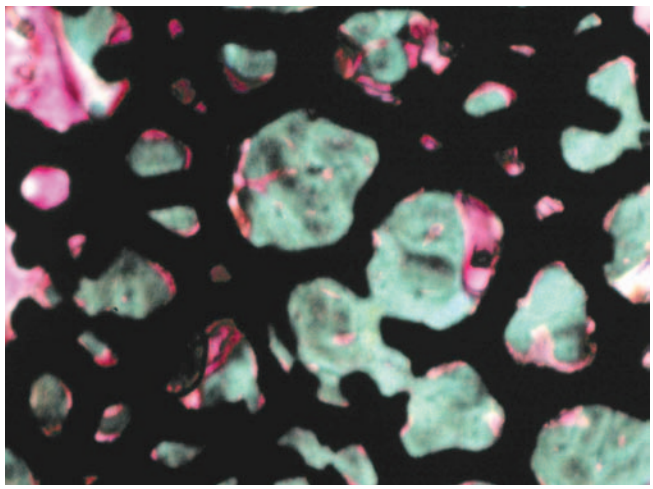

Figure 3. *Mineralized bone ingrowth into porous* Trabecular Metal *Material (seen as black in the photograph).*[37] *Osteoid matrix conversion to mineralized bone is shown*[37] *(MIBS stain).*

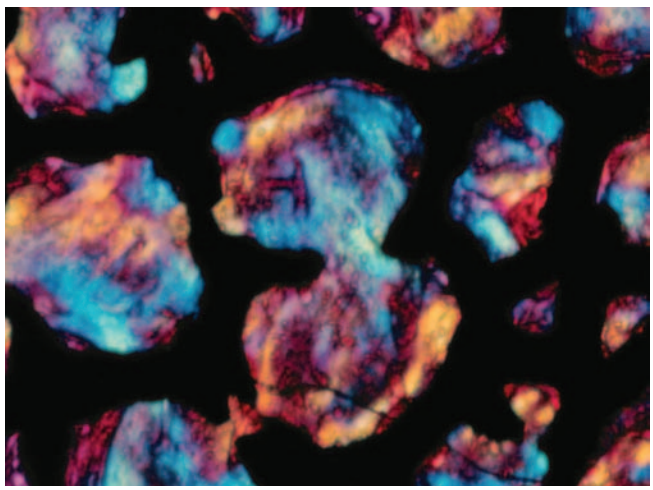

Figure 4. *Woven bone ingrowth into* Trabecular Metal *Material pores*[37] *(trichrome stain, semi-polarized light).*

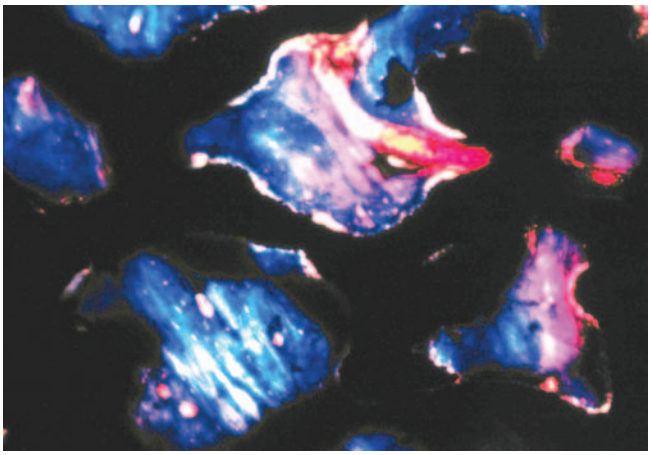

Figure 5. *Lamellar bone formation inside porous* Trabecular Metal *Material.*[37] *According to the researchers, "the maturation of woven bone into lamellar bone is indicative of normal bone and permanency"*[37] *(trichrome stain, semi-polarized light).*

Control samples exhibited good evidence of union in all cases, including the cases that were infected.[30,35-37] In comparison to the control cases, the 4 surviving test samples exhibited greater new bone formation in 1 case, less new bone formation in 1 case, and more area of bone formation in 2 cases, but the degree of mineralization was slightly less than that of the control samples.[30,35-37] The researchers[30,35-37] concluded that *Trabecular Metal* Technology and autogenous bone were equally successful in treating mandibular discontinuity defects. Bone grew into *Trabecular Metal* Material, mineralized and developed cellular components.[30,35-37]

United States Patent No. 5,282,861 Issued in 1994 The inventor of United States Patent No. 5,282,861 was also involved in research conducted under the *National Institutes of Health Research Grant (DE09781-03)* cited above.[35] This patent stated that *Trabecular Metal* Technology could be potentially used for "alveolar ridge augmentation, periodontics, and orthognathic reconstruction," and that it was "useful in orthopedic applications as well." Although *Trabecular Metal* Technology's actual commercialization has been strictly limited to orthopedic applications to date, the 1994 patent (U.S. 5,282,861) further stated that the "present invention may also be used for tooth replacement because of the ability to induce tissue and bone growth even in the face of mildly infectious conditions. For example, an artificial tooth can be joined to an open cell tantalum stem and positioned in an appropriately sized hole in the jaw. The gum is allowed to rest against the artificial tooth and some of the stem to form a seal." While this proposed dental implant design was never developed with *Trabecular Metal* Material a similar design made with titanium fiber mesh had been previously launched during the 1970s, but the fibro-osseous interface that it developed limited its success.[39-46]

Mechanical integrity between Trabecular Metal Material and a single-tooth implant Dillion et al.[38] conducted a mechanical experiment to determine the ability of a 3-dimensional *Trabecular Metal* Material bone graft to support an implant-supported, single-tooth restoration.

A 3.7mm-diameter threaded titanium implant (*Screw-Vent*® Implant, Zimmer Dental Inc.) was placed in a 10mm x 20mm x 25mm *Trabecular Metal* Material porous tantalum block, which was currently under investigation for use as a bone substitute for large segmental defects.[38] The system was evaluated in single-cycle and fatigue in axial compression and cantilever bending. Compression samples were loaded at 25N/sec in air to a maximum of 300N, and bending samples were loaded at 25N/sec in air to failure.[38] Fatigue samples were tested in Ringers at 37ºC at 5Hz to 2.5 x 10^6 cycles.[38] Compressive fatigue failure was defined as 0.03mm of permanent deformation.[38] Results showed a mean single-cycle bending strength of 1.04 ± 0.13kN·mm and a mean displacement of 2.47 ± 0.61mm using a lever arm of 7.5mm.[38] Axial compression tests showed a mean displacement of 0.17 ± 0.01mm at the maximum 300N load and the average load value at which the sample began to yield was 0.07kN (± .028kN).[38] A cantilever bending S/N curve was generated from 80% of yield to run-out at 2.5 x 10^6 cycles.[38] No failure of the *Trabecular Metal* Material or at the interface was detected.[38] All samples failed due to deformation of the abutment screw.[38] Axial compressive fatigue was performed to a maximum load of 600N, which was approximately four times normal biting force with no failure.[38] Both single-cycle and fatigue tests indicated that the implant/*Trabecular Metal* Material system was able to withstand loads that were significantly greater than those found *in vivo*.[38] Failure of the system occurred in the screw attaching the abutment rather than at the implant/*Trabecular Metal* Material interface or within the *Trabecular Metal* Material itself.[38]

Mechanical feasibility study on the potential use of Trabecular Metal Technology as a dental implant material (ZRR-ZD-00011-07) Cylindrical and hexagonal blocks of *Trabecular Metal* Material were evaluated for push-in/push-out force, removal torque, and static compression evaluations in a polyether polyurethane surrogate bone material to determine how the material might function during placement into bone, and how it might withstand direct loading. Large-diameter (6.0mm) *Trabecular Metal* Material blocks showed good initial stability and were strong enough to resist compressive loading forces that exceeded those documented for the oral environment. Smaller diameter (3.7mm, 3.0mm) *Trabecular Metal* Material blocks would benefit from an anti-rotational feature, such as external threads, to improve initial stability and internal reinforcement to resist compressive forces in the oral environment. For example, an implant made of both titanium and *Trabecular Metal* Material would be significantly stronger than solid *Trabecular Metal* Material blocks alone. Results from these experiments indicate that a combination of *Trabecular Metal* Material and titanium will provide acceptable mechanical characteristics for a dental implant.

Development of Trabecular Metal Technology as a dental implant

The implant is a tapered, multi-threaded, endosseous design similar to its predicate, the *Tapered Screw-Vent*® Implant (Zimmer Dental Inc.), but modified with a

Trabecular Metal Material midsection **(Figure 6)**. The coronal, apical and internal implant structures are made of titanium alloy (Ti-6Al-4V grade 5) with a microtextured surface created by grit-blasting with hydroxylapatite (*MTX*® Surface). The coronal section features cervical micro-grooves and Zimmer Dental's internal hex, friction-fit connection, and the apical section features self-tapping threads. In the midsection of the implant, the *Trabecular Metal* Material is made of tantalum (98%) over a vitreous carbon substrate (2%) **(Figure 2)**.

Figure 6. Trabecular Metal *Dental Implant.*

Tantalum This highly biocompatible[47-49] metal has been widely used for over half a century in implanted medical devices for humans: dental implants,[2, 4-5] orthopedic implants,[24-26, 29, 32-34, 49-50] surgical ligation clips,[47, 51] plates, nets and wires used in neurosurgery, cranioplasty, and oral and maxillofacial reconstructions,[47, 52-56] electrodes for pacemakers,[47, 57] and many other clinical applications.[47, 58-59] It has been reported that tantalum does not elicit the cytotoxicity levels associated with some other metals, such as nickel, cobalt and chromium,[47, 60] and that it exhibits strong resistance to oxidation, corrosion and concomitant ion production.[47, 41, 60-63] Tantalum was initially Brånemark's[13] biomaterial of choice for his early bone growth research. The high cost of tantalum, however, made titanium a more feasible material at the time.

Vitreous carbon One early clinical concern in the development of a *Trabecular Metal* Implant was the effect that exposure of its internal vitreous carbon core **(Figure 2)** might have in the osseous environment. Long-term use as a dental implant material in humans,[6-8] and short-[64-65] and long-term[66] animal studies have demonstrated that vitreous carbon is well-tolerated in the oral environment.[6] A five-year systemic, toxicological, carcinogenic study in dogs reported that vitreous carbon implants exhibited no systemic responses in the major organs, tissues, blood or urine, and no evidence of inflammatory response or foreign body reactions in the adjacent tissues.[6, 66] Large-scale hard- and soft-tissue ingrowth into the macroscopic grooves and other surface architecture of vitreous carbon has been extensively documented.[6, 67-68]

Mechanical evaluation of 4.7mm-diameter Trabecular Metal Dental Implants (ZRR-ZD-00065-00) The purpose of this experiment was to determine if *Trabecular Metal* Implants would exhibit an adequate fatigue endurance limit that was equal to or greater than 90 lbs (400N), when subjected to cyclic compressive loading. This strength limitation was based on expected bite force ranges reported in the molar region.[69] Other important data collected for investigative purposes included ultimate strength during static compression loading and failure modes under static and fatigue loading. Evaluations were performed with *Trabecular Metal* Dental Implants, 4.7mm in diameter, in accordance with corporate requirements (ZRP-ZD-00065-00 and TP-307, Zimmer Dental Inc.), good manufacturing practices, and international standards.[70] The 4.7mm diameter *Trabecular Metal* Implants had an endurance limit of 100 lbs (445N); therefore, it was concluded that both the 4.7mm and 6.0mm diameter *Trabecular Metal* Implants could withstand the forces anticipated in the molar region.

Abrasion evaluations of dental implants with porous surfaces (ZRM-ZD-00028-00) This experiment was conducted to evaluate whether the friction caused by implant placement into an osteotomy was capable of damaging porous implant surfaces. Implants with two different porous surfaces were evaluated: *Trabecular Metal* Dental Implants and Cancellous-Structured Titanium (*CSTi*) dental implants. Test samples were microscopically examined at various magnifications, and compared before and after placement into two substrates: a synthetic surrogate bone material made of rigid, polyether polyurethane with a fine, closed-cell structure (density = 0.32g/cm^3; 20 lb/ft^3) (Last-A-Foam®, General Plastics Manufacturing Co., Tacoma, WA) (bone foam) and bovine condyle. Abrasion leading to subsequent release of metal debris from the implant surfaces was not expected because of differences in shear strengths between porous metal implants and bone. In this study, the *Trabecular Metal* Material and *CSTi* dental implants showed no evidence of abrasion or subsequent release of metal debris into the osteotomy. This was identified under 24X magnification, and was more evident under 65X and 137X magnification levels, where porous sections oriented both parallel and perpendicular to the long axis of the implants showed no deformation after implant placement.

Insertion torque analysis of Zimmer Trabecular Metal Dental Implants in simulated dense bone (ZRR-ZD-00060-00 Add 1, ZRM-ZD-00034-00, ZRR-ZD-00098-00, ZRR-ZD-00060-00 Add 3) Implant insertion torque values for *Trabecular Metal* Technology test implants and 2 titanium control implants (*Tapered Screw-Vent* Implant, Zimmer Dental Inc.; NobelReplace,® Nobel Biocare Implant, Yorba Linda, CA) were evaluated in bone foam. The composition of the bone foam consisted of a dense outer layer (50 lb/ft^3) analogous to cortical bone, and a solid, rigid foam core (30 lb/ft^3) analogous to trabecular bone. This experiment was conducted to determine if the insertion torque required to place the *Trabecular Metal* Implant in simulated dense bone was comparable to that of the control implants. The *Tapered Screw-Vent* Implant[71-72] and NobelReplace[73-74] implants were selected as controls because of their high documented success rates under delayed and immediate loading conditions. Control implant insertion torque values ranged from a maximum of 186.5Ncm (average = 157.9 ± 21.2Ncm) (*Tapered Screw-Vent*, 6.0mm x 13mm) to a minimum of 84.5Ncm (average = 89.5 ± 3.9Ncm) (NobelReplace Implant, 5.0mm x 13mm) **(Table 1)**.

In a preliminary insertion torque experiment, insertion torque values were recorded for both implants in the same simulated bone model. *Tapered Screw-Vent* Implants (6.0mm x 13mm) exhibited significantly higher insertion torque values than NobelReplace implants (5.0mm x 13mm). These implants were selected as control implants in the present study because they represented a theoretical range of highest and lowest acceptable insertion torque values, respectively. *Trabecular Metal* test implants (6.0mm x 13mm and 4.7mm x 13mm) approximated the dimensions of the control implants. Acceptance criteria for this experiment required that the average insertion torque values for *Trabecular Metal* Implants were equivalent or fell between the maximum and minimum torque values exhibited by the control implants, and that the differences between test and control implants be statistically significant. Insertion torque values of the *Trabecular Metal* test implants ranged from a maximum 169.0Ncm (average = 161.1 ± 5.7Ncm) for 6.0mm x 13mm implants to a minimum of 100.5Ncm (average = 104.1 ± 3.8Ncm) for implants 4.7mm x 13mm **(Table 1)**. Differences between the 4.7mmD test and 5.0mmD control implants were statistically significant. Average insertion torque data for 6.0mmD test and control implants were statistically equivalent.

Trabecular Metal Dental Implants exhibited insertion torque values within the range exhibited by the commercially available control implants. Numerous studies[73-77] have used insertion torque values as stability guidelines for determining whether a dental implant can sustain immediate loading, although there is no clinical consensus on what should constitute a minimum insertion torque level. In general, however, many clinicians[73-77] have selected an approximate insertion torque value of 35Ncm or greater as a determining guideline for immediate loading. The average insertion torque values of *Trabecular Metal* Material test implants in this study thus significantly exceeded this threshold **(Table 1)**.

Press-fit analysis of Trabecular Metal Dental Implants (ZRR-ZD-00064-00) As compared to conventionally threaded implants, *Trabecular Metal* Implants have fewer external threads for primary stabilization, and a porous surface that forms a frictional interface with bone. This experiment evaluated the effect of torsional forces on the structural integrity of *Trabecular Metal* Dental Implants during and after placement in bone. Previous corporate experiments (ZRR-ZD-00060-00) assessed the amount of torque required to place solid *Trabecular Metal* Material cylinders into bone, and the result frictional placement had on the structural integrity of the material. Results provided baseline data for comparing results obtained when *Trabecular Metal* Material is incorporated into a threaded implant design. The amount of torque required to compromise the structural integrity of a *Trabecular Metal* Dental Implant was found to be significantly greater than the amount of torque actually placed on the *Trabecular Metal* Material itself during implant insertion into bone. Furthermore, a fully integrated implant was found to withstand a rotational force of greater than 355Ncm, which is more than 3-times greater than the anticipated worst-case torsional forces on molars during immediate occlusal loading (110Ncm, per Engineering Analysis, Lab notebook ZDI-269 pp. 28-31). These findings suggest that the *Trabecular Metal* Material region of the dental implant will not be structurally compromised by torsional forces during placement or immediate loading.

Trabecular Metal Dental Implant placement utilizing soft bone and dense bone surgical protocols (ZRR-ZD-00076-00) Implant placement in bone with moderate to high density (types 1 to 3)[78] utilizes a final step-drill that prepares a narrower diameter in the apical region of the osteotomy. This technique enables approximately one-third of a tapered implant design to enter the osteotomy before the self-tapping implant threads engage the walls of the receptor site, which may facilitate implant placement in sites with limited vertical access.[79] In low-density (type 4)[78] bone, final osteotomy preparation is performed with a straight drill that is 0.2mm to 0.3mm smaller than the apical end of a tapered implant, depending on the implant diameter.[79] This soft-bone surgical technique is designed to enable the tapered, apical end of an implant to laterally engage the osteotomy walls and gradually compress the surrounding bone to a maximum of 0.6mm or 0.7mm at the crest of the ridge, depending on the implant diameter.[79] When the diameter of an osteotomy is a minimum of 100µm smaller than that of the implant, force-fitting stresses generated during placement have been reported to increase placement torque and implant stability, as compared to implants not placed into smaller diameter osteotomies in low-density bone.[79-81]

The present experiment was primarily designed to determine if *Trabecular Metal* Dental Implants could be successfully placed in a surrogate soft bone substrate utilizing a soft bone surgical protocol. A second part to this experiment evaluated whether *Trabecular Metal* Dental Implants could also be placed into dense bone when a soft bone protocol was used. In this case, a successful test was

Table 1. Insertion torque results (Ncm), *=statistically equivalent

NobelReplace Implant 5.0mm x 13mm	Trabecular Metal Implant 4.7mm x 13mm	6.0mm x 13mm	Tapered Screw-Vent Implant 6.0mm x 13mm	
84.5 Ncm	103.0	154.0	174.0	177.0
89.5 Ncm	103.0	169.0	160.5	174.0
95.0 Ncm	100.5	158.5	141.5	186.5
91.0 Ncm	103.5	164.0	146.0	131.0
87.5 Ncm	110.5	160.0	130.5	
Min: 84.5 Max: 95.0	**Min: 100.5 Max: 110.5**	**Min: 154 Max: 169**	**Min: 130.5 Max: 186.5**	
Avg: 89.5	Avg: 104.1	Avg: 161.1*	Avg: 157.9*	
Std Dev: 3.9	Std Dev: 3.8	Std Dev: 5.7	Std Dev: 21.2	

Note: Sample sizes determined based on part availability and requirement for normally distributed data.

classified as either full placement with a soft bone protocol, or subsequent dense bone protocol, if needed. Experiments showed that *Trabecular Metal* Implants could be optimally placed if the soft bone surgical protocol was used in soft bone, and the dense bone surgical protocol was used in all other bone densities.

Material analysis of Trabecular Metal Dental Implants following exposure to surface cleaning solutions (ZRR-ZD-00054-00) This experiment evaluated the effect of cleaning materials used to remove hydroxylapatite residue following secondary grit-blasting. The contact materials consisted of 5% hydrochloride (HCl), distilled water, acetone, isopropyl alcohol (IPA), and sustained heat on *Trabecular Metal* Material cylinders. The impact of the contact materials on *Trabecular Metal* Material was analyzed by mechanical/chemical methods. Results of the analysis indicated that the *Trabecular Metal* Material cylinders did not suffer adverse effects from the production cleaning methods used in this experiment.

Evaluation of Trabecular Metal Dental Implants in the canine model In 2009, researchers[82] from The Ohio State University and Zimmer Dental collaborated on the first *in vivo* study of a *Trabecular Metal* Dental Implant design. The objectives of the study were to investigate whether *Trabecular Metal* Material applied to a dental implant would osseointegrate.[82] A total of 24 experimental *Trabecular Metal* Implants were placed in mandibles of 8 dogs (3 implants per dog).[82] Additionally 24 control implants (*Tapered Screw-Vent* Implant, Zimmer Dental Inc.) were placed in the mandibles of the same 8 dogs (3 implants per dog).[82] Two (2) animals each were euthanized at 2, 4, 8 and 12 weeks after implantation.[82] Calcein was injected prior to necropsy to label newly mineralizing bone tissue.[82] Two histological sections from each implant were prepared: one section was used to assess the calcein-labeled tissue and the other was stained by Goldner's Trichrome to assess osteoid and matured bone.[82] Effects of healing time on the histomorphometric analysis measurements were statistically analyzed.[82]

At all time periods, average bone-to-implant contact (BIC) on the titanium alloy (i.e. non-*Trabecular Metal* Material) portions of the implants exceeded 70%. New bone formation inside *Trabecular Metal* Material pores was evident at 2 weeks and bone ingrowth across the full thickness of the porous surface was observed at 4 weeks.[82] Histomorphometric analyses of bone in *Trabecular Metal* Material pores indicated rapid bone fill and remodeling: 1) the highest amount of newly mineralizing tissue was observed at week 2 (36.08%) and significantly lower at later weeks (17.69%, 22.40% and 19.95% respectively, $p<0.05$) and 2) osteoid was highest at week 2 (63.53%) and significantly lower at weeks 8 and 12 (35.97% and 41.94%, respectively, $p<0.05$).[82] Matured bone significantly increased during the same time intervals (3.32%, 9.01% and 18.69% at 2, 8 and 12 weeks, respectively, $p<0.05$).[82] Active bone formation into the porous surface of *Trabecular Metal* Implants observed at the early healing stage supports its potential use in dental implant applications.[82] Unlike the experimental titanium fiber mesh implants previously cited,[39-46] the *Trabecular Metal* Implants in the present study did not exhibit fibrous tissue anywhere along the bone-implant interface or inside the *Trabecular Metal* Material pores.

Discussion

Early development and evaluations of *Trabecular Metal* Dental Implants have demonstrated their ability to adequately meet the biomechanical demands encountered in the dental environment and to biologically integrate in the canine model. How the material will function in human dental patients, especially when immediately loaded, will be the next research phase of *Trabecular Metal* Dental Implants. In 2010, Zimmer Dental established a prospective pilot clinical study of *Trabecular Metal* Dental Implants, and a multi-national *Trabecular Metal* Implant Longitudinal Data Collection Program that will continue to monitor and gather data on the implants over the coming years. New data will be published as it is accrued.

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