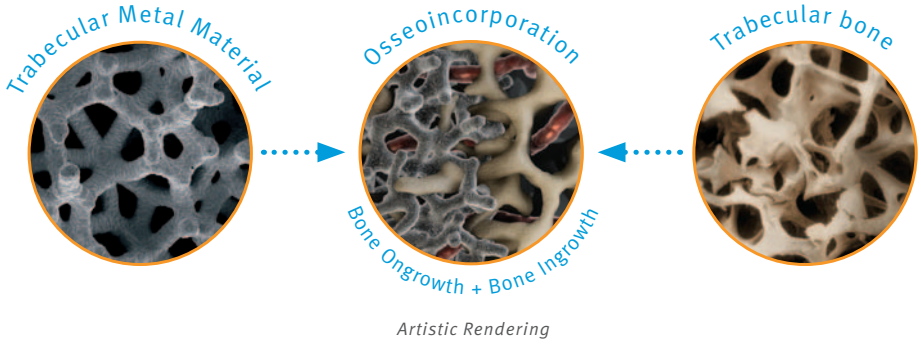
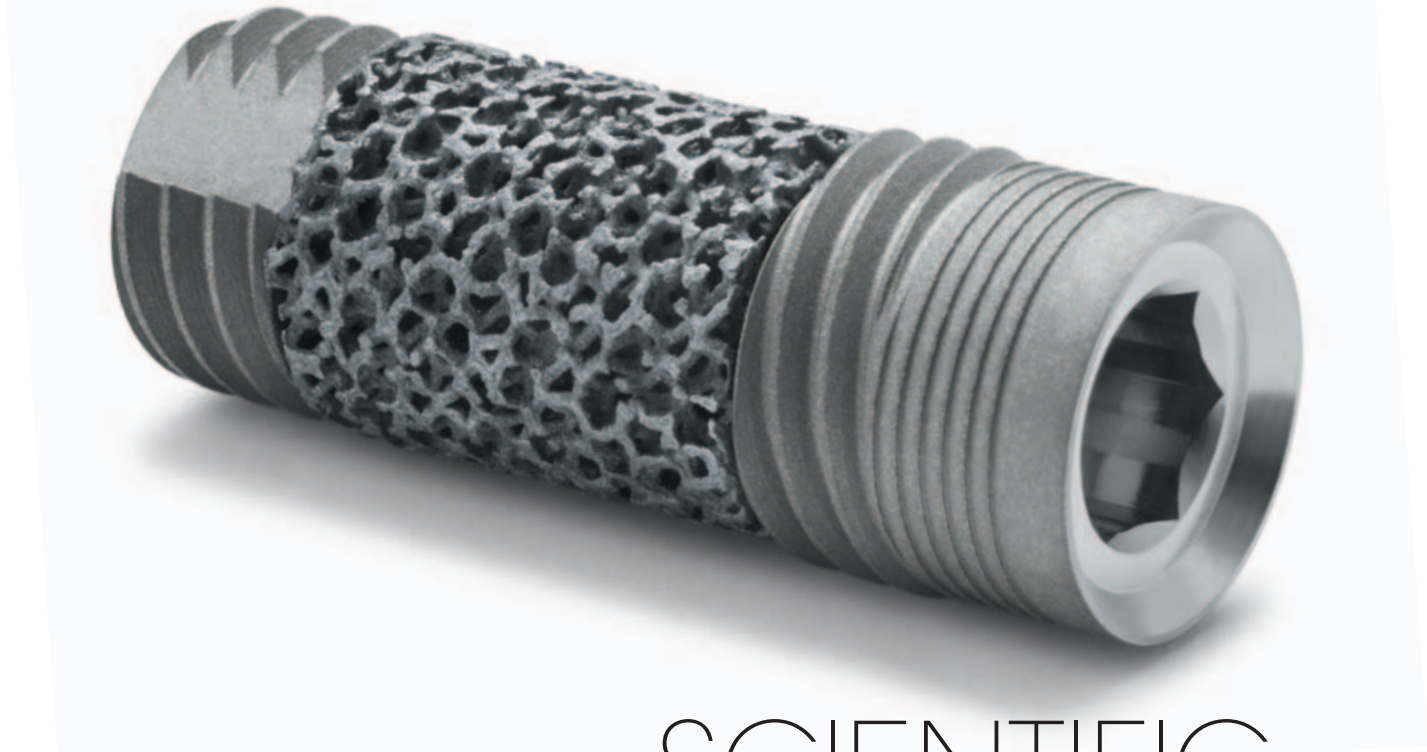


Artistic Rendering

Zimmer® Trabecular Metal™ Dental Implant



SCIENTIFIC COMPENDIUM

TRABECULAR METAL MATERIAL:
Designed to Enhance Secondary Stability Through Bone Ingrowth.

zimmer | dental

TABLE OF CONTENTS

PRE-CLINICAL STUDIES

CLINICAL STUDIES AND PROGRAMS

1. *TRABECULAR METAL* MATERIAL CHARACTERISTICS[1]

Objective(s)	• Determine bone ingrowth characteristics and interface mechanics of *Trabecular Metal* Material (Figure 1).
Methods	• Evaluation of 5 x 10 mm cylindrical implants (n=48) in a simple 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 for clinical reconstructive orthopaedics.

Human Cancellous Bone

Trabecular Metal Material

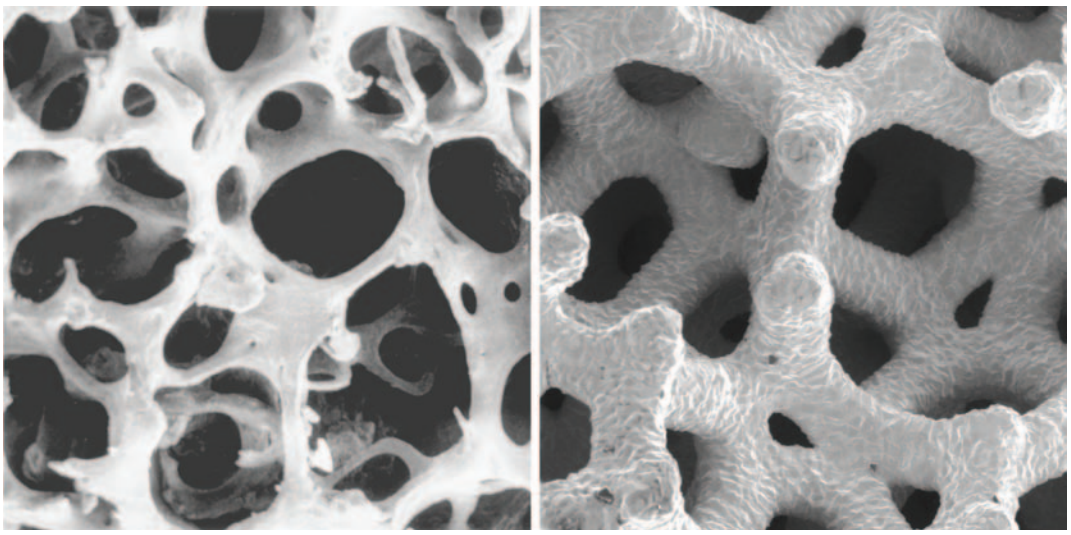


FIGURE 1. SEM view of trabecular bone (left) and *Trabecular Metal* Material (right).[2]

2. STRUCTURAL INTEGRITY OF *TRABECULAR METAL* DENTAL IMPLANT[3-7]

Objective(s)	• Evaluate the structural integrity of the *Trabecular Metal* 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).[5-7] • Evaluation of abrasion on *Trabecular Metal* Dental Implants (n=3 for each of 4.1, 4.7 & 6.0mmD) during placement in dense artificial bone and bovine bone condyles. [6-7]
RESULTS	• The *Trabecular Metal* Implant assembly remained intact during pullout with no evidence of assembly failure, damage to the *Trabecular Metal* Material, or particulate generation.[5-7] • 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[3,4,7] (Figure 2).
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

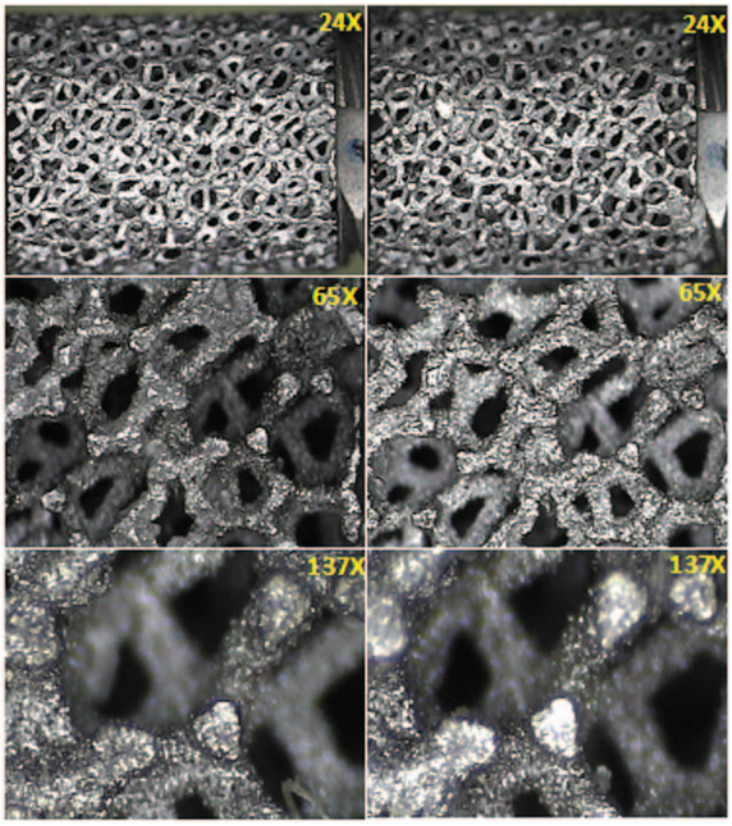


FIGURE 2. Microscopic images of the *Trabecular Metal* Dental Implant, with porous tantalum material, prior to implantation and after removal of implant from bovine condyle.[6,7]

3. *TRABECULAR METAL* DENTAL IMPLANT FATIGUE STRENGTH[8-12]

Objective(s)	• 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 & 4.7mmD).
RESULTS	• Compression loads were substantially greater [8,10,12] than the reported maximum bite force in the molar region.[13] 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* & 4.7mmD *Trabecular Metal* Dental Implants was greater than reported functional loads in the molar region.[9-12,14,15]
CLINICAL IMPLICATIONS	• The *Trabecular Metal* Dental Implant withstands physiological loads experienced in the oral cavity.

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

4. *TRABECULAR METAL* DENTAL IMPLANT INTERFACIAL STRENGTH[2,11,12,16-18]

Objective(s)	• Mechanical evaluation of the *Trabecular Metal* Dental Implant assembly to assess the interfacial and structural integrity (Figure 3).
Methods	• Evaluation of the interfacial strength between *Trabecular Metal* sleeve (700-800µm thick) and titanium components using normal (threaded) and simulated worst-case (non-threaded, no macro-threads) configurations of 4.1, 4.7 & 6.0mm implant diameters (n=8, without component "c", see Figure 3) 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.[2,11,12,17,18] A fully integrated *Trabecular Metal* Dental Implant assembly can withstand 3x the worst-case, molar torsional force estimated in immediate occlusal loading.[2,16]
CLINICAL IMPLICATIONS	• The *Trabecular Metal* Dental Implant assembly has the interfacial strength to maintain its structural integrity during implant placement.

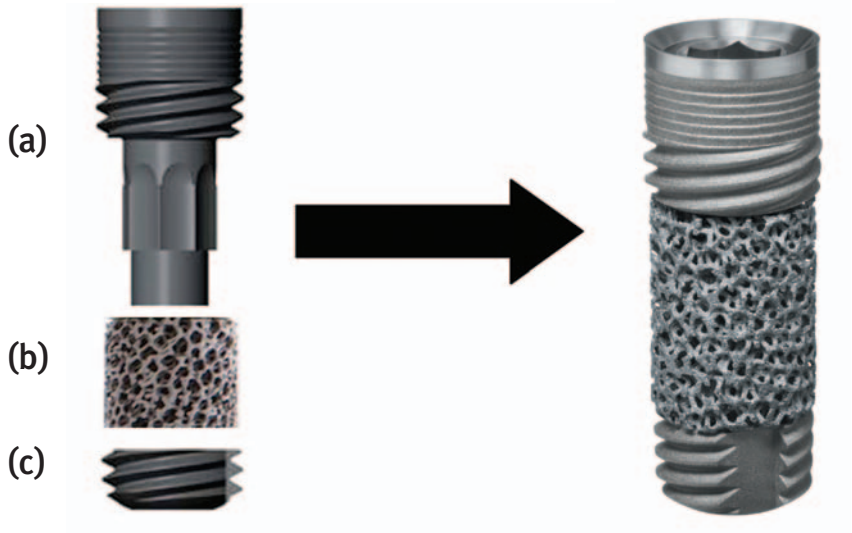


FIGURE 3. *Trabecular Metal* Dental Implant assembly consisting of (a) a titanium cervical and internal core section covered by a (b) *Trabecular Metal* sleeve and joined by (c) a titanium apical section.[6]

5. PRIMARY STABILITY OF *TRABECULAR METAL* DENTAL IMPLANT [2,6,7,19-21]

Objective(s)	• In vitro primary stability assessment of *Trabecular Metal* Dental Implants and evaluation of suitability for immediate loading.
Methods	• Evaluation to determine insertion torque (IT) for six 4.7mmD x 13mmL *Trabecular Metal* Dental Implants and comparison with conventional dental implants of similar dimensions (*Zimmer Tapered Screw-Vent*® Implant, NobelReplace Implant, NobelActive Implant and SLActive Bone Level Implant) in artificial bone (n=6).
RESULTS	• The mean IT value of the *Trabecular Metal* Dental Implant was 104.1 ±3.8 Ncm.[2,19] The corresponding IT values for conventional threaded implants were 119.9 ±10.4 Ncm[21] for *Tapered Screw-Vent*, 89.5 ±3.9 Ncm for NobelReplace[19,20], 93.0 ±15.7 Ncm for NobelActive[21] and 60.5 ±4.7 Ncm for SLActive Bone Level[21] implants (Chart 1). Many clinicians have selected an approximate insertion torque value of 35Ncm or greater as a determining guideline for immediate loading.[2]
CLINICAL IMPLICATIONS	• *Trabecular Metal* Dental Implants demonstrate sufficient primary fixation to facilitate immediate loading.

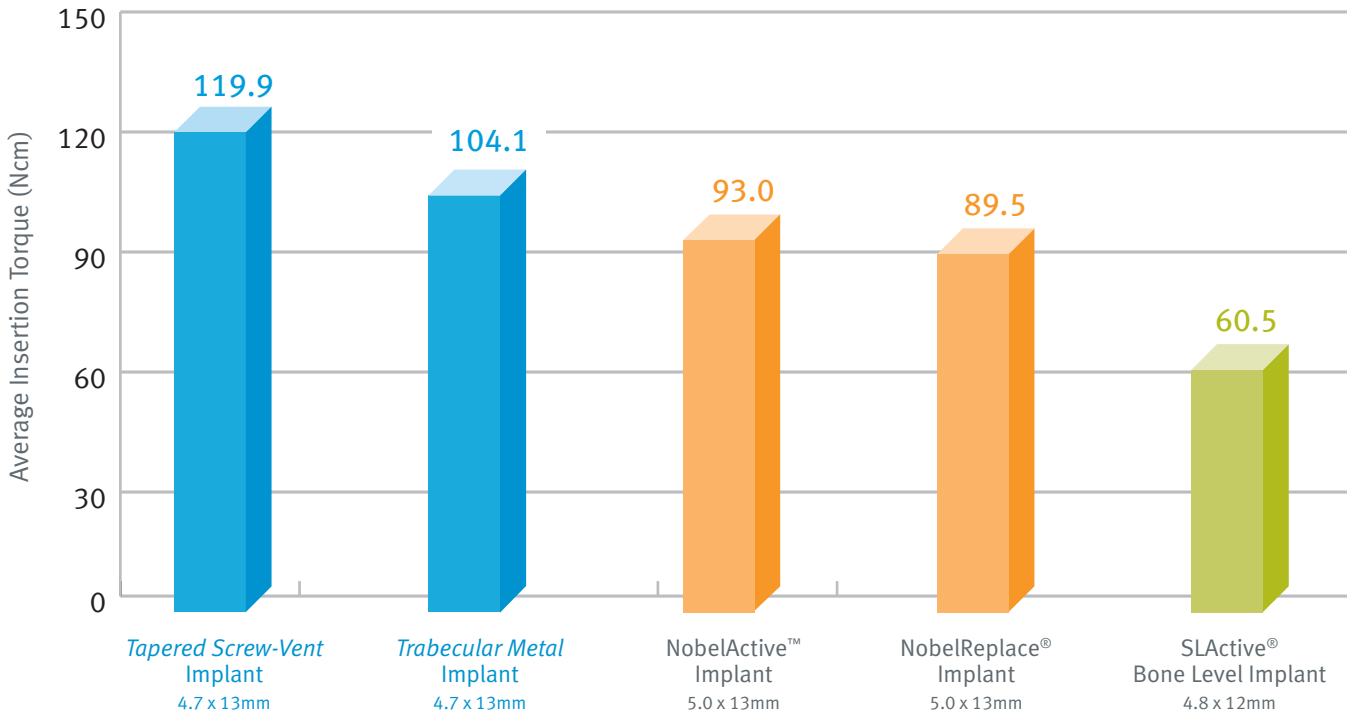


CHART 1. Insertion torque results (Ncm). Average insertion torque in 50/30 bone foam block simulating a dense bone. [2,19-21]

NobelReplace® and NobelActive™ are trademarks of the Nobel Biocare group. SLActive® is a trademark of Straumann Holding AG.

6. SURFACE AREA AVAILABLE FOR OSSEOINTEGRATION[22-25]

Objective(s)	• 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* 4.1, 4.7 & 6.0mmD). Consecutive transverse 200µm 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 67.7%, 89.7% & 89.9% more surface area for bone apposition than conventional threaded implants of 4.1, 4.7 & 6.0mmD, respectively (Chart 2).[22-25]
CLINICAL IMPLICATIONS	• Due to the high porosity of *Trabecular Metal* Material, the *Trabecular Metal* Dental Implant provides more surface area than conventional textured titanium dental implants.

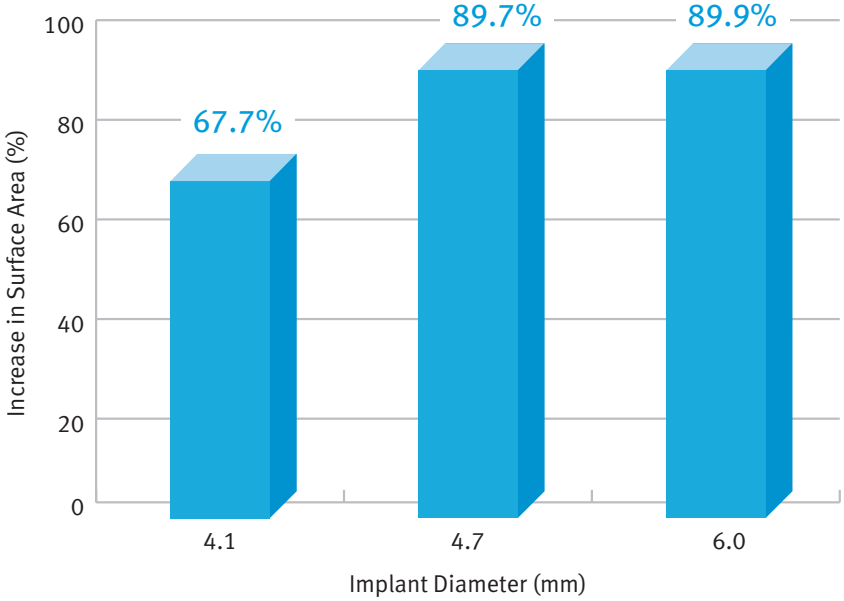
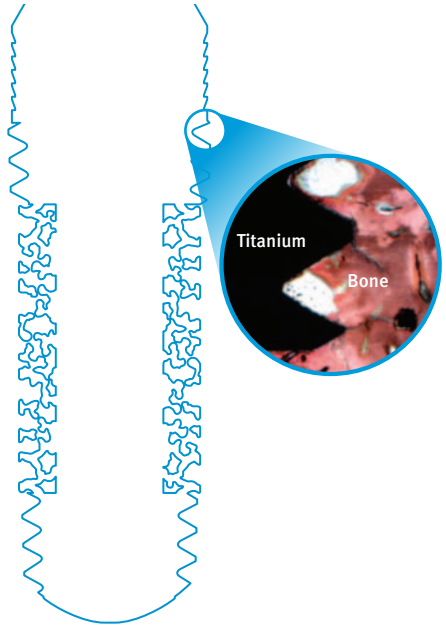
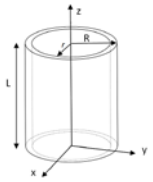


CHART 2. Surface area percentage increase for *Zimmer Trabecular Metal* Dental Implant as compared with conventional threaded implants. [22-25]

FIGURE 4.
Trabecular Metal Dental Implant
Surface area available for Ongrowth
Vertical Cross sectional view



7. PORE VOLUME AVAILABLE FOR BONE INGROWTH[25-26]

Objective(s)	• Determination of the pore volume available in the *Trabecular Metal* Material component of the *Trabecular Metal* Dental Implants.
Methods	• Determination of the available pore volume of *Trabecular Metal* Implants (n=6, 4.1, 4.7 & 6.0mmD) via gravimetric and other analytical methods[25-26] $\text{Pore Volume} = \int_0^{2\pi}\int_r^{R}\int_0^{L} V(r, \Theta, z)\, dz\, r\, dr\, d\Theta - \left(\frac{\text{mass}_{TM}}{\text{density}_{TM}}\right)$ 
RESULTS	• *Trabecular Metal* Dental Implants had 23.8, 32.9, & 44.8 mm3 of available pore volume for ingrowth for 4.1, 4.7 & 6.0mmD, respectively (Chart 3, Figure 5).[26]
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.

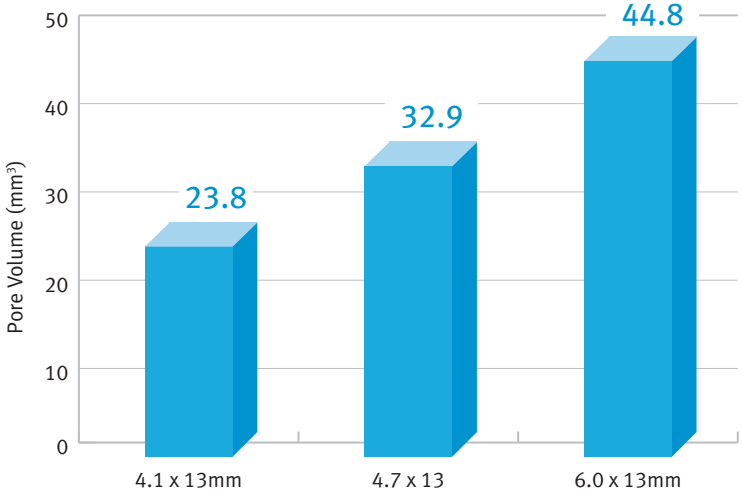
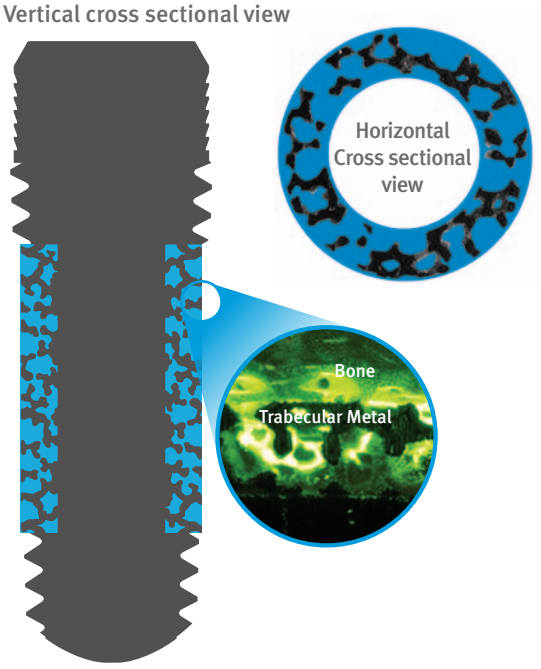


CHART 3. Average pore volume available for bone ingrowth in *Trabecular Metal* Dental Implants of various diameters.[26]

FIGURE 5.
Trabecular Metal Dental Implant
Pore Volume available for Ingrowth (blue)
Vertical cross sectional view



8. *TRABECULAR METAL* DENTAL IMPLANT STABILITY AND OSSEOINTEGRATION[27-29]

Objective(s)	• Evaluation of the stability and osseointegration patterns for the *Trabecular Metal* Dental Implants: a pilot study in dogs.
Methods	• Comparison of *Trabecular Metal* Dental Implants (n=24, test) and *Tapered Screw-Vent* Implants (n=24, control) in dogs (n=8) in mandibular premolar sites. Study conducted at Ohio State University, Columbus, Ohio, USA. • Resonance frequency analysis measurement (Implant Stability Quotient/ ISQ) was employed to analyze implant stability after 2, 4, 8 and 12 weeks of healing. Histological analysis assessed tissue responses to the implants, and backscattered secondary electron imaging (BSE) confirmed new bone.
RESULTS	• Mean ISQ values were ≥ 60 for control and ≥ 65 for test group at all time points (no statistical difference).[28-29] • New bone inside the *Trabecular Metal* Material pores in test group was first observed at 2 weeks[28-29] and continuously increased over the healing period (Figure 5).[27-29] • BSE showed progressive tissue mineralization inside porous sections during the healing period (Figure 6).[29]
CONCLUSION	• Histological and SEM/EDS examinations in a canine model demonstrated that newly mineralized bone tissue formed within the *Trabecular Metal* pores as early as 2 weeks in the *Trabecular Metal* Dental Implants. The ISQ values of the *Trabecular Metal* Dental Implants were statistically comparable to the control groups, reflecting implant stability.

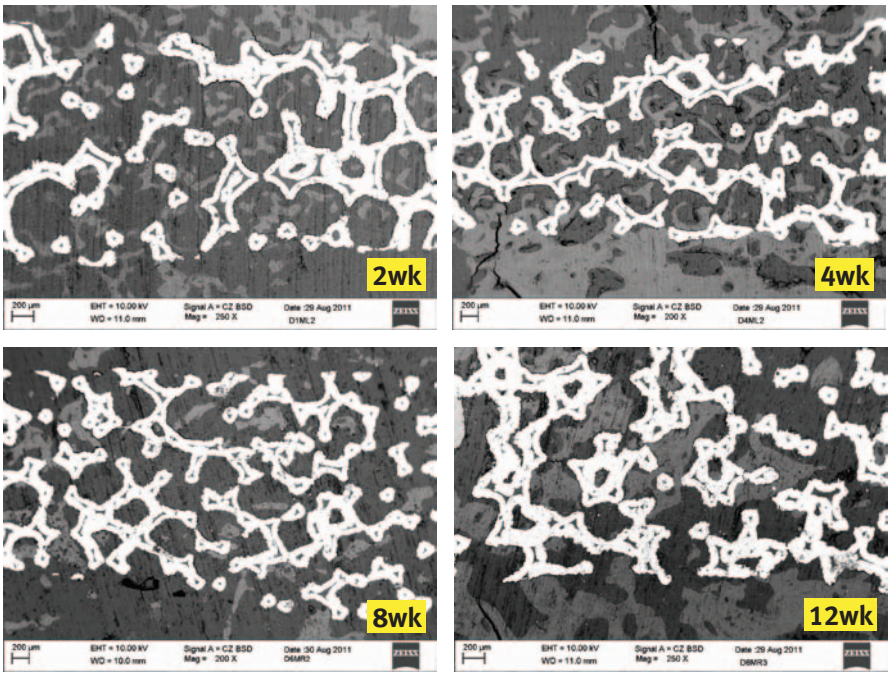
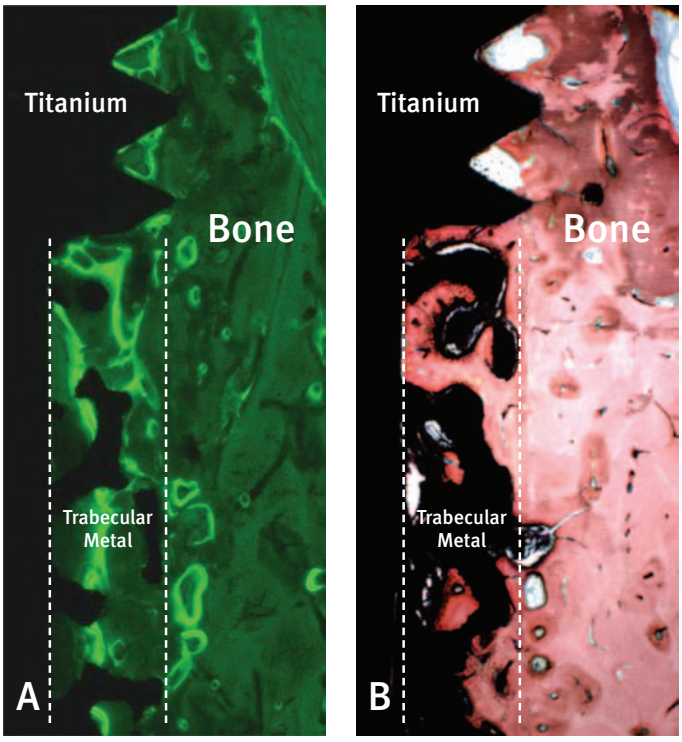


FIGURE 6. Backscattered images show new bone formation (gray) within the *Trabecular Metal* Material (white) during the healing period. Dark areas are the resin block.[29]

9. IMPLANT STABILITY AND HEALING IN EXTRACTION SOCKETS: EARLY FINDINGS[30]

Objective(s)	• Evaluate implant stability and biological tissue responses in hound dogs.
Methods	• Evaluation of implant stability and histology. *Trabecular Metal* Dental Implants (4.1 mm x 13 mm; n = 24, test) and *Tapered Screw-Vent* Implants (4.1 mm x 13 mm; n = 24, control) were placed bilaterally in mandibular extraction sockets of a canine model. • Resonance Frequency Analysis (RFA) values were captured at baseline and necropsy (0, 2, 4, and 12 weeks post implant placement). • Histological evaluation assessed healing patterns at necropsy (2, 4, and 12 weeks post implant placement).
RESULTS	• Stability of *Trabecular Metal* Dental Implants increased over the healing period. Mean RFA values were higher for *Trabecular Metal* Dental Implants than for the controls. • Higher amounts of newly formed bone was observed in *Trabecular Metal* Dental Implant sites than sites with control implants (Figure 7). • No evidence of acute inflammation or bacterial infection was seen in either group.
CONCLUSION	• *Trabecular Metal* Dental Implants placed in extraction sockets demonstrated osseointegration via bone ongrowth and ingrowth, provide equivalent implant stability, and had no increased number of infections relative to the control implants.

FIGURE 7. (A) Histology section with calcein labeling shows new bone formation in and around pores of the *Trabecular Metal* implant at 12 weeks post-surgery. (B) Histology section stained with Sanderson's Bone Stain shows bone ingrowth into the pores of the *Trabecular Metal* Dental Implant 12 weeks post-surgery.[30]



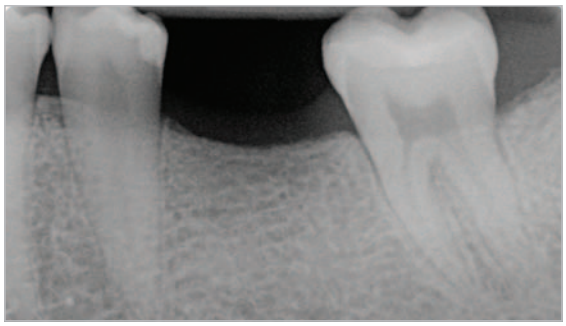
10. IMMEDIATE LOADING: IMPLANT SURVIVAL AND CRESTAL BONE MAINTENANCE[31]

Study Objective	• A prospective, non-randomized pilot study to evaluate the clinical survival and crestal bone maintenance of the immediately loaded *Trabecular Metal* Dental Implants in the posterior maxilla and mandible.
Study Design	• Placement of 37 implants in 30 patients in Germany and Netherlands. • Provisionalization out of occlusion within 48 hours of implant placement, with a definitive fully occluding restoration within 14 days of implant placement. • Exclusions: smokers, bone augmentation, and type IV bone. • Start: August 2010; Study is currently in progress. • Follow-up: 6 months and at year 1, 2 and 3.
Key Endpoints	• Implant survival rate over 3 years. • Change in crestal bone levels.
STATUS	• 12-month follow-up data collection completed.
INTERIM RESULTS	**IMPLANT SURVIVAL RATE:** • 97.2% (n=35/36) at 6 months[31] • No additional failures (n=28/28) at 12 months for implants continuing a 3-year evaluation[31] **CUMULATIVE MARGINAL BONE LOSS FROM DAY OF IMPLANT PLACEMENT:** • 0.42mm at 6 months[31] • 0.52mm at 12 months[31]

FIGURE 8: *Trabecular Metal* Dental Implant placed in the maxilla and immediately loaded.
Image ©2012 Dr. Markus Schlee, Forchheim, Germany.

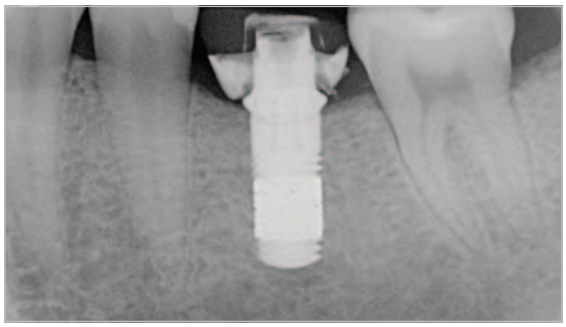
IMMEDIATE LOADING OF *ZIMMER TRABECULAR METAL* DENTAL IMPLANT CASE STUDY

Immediate Placement and Provisionalization of the *Zimmer Trabecular Metal* Dental Implant in the Left Mandibular Posterior Jaw: One-Year Follow-up after Definitive Restoration



1 Female patient presented with a healed edentulous space in the mandibular left first molar area. Radiographic analysis indicated adequate bone volume to accommodate an implant-supported restoration.

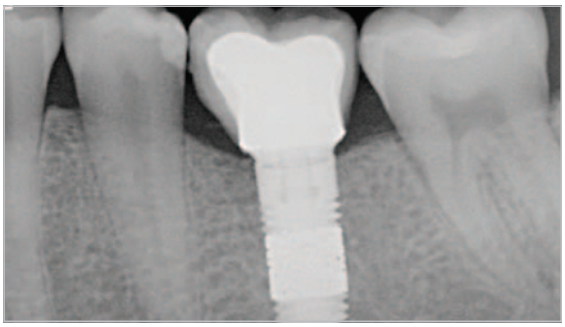
2 Preoperative clinical view shows the edentulous space.



3 A *Trabecular Metal* Dental Implant (4.7 mm x 10 mm) was placed using a standard surgical protocol for dense bone. Final implant insertion torque was between 30-44Ncm. A provisional, non-occluding restoration was delivered within 48 hours of implant placement.

4 The definitive restorative abutment is surrounded by healing soft tissue at suture removal.

5 Clinical view of the final restoration in place within 2 weeks of implant placement. Note the complete soft tissue healing.

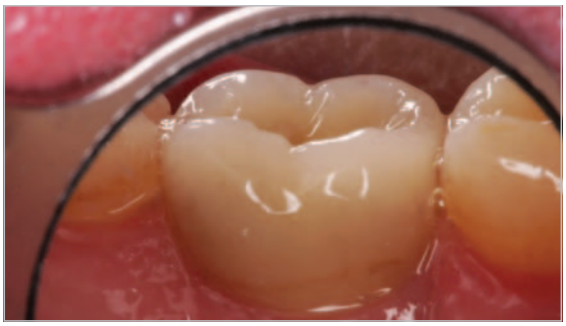


6 Radiographic view of the final prosthesis in place within 2 weeks of implant placement.

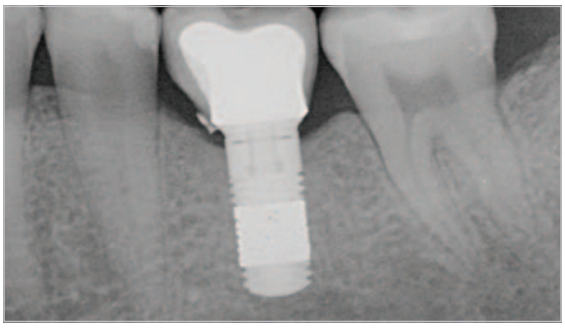
IMMEDIATE LOADING OF *ZIMMER TRABECULAR METAL* DENTAL IMPLANT CASE STUDY

Immediate Placement and Provisionalization of the *Zimmer Trabecular Metal* Dental Implant in the Left Mandibular Posterior Jaw: One-Year Follow-up after Definitive Restoration (continued)

7 Restoration one month after implant placement.

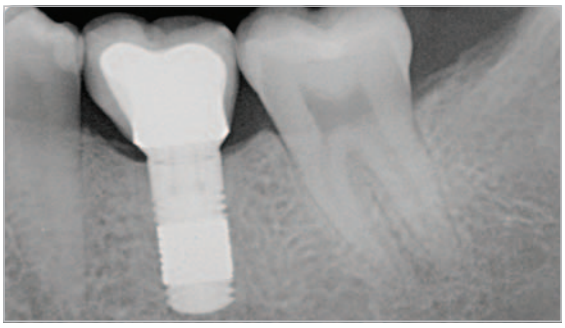


8 A fully functional implant and esthetic restoration with no complications 6 months after implant placement.



9 Radiographic view 6 months postoperative.

10 Clinical view 1 year after implant placement.



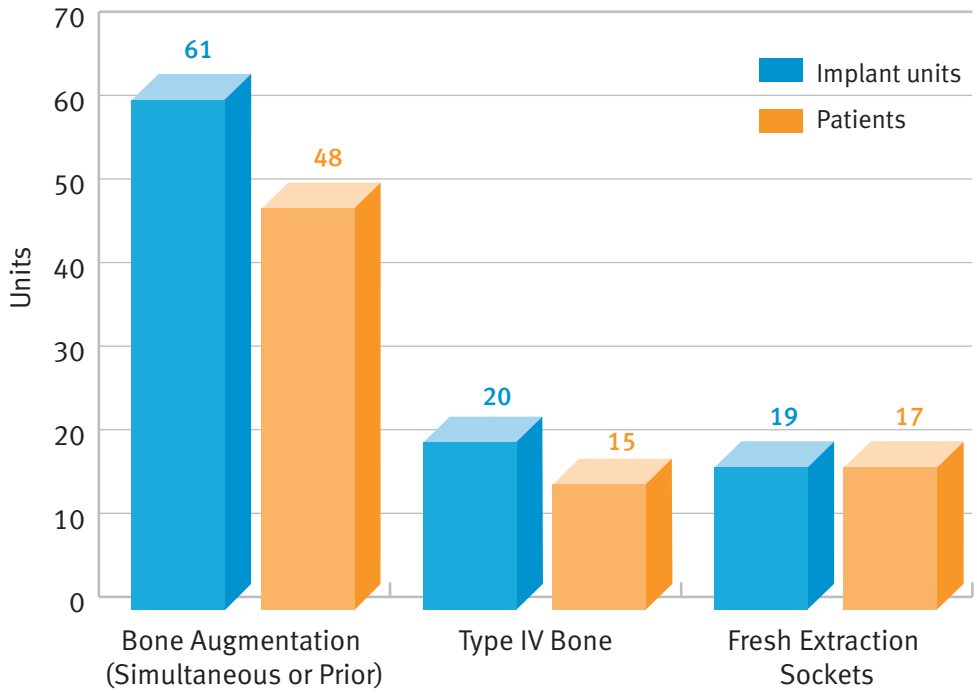
11 One year after placement, the implant was stable and fully functional. Crestal bone loss was 0.19mm.

Images courtesy of *©2012 Dr. Markus Schlee, Forchheim, Germany.*

11. IMPLANT SURVIVAL BY APPLICATION AND PATIENT POPULATION (DATA REGISTRY)[31-32]

Study Objective	• A multicenter, prospective, non-randomized post-market Longitudinal Data Collection Program to evaluate the long-term survival of *Trabecular Metal* Dental Implants in partially edentulous patients treated in routine clinical practices.
Study Design	• Placement of up to 420 implants in a broad cross-section of patients (n ≤ 300). Twenty-three clinical sites in France, Italy, Germany, Spain and the Netherlands are participating. Clinical protocol is uncontrolled and requires adherence to IFU and surgical technique recommended by manufacturer. • Start: October 2010; Study is currently in progress.
Key Endpoints	• Implant survival rate over 5 years. • Crestal bone maintenance. • Case type cross-sections: Type IV bone, smokers, fresh extraction sockets with and without augmentation, augmentation with simultaneous implant placement, prior grafted sites, sinus lifts.
STATUS	• 368 implants placed in 257 patients[32]
INTERIM RESULTS	• Survival rate for implants completing 1 year follow up: 97.9% (n=138/141)[31]

CHART 4: Key clinical applications under evaluation.



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32. Data on file.

For available study abstracts,
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