Zimmer® Trabecular Metal™ Dental Implant Research: A Brief Overview

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Trabecular Metal Material (Zimmer TMT, Parsippany, NJ), an implantable biomaterial with up to 80% porosity, has been used to facilitate anchorage of orthopedic knee, hip and spine implants through a combination of bone ingrowth and ongrowth (osseoincorporation) for more than a decade. Since the late 1990s, numerous mechanical, animal and human clinical studies have also been conducted to evaluate the use of *Trabecular Metal* Material for orthopedic applications. *Trabecular Metal* Material is formed by applying tantalum over a vitreous carbon substrate through a proprietary chemical vapor deposition process. Both tantalum and vitreous carbon are highly biocompatible materials with a longer clinical history as biological implants than titanium.

Based on its extensive clinical use in orthopedics and experimental use in oral and maxillofacial surgery, Zimmer Dental Inc. has developed a tapered, multi-threaded, endosseous *Trabecular Metal* Dental Implant similar to its predicate, the *Tapered Screw-Vent*® Implant (Zimmer Dental Inc.), but modified with a *Trabecular Metal* Material midsection (Fig.1). 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, Zimmer Dental Inc.). The implant features a microgrooved cervical region, Zimmer Dental's internal hex, friction-fit connection, and apical self-tapping threads.

Mechanical Testing: *Trabecular Metal* Dental Implants subjected to cyclic loading and compression bending resisted fatigue fracture and deformation and surpassed strength requirements for normal loading conditions in the posterior human jaw (Table 1).[1-11] Insertion and removal torque testing in bone revealed no structural compromise to the implant or its porous section. Implant stability tests showed that the dental implant design was able to achieve adequate mechanical stabilization for immediate loading in selected patients using both standard (hard bone) and osteocompressive (soft bone) surgical protocols (Table 1).[1-11] *In vitro* immersion corosion testing and *in vivo* animal and human studies have found no increased risk of corrosion when *Trabecular Metal* Material was used alone as a bone replacement implant or when it was combined with titanium alloy and used as an orthopedic or dental implant.[1-11]

FIGURE 1. *ZIMMER* TRABECULAR METAL *DENTAL IMPLANTS*

Animal Studies: In 2000, under a grant from the National Institutes of Health, a study was conducted to evaluate bone ingrowth and turnover in *Trabecular Metal* blocks used for the treatment of surgically created mandibular continuity defects in canines (Table 2).[12-15] After 6 months of healing, all 4 surviving samples had developing bone (osteoid) crossing through the *Trabecular Metal* Material, and 3 out of 4 samples had mineralized bone in the center of the material. One sample had mineralized bone at the edges, but the center was not yet mineralized. More recently, biological responses to *Trabecular Metal* Material in the dental implant configuration were evaluated in the canine model by comparing *Tapered Screw-Vent* Implants to *Trabecular Metal* Dental Implants over a 12 week period (2, 4, 8, and 12 week follow up) using ISQ and histological examination. The results are summarized in Table 2.[16-17] A second phase of this canine study, as well as a new comparative implant study in sheep are currently in progress; preliminary findings are anticipated in 2012.

Human Clinical Studies: In 2010, Zimmer Dental began two international, prospective human clinical studies of

Trabecular Metal Dental Implants. The first, a proof-of-principle pilot study, is evaluating the use of *Trabecular Metal* Dental Implants for immediate loading. The second study is a Longitudinal Data Collection Program that is prospectively gathering data on the placement and functioning of *Trabecular Metal* Dental Implants in routine clinical practices. Preliminary results are scheduled for presentation at the 2011 European Academy of Osseointegration (EAO) and the 2012 Annual Meeting of the Academy of Osseointegration (AO). Data collection will continue for subsequent years according to protocols.

Table 1. Results of Mechanical Testing Completed to Date

Category	Findings About *Trabecular Metal* Material
Preliminary Testing of *Trabecular Metal* Material[1-2]	(1) Material was able to support a dental implant under loading.[1] (2) Assembly of material on a titanium core is the preferred assembly method of a dental implant.[2] (3) Combined with titanium, material provides adequate strength for use as a dental implant.[2]
Development of *Trabecular Metal* Dental Implants[3-11]	(1) Implants 4.7mm and 6.0mm in diameter can withstand functional loading in any jaw location.[3] (2) *Trabecular Metal* Dental Implants achieve insertion torque levels comparable to *Tapered Screw-Vent* and NobelReplace® Implants in simulated bone (bone foam).[4] (3) Insertion torque of *Trabecular Metal* Dental Implants modified with expanded thread and collar diameters did not significantly differ from the *Tapered Screw-Vent* and NobelReplace control implants.[4] (4) Structural integrity of *Trabecular Metal* Material portion of the implant is not compromised by insertion torque.[5] (5) *Trabecular Metal* Dental Implant did not corrode in Ringer's solution.[6] (6) *Trabecular Metal* Dental Implant was not altered by production cleaning methods.[7] (7) Higher assembly forces did not impact fatigue performance of *Trabecular Metal* Dental Implants.[8] (8) *Trabecular Metal* Dental Implants 4.1mm in diameter exhibited endurance levels under insertion torque and cyclic loading that were mechanically adequate for immediate loading.[9] (9) *Trabecular Metal* Material portion of implants 4.1mm in diameter did not abrade or deform from insertion torque.[10] (10) *Trabecular Metal* Material could withstand manufacturing forces required for implant assembly.[11]

Table 2. Results of Animal Studies Completed to Date

Study	Survival Parameter
Trabecular Metal Material for Mandibular Continuity defects in Dogs (NIH Grant DE09781-03)[12-15]	- Mandibular resections were created bilaterally in six dogs. - Left defects were grafted with *Trabecular Metal* blocks (test) and right defects were grafted with autogenous bone blocks (control). - Two *Trabecular Metal* blocks failed because of infection. - Surviving blocks were histomorphologically analyzed after three months. - *Trabecular Metal* Material had osteoid crossing through the material. - Three out of four samples had mineralized bone in the center of the material. - *Trabecular Metal* Material and autogenous bone blocks were equally as successful. - Bone grew into *Trabecular Metal* Material, mineralized and developed cellular components.
Evaluation of *Trabecular Metal* Dental Implants in Dogs (The Ohio State University Canine Study)[16-17]	- Twenty-four *Trabecular Metal* Dental Implants (test) and twenty-four *Screw-Vent*® Implants (control) were randomly placed in the healed mandibular premolar locations of eight dogs. - Calcein was injected into the animals to label newly formed bone. - Histomorphological analysis were performed on two dog mandibles at two, four, eight and twelve weeks. - Resonance frequency analysis was used to determine changes in implant stability at placement and animal sacrifice. - New bone formed at test and control implant surface at two and four weeks. - New bone was forming inside *Trabecular Metal* Material pores at two weeks. - Stability of control implants decreased but increased for test implants between weeks two and twelve; differences were not significant. - New bone growth was evident in *Trabecular Metal* Material at every assessment period.

References

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