Technology
Brochure

Trabecular Metal®
Dental Implant

ZimVie

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Introduction

Trabecular Metal Technology

Trabecular Metal Technology is an innovative material utilized by ZimVie for two decades in implantable orthopaedic devices. Uses of Trabecular Metal Material are varied and have included joint reconstruction, bone void filling, and soft-tissue repair.[1-3] ZimVie integrated Trabecular Metal Technology into its dental implant portfolio in 2011.

What is Trabecular Metal Technology?

Trabecular Metal Technology is a three-dimensional material, not an implant surface or coating. Its structure and function are similar to cancellous bone.[4-6]

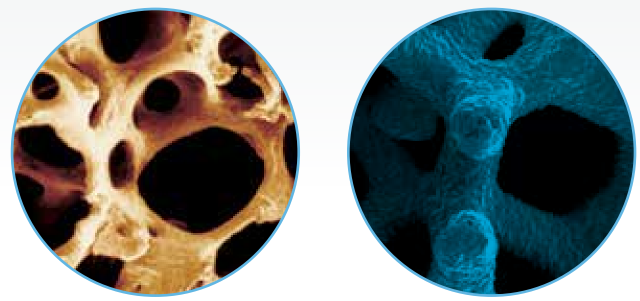

Figure 1

Trabecular Metal Material is similar to cancellous bone[4-6]

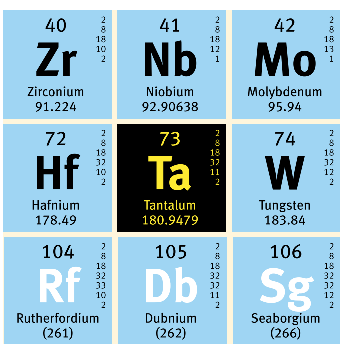

Figure 2

Tantalum is element 73 in the periodic table

Tantalum

Trabecular Metal Material is made of tantalum, element number 73 in the periodic table. Tantalum is a highly biocompatible and corrosion-resistant metal[7-11] used in various implantable devices for over 60 years,[12-16] including a dental implant in the 1940s.[16] Per-Ingvar Brånemark, known as the father of modern dental implantology, conducted osseointegration research in the 1950s utilizing tantalum.[17]

While the highly biocompatible and passive characteristics of tantalum were documented long ago, its cost and methods of production limited its use[12] until the late 1990s. Since then, hundreds of thousands of Trabecular Metal Dental Implants have been sold.[18]

Topography

A glimpse inside Trabecular Metal Material reveals its uniform three-dimensional cellular architecture with up to 80% porosity.[2-4, 6] The entire surface area of Trabecular Metal Material exhibits a nanotextured topography.[19]

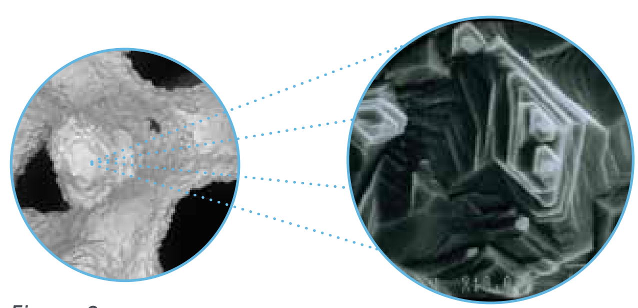

Figure 3

Nanotextured surface topography of Trabecular Metal struts

Osseoincorporation

Conventional textured or coated implant surfaces achieve bone-to-implant contact, or ongrowth.[17] However, Trabecular Metal Material's consistent, open, and interconnected network of pores is designed for both ongrowth and ingrowth, or osseoincorporation.[2, 4, 20] Bone has the potential to grow onto the nanosurface of the Trabecular Metal Material, into its interconnected pores and around its struts.[4, 5, 20]

Pre-clinical Studies

Trabecular Metal Material Characteristics[20,21†]

Objective	• Determine bone ingrowth characteristics and interface mechanics of Trabecular Metal Material [*Figure 4*].
Methods	• Evaluation of 5 x 10 mm cylindrical implants (n=48) in a transcortical canine model. The material was 75% to 80% porous by volume. • Histological studies were performed on two types of material, one with a smaller pore size averaging 430 µm (547 µm using an alternative measurement method) at 4,16, and 52 weeks and the other with a larger pore size averaging 650 µm (710 µm using an alternative measurement method) at 2, 3, 4, 16, and 52 weeks. • Mechanical push-out testing was also performed at 4 and 16 weeks to assess the shear strength of the bone-implant interface on implants of the smaller pore size.
Results	• The extent to which the pores of tantalum material were filled with new bone increased from 13% at two weeks to 42-53% at four weeks. By 16 and 52 weeks the average amount of bone ingrowth ranged from 63% to 80%. The tissue response to the small and large pore sizes was similar. Both sizes demonstrated increased contact between bone and implant over time, with evidence of Haversian remodeling within the pores at later periods. • Mechanical tests at four weeks indicated a minimum shear fixation strength of 18.5 MPa, substantially higher than other porous materials with less volumetric porosity.
Clinical Implications	• The Trabecular Metal Material has desirable characteristics for bone ingrowth. Further studies are warranted to evaluate its potential in medical device applications.

Human Cancellous Bone

Trabecular Metal Material

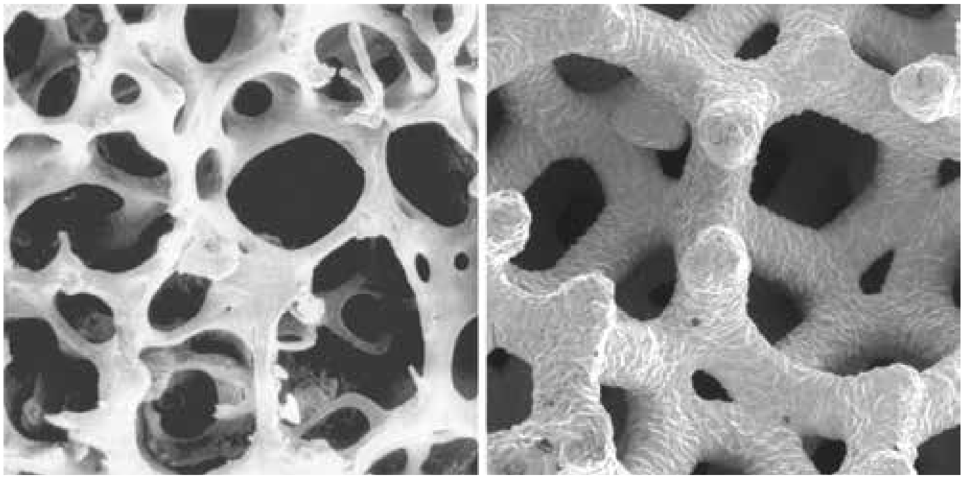

Figure 4

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

†Pre-clinical studies are not necessarily indicative of clinical performance.

Structural Integrity of Trabecular Metal Dental Implant[22*†]

Objective	• Evaluate the structural integrity of the Trabecular Metal Dental Implant assembly by pull-out and abrasion testing.
Methods	• Evaluation of interfacial fixation strength (structural integrity) for Trabecular Metal Dental Implants (n=6) embedded in artificial bone material by subjecting the bone-implant assembly interface to shear loads (pullout test). • Evaluation of abrasion on Trabecular Metal Dental Implants (n=3 for each of 4.1, 4.7, and 6.0 mmD) during placement in dense artificial bone and bovine bone condyles.
Results	• The Trabecular Metal Dental Implant assembly remained intact during pullout with no evidence of assembly failure, damage to the Trabecular Metal Material, or particulate generation. • The implant assembly retained its porous structure with no evidence of abrasion and structural deformation of the Trabecular Metal Material. There was no evidence of metal debris in the osteotomy [*Figure 5*].
Clinical Implications	• The Trabecular Metal Dental Implant maintains structural integrity during placement and can withstand shear loads higher than those experienced during the normal range of clinical function.

Before Implantation in Bovine Bone   After Removal from Bovine Bone

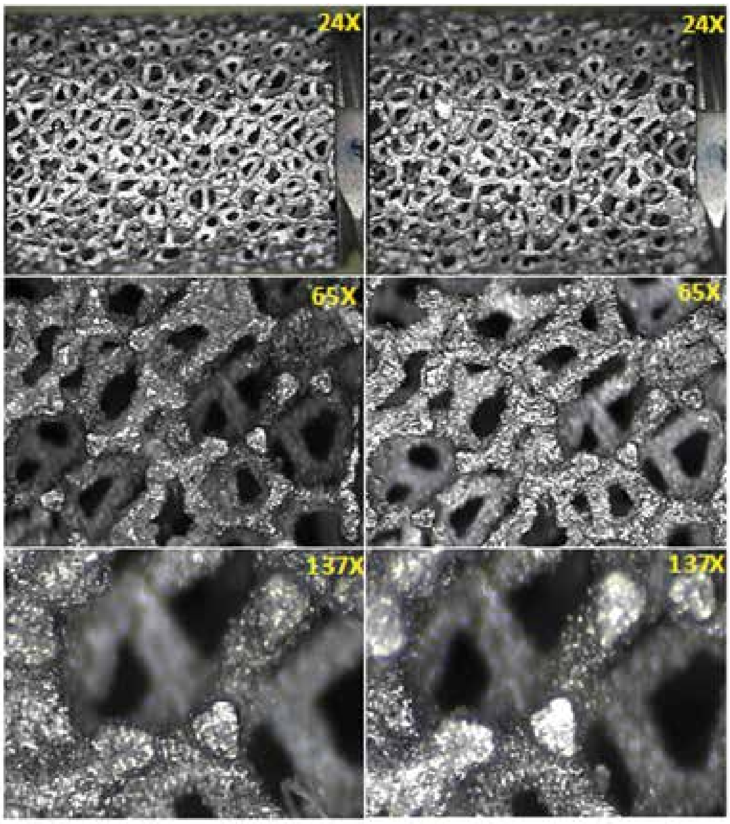

Figure 5

Microscopic images of the Trabecular Metal Dental Implant, with porous tantalum material, prior to implantation and after removal of implant from bovine condyle.

†Pre-clinical studies are not necessarily indicative of clinical performance.

Fatigue Strength of Trabecular Metal Dental Implant[23*†]

Objective	•	Mechanical evaluation of the *Trabecular Metal* Dental Implant to determine the implant strength under simulated physiological loads in the oral cavity.
Methods	•	Evaluation of dynamic fatigue and static compression characteristics of *Trabecular Metal* Dental Implant assembly per ISO 14801 (n=8 each for 4.1 and 4.7 mmD).
Results	•	Compression loads were substantially greater than the reported maximum bite force in the molar region. Implants are normally subjected to masticatory stress far below the maximum tooth bite force. The endurance limit at 5 million cycles for the 4.1 and 4.7 mmD *Trabecular Metal* Dental Implants was greater than reported functional loads in the molar region.[**]
Clinical Implications	•	The *Trabecular Metal* Dental Implant withstands physiological loads experienced in the oral cavity.

†Pre-clinical studies are not necessarily indicative of clinical performance.

**The 4.1mmD Trabecular Metal Dental Implants should be splinted to additional implants when used in the posterior region.

Interfacial Strength of Trabecular Metal Dental Implant[21-23*†]

Objective	• Mechanical evaluation of the Trabecular Metal Dental Implant assembly to assess the interfacial and structural integrity [*Figure 6*].
Methods	• Evaluation of the interfacial strength between Trabecular Metal sleeve (700-800 μm thick) and titanium components using normal (threaded) and simulated worst-case (non-threaded, no macro-threads) configurations of 4.1, 4.7, and 6.0 mm implant diameters (n=8, without component "c", see *Figure 5*) in artificial bone.
Results	• Torsional force required to overcome the frictional engagement between the Trabecular Metal sleeve and the titanium implant components significantly exceeded the amount of torque generated during simulation of placement in worst case situations. A fully integrated Trabecular Metal Dental Implant assembly can withstand 3x the worst-case, molar torsional force estimated in immediate occlusal loading.
Clinical Implications	• The Trabecular Metal Dental Implant assembly has the interfacial strength to maintain its structural integrity during implant placement.

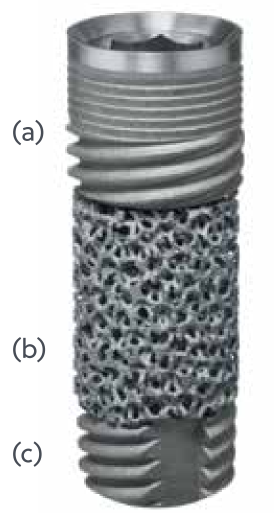

Figure 6

Trabecular Metal Dental Implant assembly consisting of (a) a titanium cervical and internal core section covered by (b) a Trabecular Metal sleeve and joined by (c) a titanium apical section.

†Pre-clinical studies are not necessarily indicative of clinical performance.

Surface Area for Osseointegration[24*†]

Objective	• Determination of the surface area for Trabecular Metal Dental Implants and conventional threaded implants.
Methods	• Determination of the surface area of Trabecular Metal Dental Implants and threaded implants of (n=6, Tapered Screw-Vent 3.7, 4.1, 4.7, and 6.0 mmD). Consecutive transverse 200 µm sections and 3D models of the implants were used to determine the surface area available for bone apposition.
Results	• Trabecular Metal Dental Implant exhibited up to 52.7%, 79.4%, 85.7%, and 81.8% more surface area for bone apposition than conventional threaded implants of 3.7, 4.1, 4.7, and 6.0 mmD, respectively [*Chart 1*].
Clinical Implications	• Due to the porous structure of Trabecular Metal Material, the Trabecular Metal Dental Implant provides significantly more surface area than conventional textured titanium dental implants.

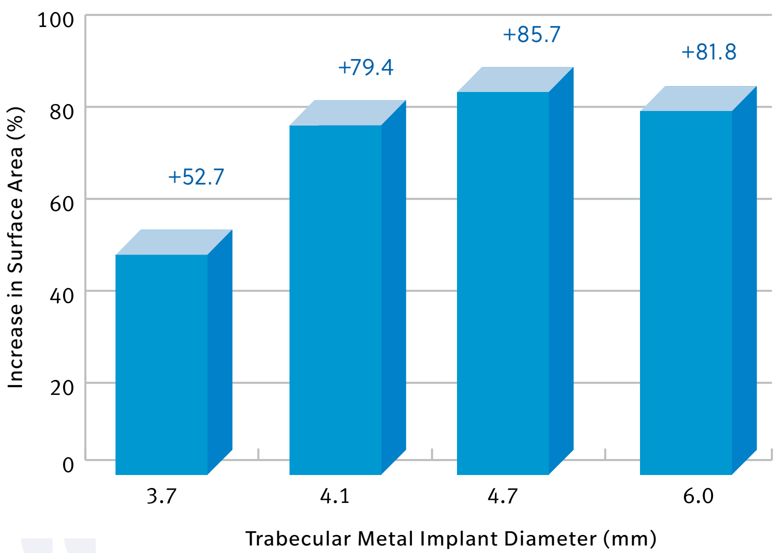

Chart 1

The highest surface area percentage increase observed for Trabecular Metal Dental Implants as compared with conventional threaded implants of similar length and diameter.

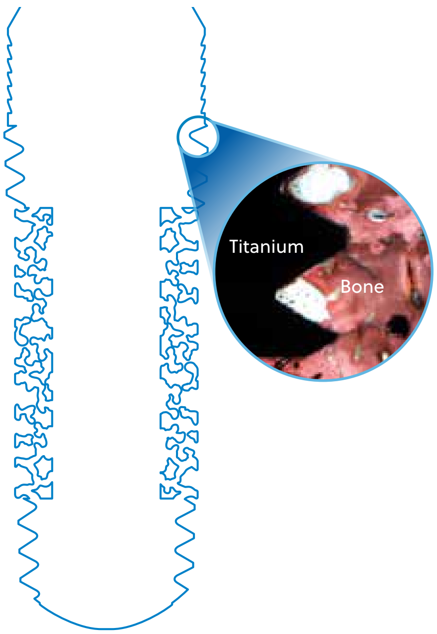

Figure 7

Trabecular Metal Dental Implant

Surface area available for ongrowth
Vertical cross sectional view

†Pre-clinical studies are not necessarily indicative of clinical performance.

Pore Volume Available for Bone Ingrowth[24,25*†]

Objective	• Determination of the pore volume available in the Trabecular Metal Material component of Trabecular Metal Dental Implants.
Methods	• Determination of the available pore volume of Trabecular Metal Implants (n=6, 3.7, 4.1, 4.7, and 6.0 mmD) via gravimetric and other analytical methods. $$\text{Pore Volume} = \int_0^{2\pi}\int_r^{R}\int_0^{L} V(r, \Theta, z)\, dzr\, dr\, d\Theta - \left(\frac{\text{mass}_{TM}}{\text{density}_{TM}}\right)$$ 
Results	• Trabecular Metal Dental Implants had 13.3, 23.8, 32.9, and 44.8 mm^3 of available pore volume for ingrowth for 3.7, 4.1, 4.7, and 6.0 mmD, respectively [*Chart 2, Figure 8*].
Clinical Implications	• Due to the high porosity of Trabecular Metal Material, the Trabecular Metal Dental Implant provides volume for bone ingrowth in addition to surface area for ongrowth.

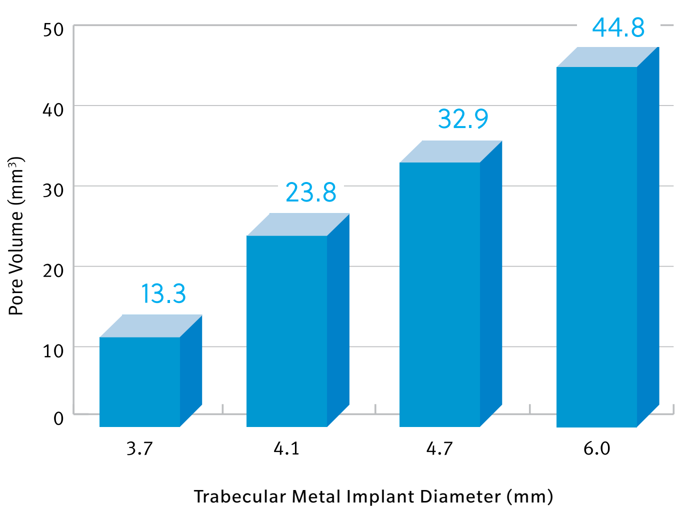

Chart 2

Average pore volume available for bone ingrowth in Trabecular Metal Dental Implants of various diameters and 13 mm lengths.

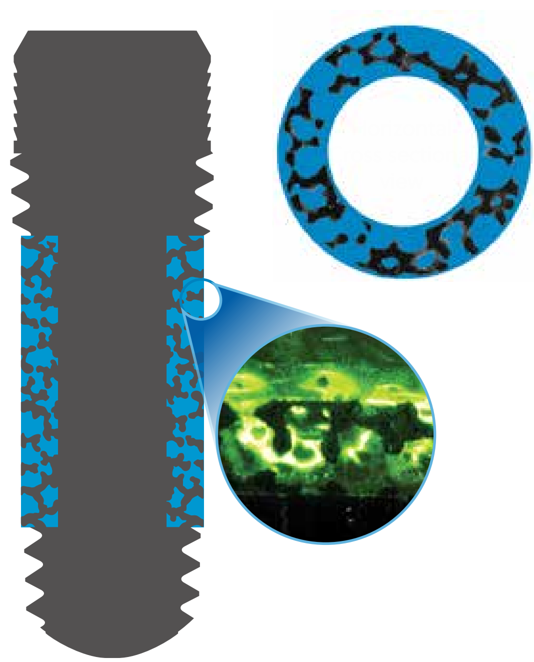

Figure 8

Trabecular Metal Dental Implant

Pore volume available for ingrowth (blue)
Vertical cross sectional view

†Pre-clinical studies are not necessarily indicative of clinical performance.

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*Data on file with ZimVie Dental.

Notes

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