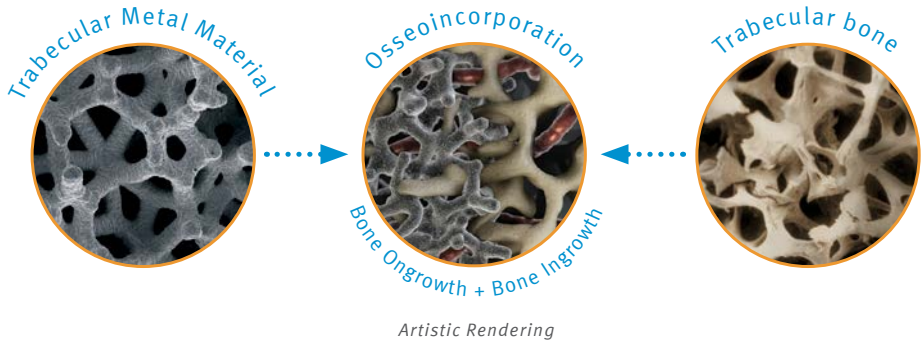


Artistic Rendering

Zimmer® Trabecular Metal™ Dental Implant

SCIENTIFIC COMPENDIUM

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

zimmer | dental

PRE-CLINICAL STUDIES

CLINICAL STUDIES & PROGRAMS

1. *TRABECULAR METAL* MATERIAL CHARACTERISTICS[1]

Bobyn et al.

Objective	• 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 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

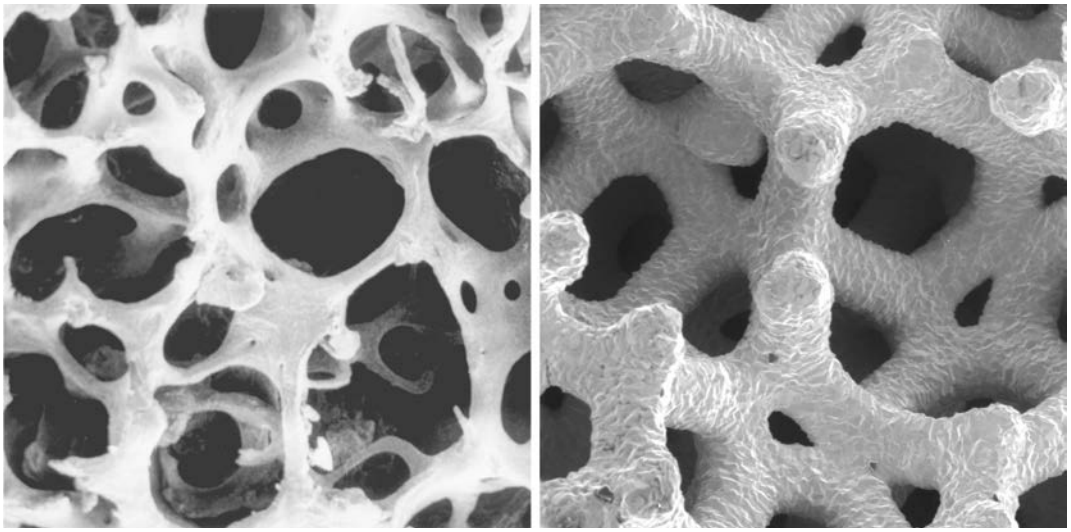


FIGURE 1. SEM view of trabecular bone (left) and *Trabecular Metal* Material (right).[2]

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

Battula et al.

Objective	• 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.

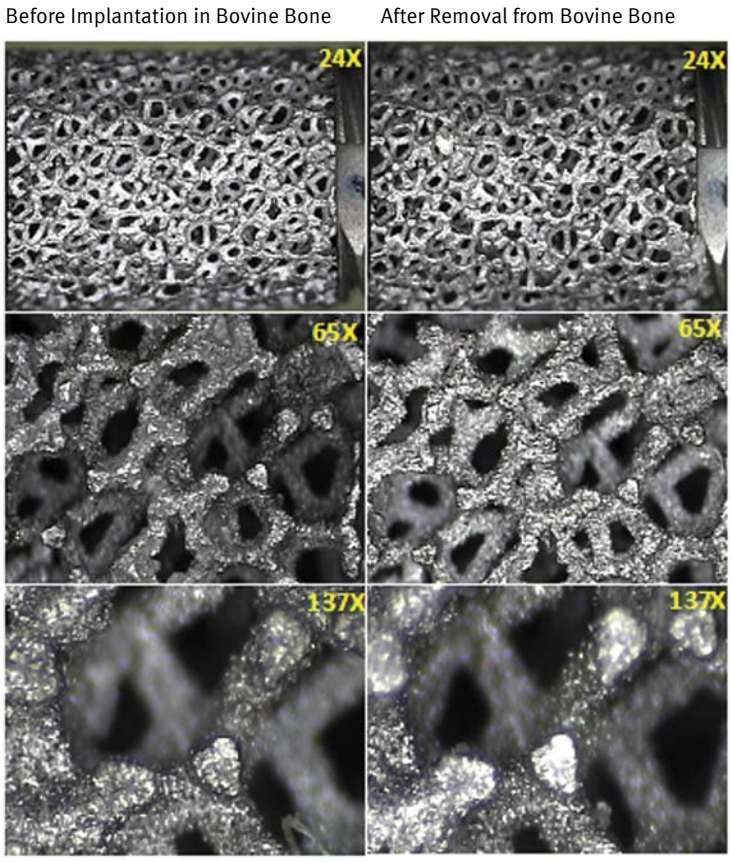


FIGURE 2. Microscopic images of the *Trabecular Metal* Dental Implant, with porous tantalum material, prior to implantation and after removal of implant from bovine condyle.[6,7]

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

Battula et al.

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

Battula et al.

Objective	• 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.

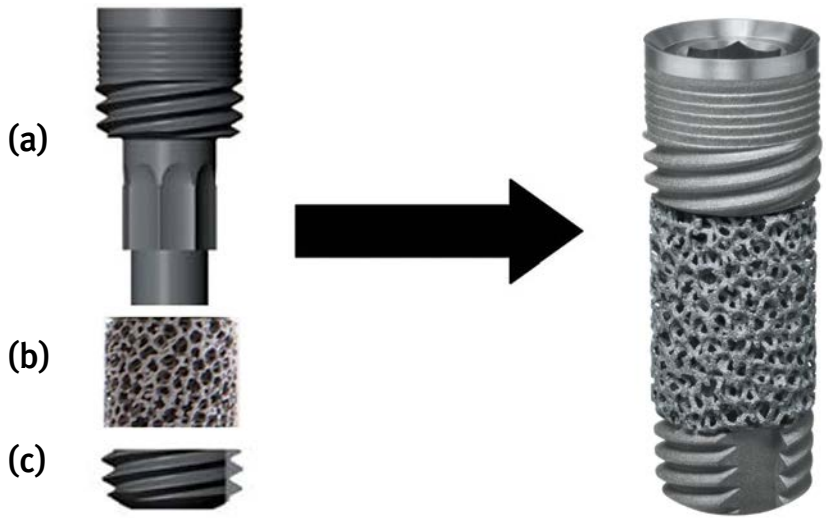


FIGURE 3. *Trabecular Metal* Dental Implant assembly consisting of (a) a titanium cervical and internal core section covered by (b) a *Trabecular Metal* sleeve and joined by (c) a titanium apical section.[6]

5. PRIMARY STABILITY OF *TRABECULAR METAL* DENTAL IMPLANT [2,6,7,19-22]

Battula et al.

Objective	• 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); Dentsply OsseoSpeed Implant in artificial bone (n=5). • Each company's prescribed surgical protocol was followed.
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] 60.5 ±4.7 Ncm for SLActive Bone Level[21] implants and 8.4 ±1.6 for OsseoSpeed[22] 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.

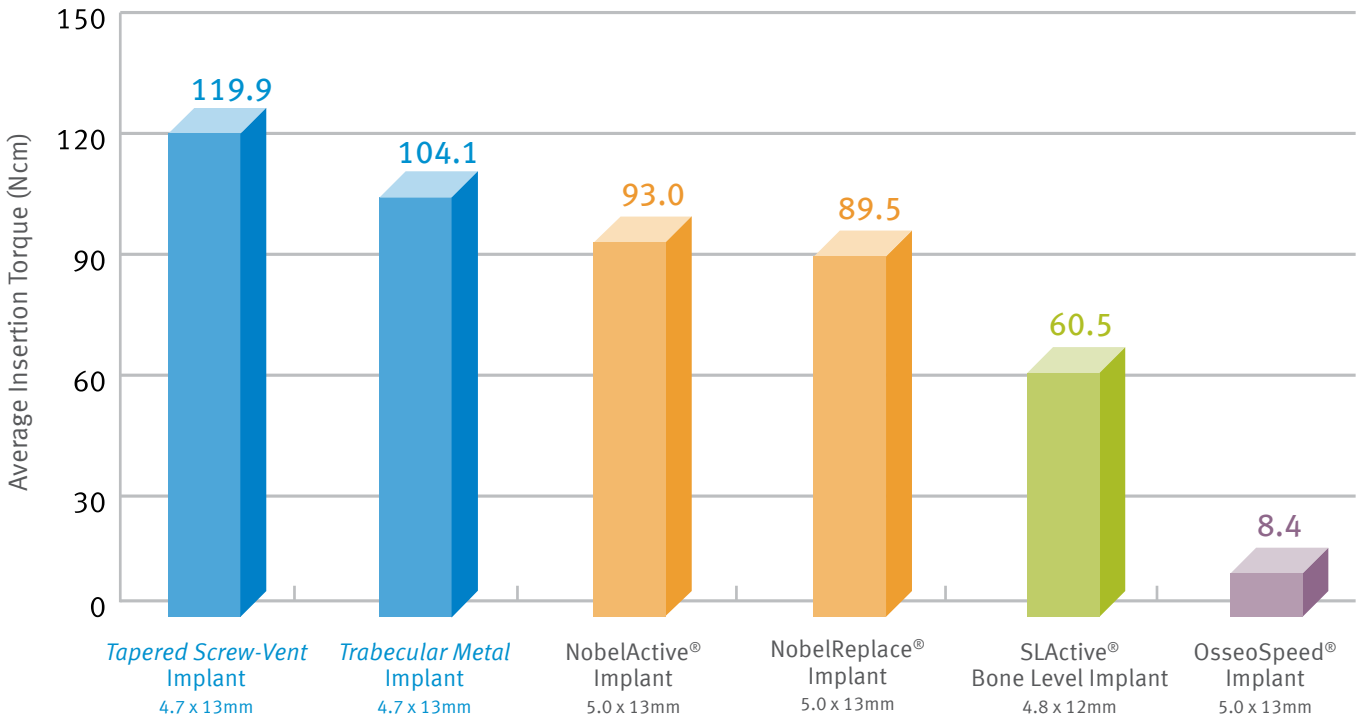


CHART 1. Insertion torque results (Ncm). Average insertion torque in 50/30 bone foam block simulating a dense bone. [2,19-22]

NobelReplace® and NobelActive® are trademarks of the Nobel Biocare group. SLActive® is a trademark of Straumann Holding AG. Osseospeed® is a trademark or Dentsply IH AB.

6. SURFACE AREA FOR OSSEOINTEGRATION[23-27]

Battula et al.

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 & 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 52.7%, 79.4%, 85.7% & 81.8% more surface area for bone apposition than conventional threaded implants of 3.7, 4.1, 4.7 & 6.0mmD, respectively (Chart 2).[23-27]
CLINICAL IMPLICATIONS	• Due to the porous structure of *Trabecular Metal* Material, the *Trabecular Metal* Dental Implant provides more surface area than conventional textured titanium dental implants.

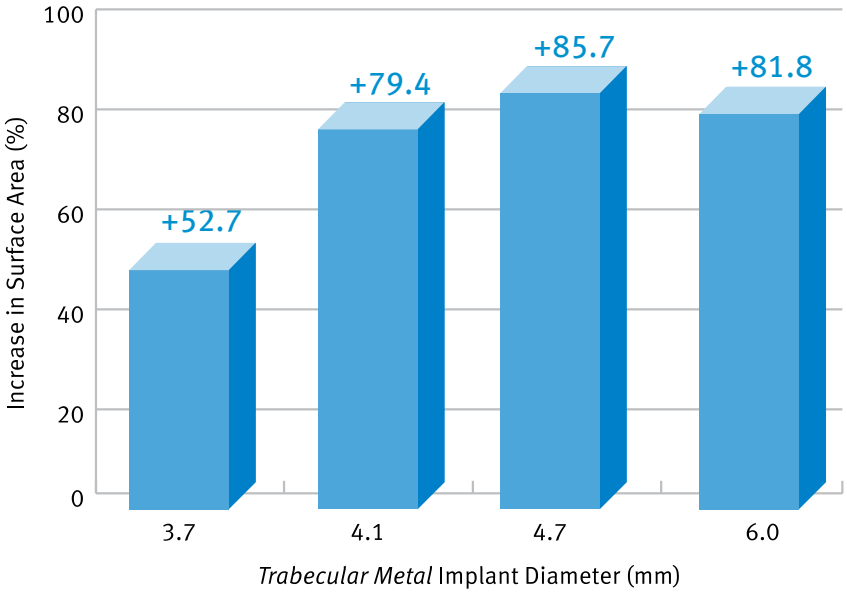
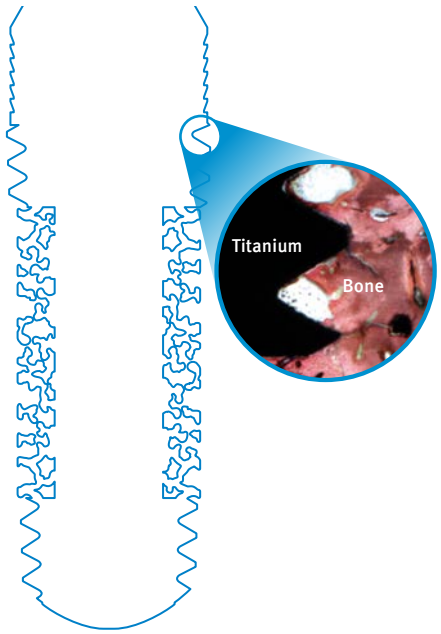


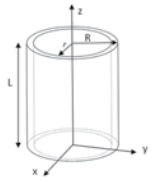
CHART 2. The highest surface area percentage increase observed for *Zimmer Trabecular Metal* Dental Implant as compared with conventional threaded implants of similar length and diameter. [23-27]

FIGURE 4.
Trabecular Metal Dental Implant
Surface area available for ongrowth
Vertical cross sectional view



7. PORE VOLUME AVAILABLE FOR BONE INGROWTH[26-29]

Battula et al.

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 & 6.0mmD) via gravimetric and other analytical methods[26-29] $\text{Pore Volume} = \int_0^{2\pi}\int_r^R\int_0^L V(r,\Theta,z)\,dz\,r\,dr\,d\Theta - \left(\frac{\text{mass}_{TM}}{\text{density}_{TM}}\right)$ 
RESULTS	• *Trabecular Metal* Dental Implants had 13.3, 23.8, 32.9, & 44.8 mm^3 of available pore volume for ingrowth for 3.7, 4.1, 4.7 & 6.0mmD, respectively (Chart 3, Figure 5).[26, 29]
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.

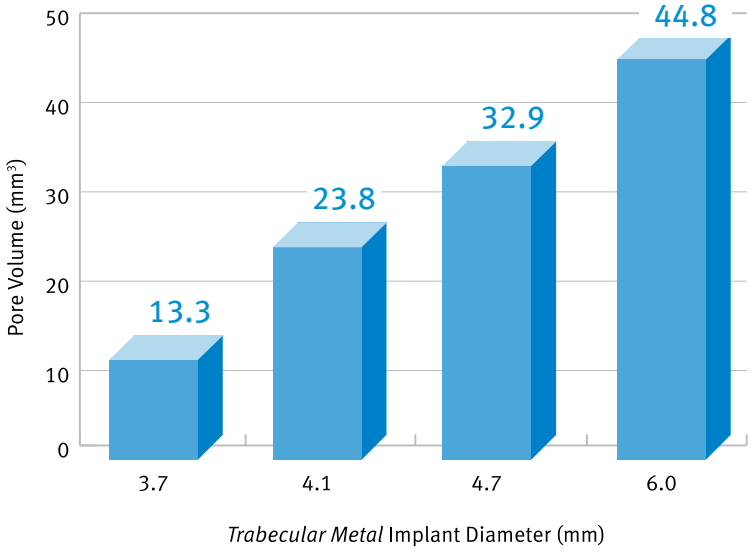
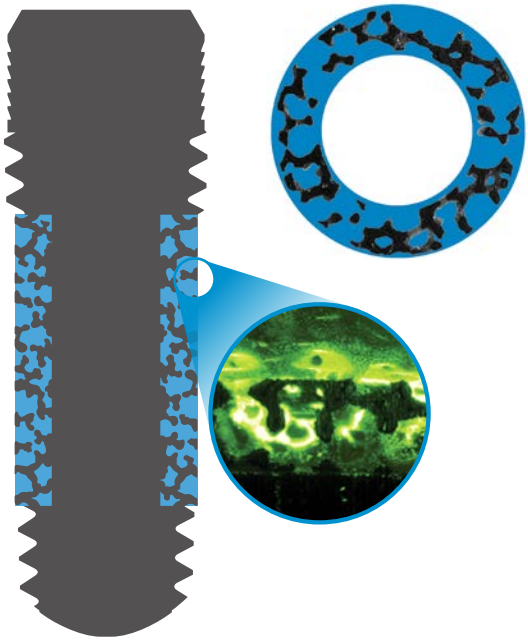


CHART 3. Average pore volume available for bone ingrowth in *Trabecular Metal* Dental Implants of various diameters and 13mm lengths.[26, 29]

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



8. STABILITY AND OSSEOINTEGRATION OF TRABECULAR METAL DENTAL IMPLANT[30-32]

Kim et al.

Objective	• 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 The Ohio State University, Columbus, Ohio, USA. • Resonance frequency analysis measurement (Implant Stability Quotient/ ISQ) was employed to measure 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 formation.
RESULTS	• Mean ISQ values were ≥ 60 for control and ≥ 65 for test group at all time points (no statistical difference).[30-32] • New bone inside the *Trabecular Metal* Material pores in test group was first observed at 2 weeks[30-32] and continuously increased over the healing period (Figure 6).[30-32] • BSE showed progressive tissue mineralization inside porous sections during the healing period (Figure 6).[30-32]
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.

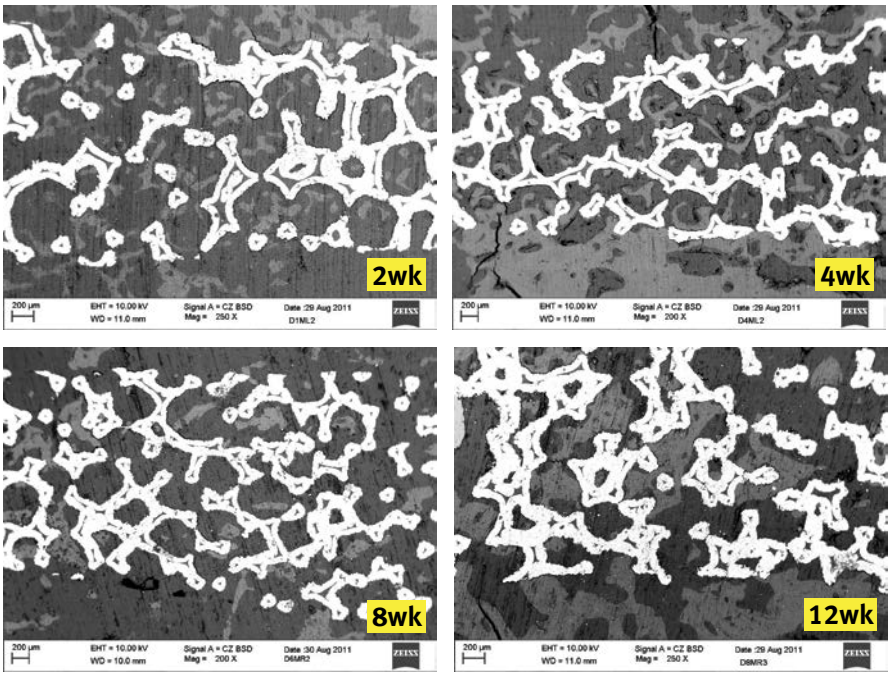


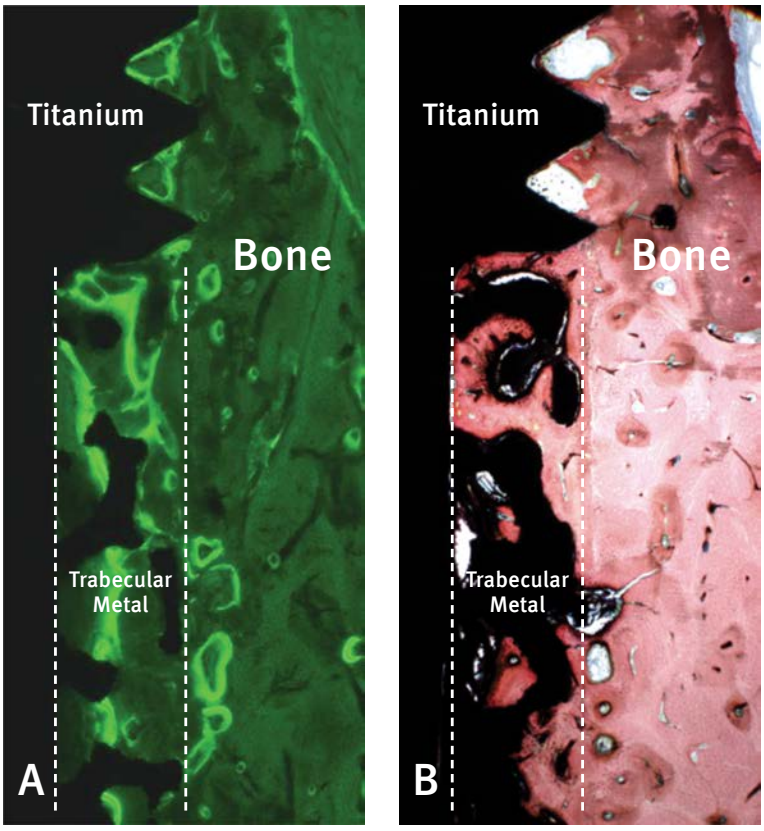
FIGURE 6. Backscattered images show new bone formation (gray) within the *Trabecular Metal* Material (white) during the healing period. Dark areas are the resin block.[30-32]

9. *TRABECULAR METAL* DENTAL IMPLANT STABILITY AND HEALING IN EXTRACTION SOCKETS: EARLY FINDINGS [33]

Battula et al.

Objective	• Evaluate *Trabecular Metal* implant stability and biological tissue responses in hound dogs.
Methods	• Evaluation of implant stability and histology. *Trabecular Metal* Dental Implants (4.1mmD x 13mmL; n = 24, test) and *Tapered Screw-Vent* Implants (4.1mmD x 13mmL; n = 24, control) were placed bilaterally in mandibular extraction sockets of a canine model. • Resonance Frequency Analysis (Implant Stability Quotient/ISQ) 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 ISQ 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, provided 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.[33]



10. PERFORMANCE OF *TRABECULAR METAL* IMPLANTS IN A PERI-IMPLANTITIS MODEL[34]

Battula et al.

Objective	• Evaluation of *Trabecular Metal* implant performance in an experimentally induced canine peri-implantitis model.
Methods	• *Trabecular Metal* Dental Implants (4.1mmD x 13mmL; n=32, test) and *Tapered Screw-Vent* Implants (4.1mmD x 13mmL; n=32, control) were placed bilaterally in mandibular premolar and molar extraction sockets of eight dogs. • Peri-implantitis was induced in 4 dogs (PI group) while 4 dogs received oral prophylaxis (sham group). • Probing depth (PD) was measured for the 24 week group at 18 & 24 weeks and for the 38 week group at 18, 24, 30 & 38 weeks. • Histological evaluation assessed bone-to-implant contact (%BIC), amount of bone formed and histopathological parameters.
RESULTS	• All implants survived. • The PI group exhibited significant loss of supporting tissue with progression of peri-implantitis. • PD of sham group for both implant types was lower than and statistically different from that of PI group after 24 and 38 weeks of healing. • More bone was found in area encompassing the threaded and porous regions of the test implant, than in the corresponding threaded regions of the control implant in both sham and PI groups (Figure 8). • Histopathological analysis showed minimal to mild incidence of acute and chronic inflammation but did not reveal any evidence of bacterial infection within peri-implant tissues or inside TM pores.
CONCLUSION	• *Trabecular Metal* implants performed similarly to the conventional threaded implants in an experimentally induced peri-implantitis environment and did not exhibit bacterial infection.[34]

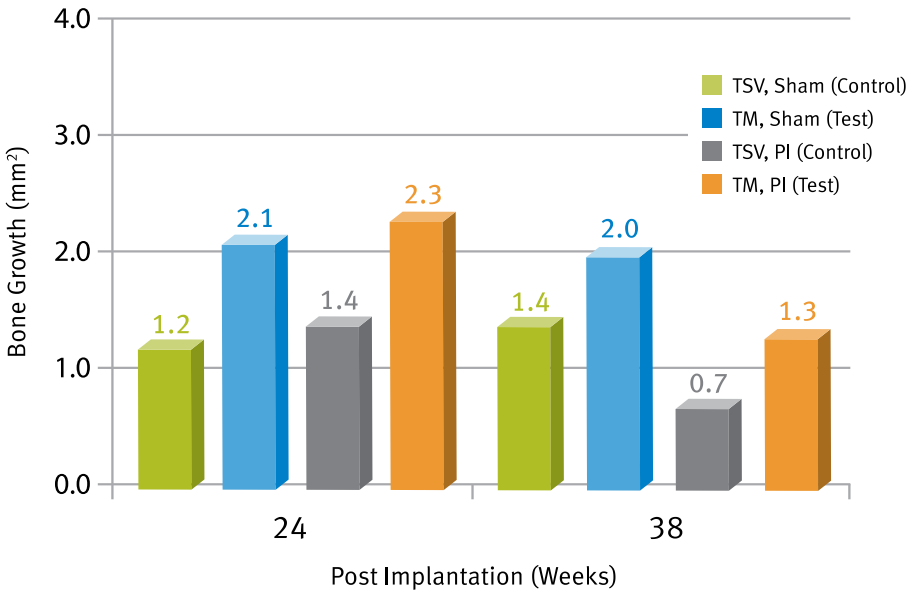


FIGURE 8: Total amount of bone formed in all groups.[35]

11. DYNAMICS OF BONE FORMATION WITHIN *TRABECULAR METAL* IMPLANTS [35]

Lee et al.

Objective	• Evaluation of bone tissue response to the porous midsection of *Trabecular Metal* implants placed in the fresh extraction sockets of canines.
Methods	• *Trabecular Metal* Dental Implants (4.1mmD x 13mmL; n=24, test) and *Tapered Screw-Vent* Implants (4.1mmD x 13mmL; n=24, control) were placed bilaterally in mandibular premolar and molar extraction sockets of six dogs. • Implants were allowed to heal for 2, 4 or 12 weeks (two animals per time point). • The mandibular jaws from all animals were removed and implants were retrieved *en bloc*. • Cross-sections of blocks were surface-stained and histological analysis was performed. • For histomorphometric analysis, the region of interest (ROI) was defined as the area encompassing the entire length of *Trabecular Metal* section in the test group and the corresponding threaded region in the control group (Figure 9).
RESULTS	• All implants survived until necropsy. • Both groups showed a progression of new bone formation over the healing periods. • After 2, 4 and 12 weeks of healing, the amount of new bone was 31.61%, 26.60% and 47.83% for the test group and 14.53%, 13.61% and 36.29% for the control group, respectively. • The amount of new bone formed in the test group was higher than that in the control group in every healing period (Figure 10).
CONCLUSION	• Progressive osseoincorporation was demonstrated in the *Trabecular Metal* group, while the control group was limited to bone growth onto the Ti alloy surfaces (osseointegration).[36] • More new bone formation was associated with *Trabecular Metal* than with the conventional threaded design during the early healing phase.[35]

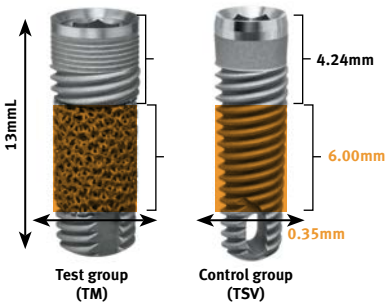


FIGURE 9: The region of interest (ROI): The entire length of *Trabecular Metal* section (6.00mm long x 0.35mm deep) for the test group and the corresponding threaded region for the control group.[35]

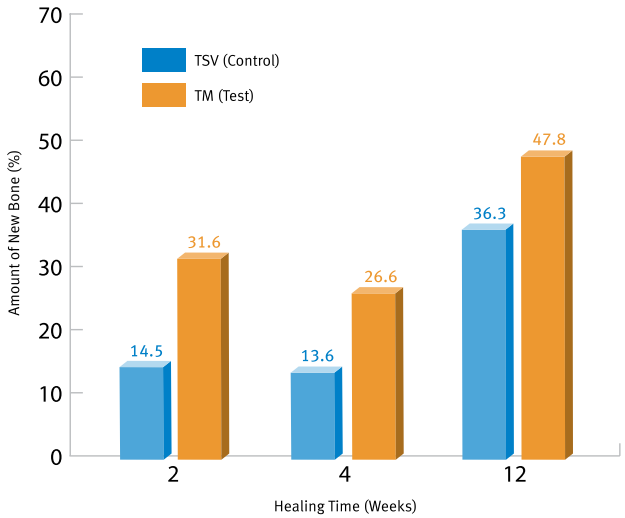


FIGURE 10: Amount of new bone observed in *Trabecular Metal* of the test group vs. corresponding threads of the control group.[35]

12. IMMEDIATE LOADING OF *TRABECULAR METAL* DENTAL IMPLANTS[36-38]

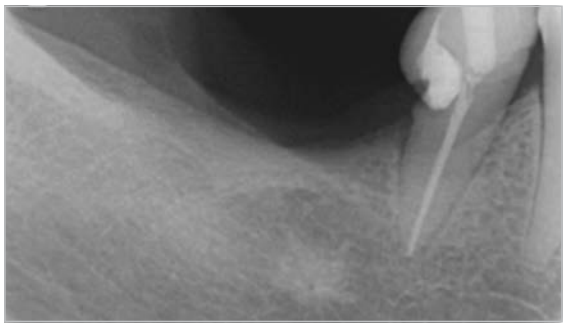
Schlee et al.

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 process. • Follow-up: 6 months and at years 1, 2 and 3.
Key Endpoints	• Implant survival rate over 3 years. • Change in crestal bone levels.
STATUS	• 2-year follow-up data collection completed.
INTERIM RESULTS	**IMPLANT SURVIVAL RATE:** • 97.2% (n=35/36) at 6 months[36] • No additional failures (n=29/29) at 24 months for implants continuing a 3-year evaluation[38] **CUMULATIVE MARGINAL BONE LOSS FROM DAY OF IMPLANT PLACEMENT:** • 0.42mm at 6 months[36] • 0.46mm at 24 months[38]

FIGURE 11: *Trabecular Metal* Dental Implant placed in the maxilla and subsequently immediately loaded. Image courtesy of *Dr. Markus Schlee, Forchheim, Germany.*

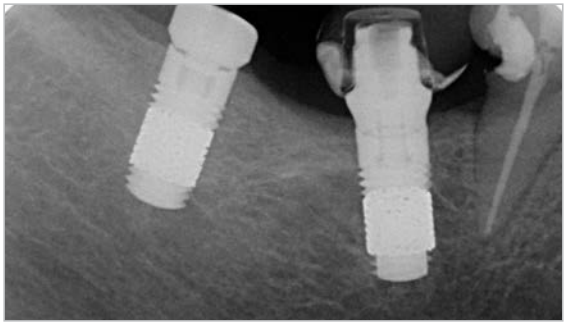
IMMEDIATE LOADING OF THE *ZIMMER TRABECULAR METAL* DENTAL IMPLANT IN THE MANDIBULAR POSTERIOR JAW: TWO-YEAR FOLLOW-UP AFTER DEFINITIVE RESTORATION

Schlee M.

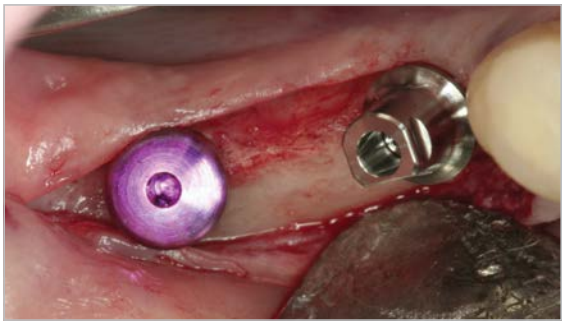


1 Female patient presented with a healed edentulous space in the mandibular right first and second molar area. Radiographic analysis indicated adequate bone volume to accommodate implant supported restorations.

2 Preoperative clinical view shows the edentulous space.



3 Two *Trabecular Metal* Dental Implants (4.7mmD x 10mmL) were placed. The mesial implant was inserted using standard surgical protocol for dense bone. Final implant insertion torque was between 45-59 Ncm. A provisional, non-occluding restoration was delivered within 48 hours of implant placement. The distal implant lacked primary stability and was excluded from the study per inclusion/exclusion criteria. A healing collar was placed on the implant and left to heal for additional time.

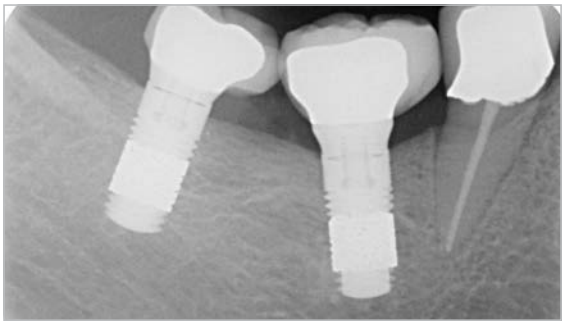


4 Clinical view of final abutment and healing collar in place immediately after implant insertion.

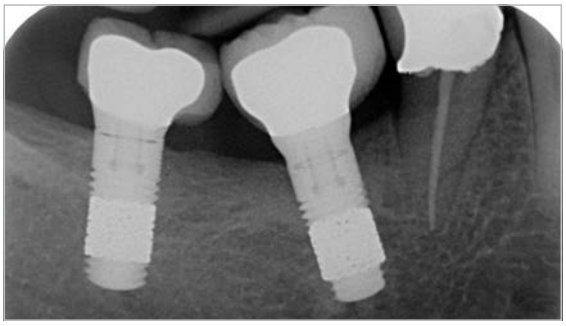
5 Clinical view of the final restoration in place within 2 weeks of implant placement. Note the complete healing of soft tissue around the implant.

6 Clinical view of restoration one month after implant placement.

IMMEDIATE LOADING OF THE *ZIMMER TRABECULAR METAL* DENTAL IMPLANT IN THE MANDIBULAR POSTERIOR JAW:
TWO-YEAR FOLLOW-UP AFTER DEFINITIVE RESTORATION
(continued)

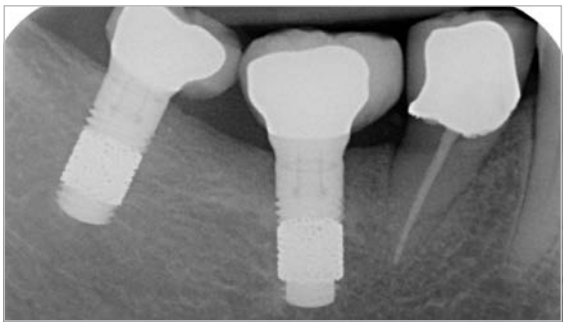


7 Radiographic view at 6 months postoperative.



8 One year after implant placement, the implants are stable and fully functional. The change in crestal bone level from provisionalization to the 1-year follow-up was - 0.10mm on the study implant.

9 Clinical view 1 year after implant placement



10 Two years after placement, the implants remain stable and fully functional. The change in crestal bone level from provisionalization to the 2-year follow-up was - 0.07mm on the study implant, which reflected 0.03 mm of bone gain from year 1 to year 2.

11 Clinical view 2 years after implant placement.

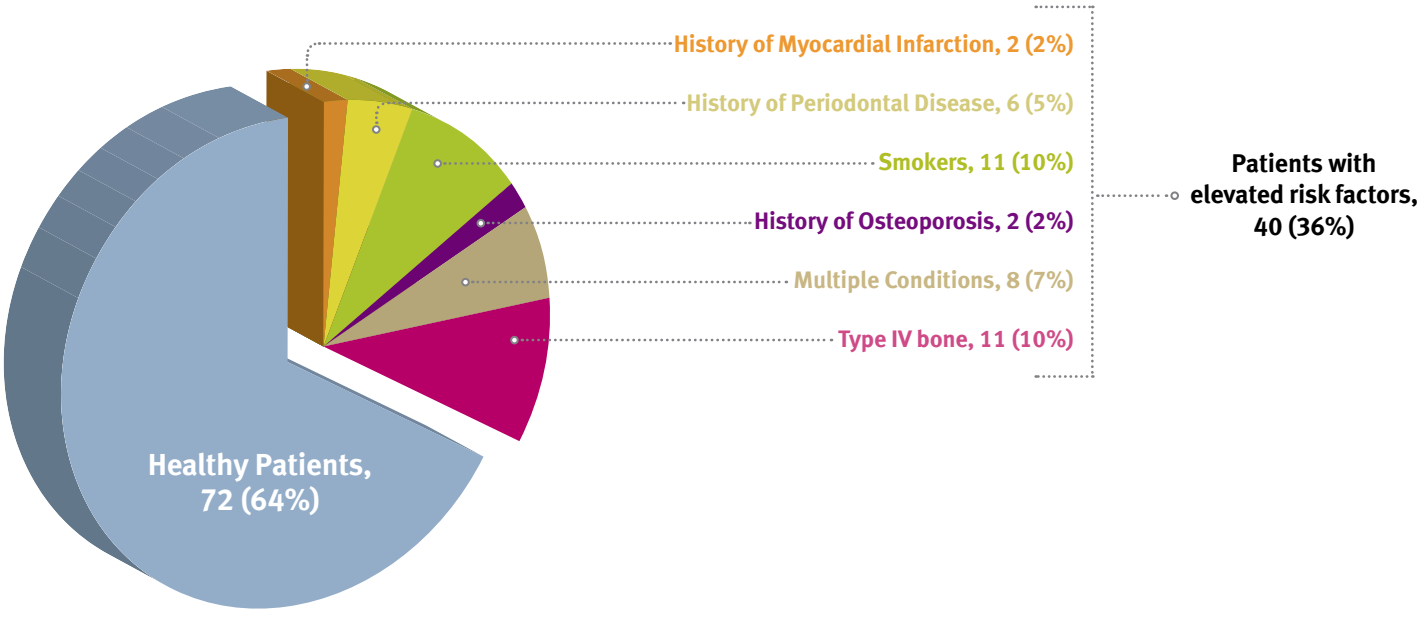
Images courtesy of *Dr. Markus Schlee, Forchheim, Germany.*

13. PERFORMANCE OF *TRABECULAR METAL* DENTAL IMPLANTS IN A ROUTINE DENTAL PRACTICE (LONGITUDINAL DATA COLLECTION)[38]

Schlee et al.

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-two 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 process.
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	• 422 implants placed in 299 patients.[38]
INTERIM RESULTS	• Survival rate for implants completing a 2-year follow up: 96.8% (n=150/155) in 112 patients[38] (Figure 12) - Survival rate for implants placed in augmented sites: 96.9% (n=63/65) - Survival rate for implants placed in Type IV bone: 100% (n=19/19) - Survival rate for implants placed in patients with elevated risk (including Type IV bone): 96.4% (n=53/55).

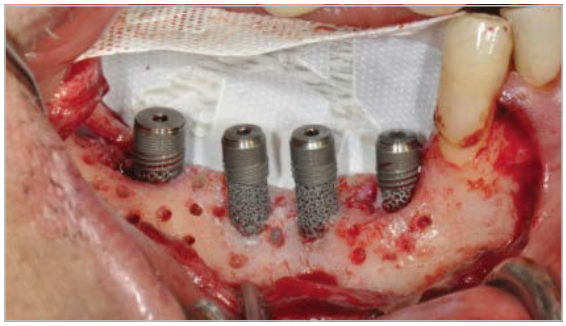
FIGURE 12: Patients completing a 2-year follow-up (n=112)



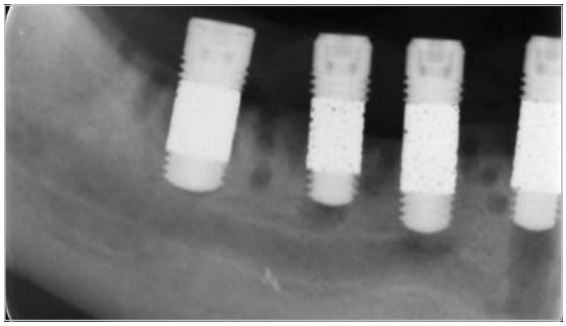
GUIDED BONE REGENERATION AND SIMULTANEOUS PLACEMENT OF *ZIMMER TRABECULAR METAL* DENTAL IMPLANTS IN A MANDIBLE WITH INADEQUATE BONE VOLUME

Ronda M.

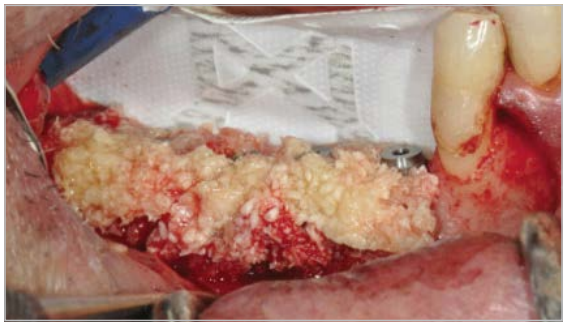
1 Male patient presented with a healed edentulous space in the mandibular right premolar and molar area. Preoperative clinical view shows inadequate bone to support an implant-supported restoration.



2 Four *Trabecular Metal* Dental Implants with machined collars were placed using a standard surgical protocol for dense bone. Final insertion torque was between 45-59 Ncm for all the implants.

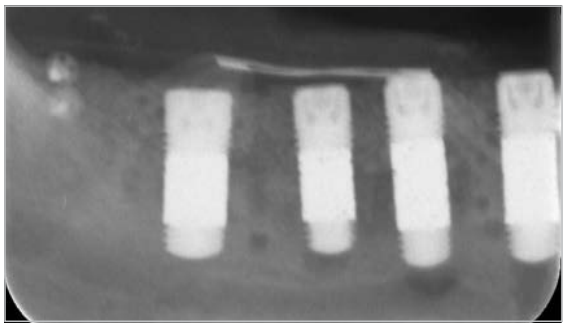


3 Radiographic view of the supra-crestal implant placement. Note the cortical perforations to induce bleeding.



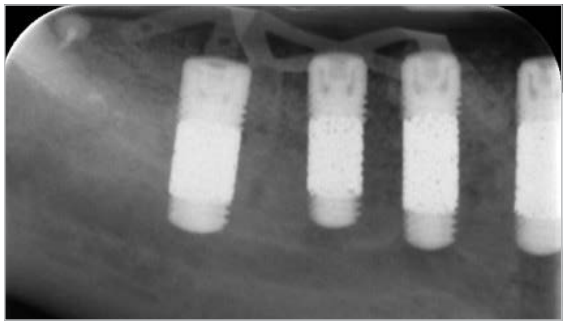
4 Simultaneous bone grafts were placed using guided bone regeneration. A cortical-cancellous mix (50:50) (*Puros*® allograft particulate) with PRGF was used as the graft along with a titanium reinforced non-resorbable d-PTFE membrane.

5 Clinical view showing the membrane used to ensure stabilization of the graft.

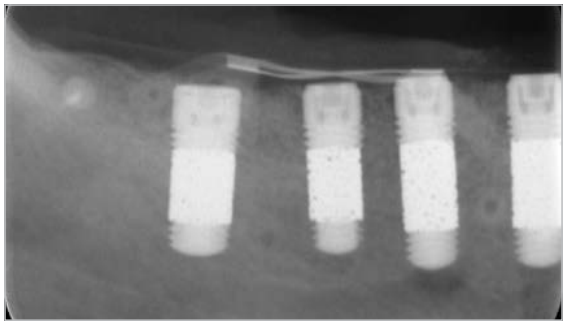


6 Radiographic view of the implants at 3 months postoperative showing graft incorporation.

GUIDED BONE REGENERATION AND SIMULTANEOUS PLACEMENT OF *ZIMMER TRABECULAR METAL* DENTAL IMPLANTS IN A MANDIBLE WITH INADEQUATE BONE VOLUME (continued)

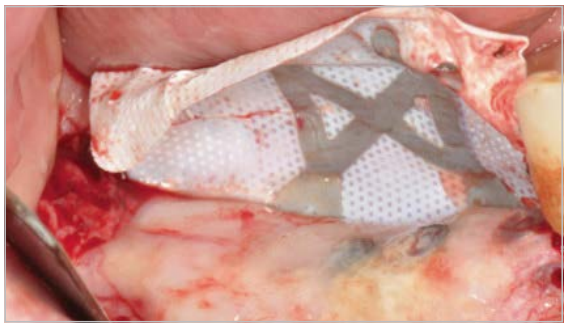


7 Radiographic view of the implants at 6 months postoperative



8 Radiographic view of the implants at 10 months postoperative. Note the restored ridge dimensions.

9 Clinical view at the 12-month reentry. Note the change in width and height of the restored ridge.



10 Note the clinical change in height and width of the alveolar ridge upon removal of the membrane.

11 The excess bone covering the implants was trimmed to expose the implants.

12 Healing collars placed on the implants upon re-entry at 12-months post surgery. All 4 implants were stable at re-entry.

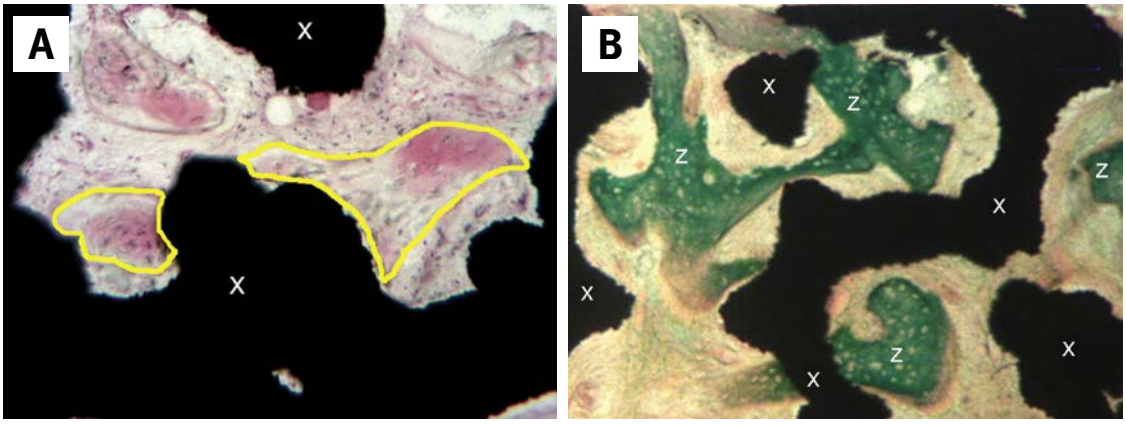
Images courtesy of Dr. Marco Ronda, Genova, Italy.

14. HUMAN BONE INGROWTH INTO *TRABECULAR METAL* MATERIAL[39]

Clemente et al.

Objective:	• Evaluation and quantification of bone ingrowth into *Trabecular Metal* Material during 2 to 12 weeks of submerged healing in human patients.
Methods:	• Placement of at least one *Trabecular Metal* cylinder (3mmD x 5mmL) in the maxilla or mandible of 23 healthy patients. • Each subject was randomly assigned to one of four time point groups: 2, 3, 6 and 12 weeks for retrieval of the cylinders. • Retrieved samples were placed in a 10% buffered formaldehyde solution and processed for histology. • Stains used: *Hematoxylin-eosin* to identify cells; Masson *trichrome* to identify osteoid tissue and *Toulidine* blue to identify markers of developing and existing trabecular bone.
Key Endpoints:	• Histology and histomorphometry of *Trabecular Metal* cylinder samples retrieved from healthy patients at 2, 3, 6 and 12 weeks.
STATUS:	• 23 subjects with 24 cylinders were enrolled into the study. • All subjects completed surgeries, retrieval and follow-up with no complications.
INTERIM RESULTS:	• Blood vessel formation and tissue infusion was observed inside the *Trabecular Metal* Material at 2 weeks. • At 3 weeks, osteoblasts and new bone formation were observed inside the *Trabecular Metal* Material (Figure 13A). • Progressive bone formation was observed inside the pores (ingrowth) and in direct contact with the external surfaces (ongrowth) of all samples from 3 to 12 weeks. In addition, intense angiogenesis and mesenchymal cells in all samples indicated good tissue response (Figure 13B).
CONCLUSION:	• At 2 weeks in humans, porous cylinders of *Trabecular Metal* Material exhibited newly formed blood vessels, cells and tissue infusion, which subsequently led to new bone formation starting at 3 weeks.[39]

FIGURE 13: Newly formed bony trabeculae partially surrounded by a front of osteoblasts (inside yellow lines) in a peripheral pore at 3 weeks (A), (Hematoxylin-eosin); bone trabeculae with osteoid tissue (z) along the edges inside the porous material at 12 weeks (B), (Masson's trichrome).[40]



Notes

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