

## Article

# Prospective Pilot Study of Immediately Provisionalized Restorations of Trabecular Metal-Enhanced Titanium Dental Implants: A 5-Year Follow-Up Report

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**Abstract:** Porous tantalum trabecular metal biomaterial has a similar structure to trabecular bone, and was recently added to titanium dental implants as a surface enhancement. The purpose of this prospective pilot study was to describe 5-year survival results and crestal bone level changes around immediately-provisionalized Trabecular Metal Dental Implants. Eligible patients were adults in need of  $\geq 1$  implants in the posterior jaw. A non-occluding single acrylic provisional crown was in place for up to 14 days before final restoration. Clinical evaluations with radiographs were conducted at each follow-up visit (1 month, 3 months, 6 months, and 1 to 5 years). The primary endpoint was implant survival, characterized using the Kaplan-Meier method. The secondary endpoint was changes in crestal bone level, evaluated using a paired *t*-test to compare mean crestal bone levels between the baseline, 6-month, and annual follow-up values. In total, 30 patients (37 implants) were treated. Mean patient age was 45.5 years, and 63% were female. There was one implant failure; cumulative survival at 5 years was 97.2%. After the initial bone loss of 0.40 mm in the first 6 months, there were no statistically significant changes in crestal bone level over time up to 5 years of follow-up.

**Keywords:** dental implant; osseoincorporation; osseointegration; trabecular metal



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## 1. Introduction

Porous tantalum has been used in the orthopedic industry since the 1980s for joint arthroplasty, bone augmentation, and as an integral part of orthopedic implants to facilitate bone ingrowth [1]. Although tantalum is highly biocompatible and resistant to corrosion, its use in orthopedics was initially limited due to cost and difficulties in manipulating solid tantalum [2]. However, in the early 1990s porous tantalum trabecular metal (PTTM) was introduced [2]. Porous tantalum trabecular metal, known commercially as Trabecular Metal (TM) Material (Zimmer Trabecular Metal Technology, Inc., Parsippany, NJ, USA) is a highly porous biomaterial made from elemental tantalum, with a similar structure to trabecular bone by having a repeating pattern of regular, interconnecting pores, which provide a high volume (70% to 80%) of porosity [1–3]. Using a proprietary chemical deposition process, elemental tantalum is deposited onto a substrate, creating a nanotextured surface topography to build the TM material [4].

Early nonclinical (canine and bovine) research showed that the multi-dimensional enhancement of implant surfaces with PTTM allowed for excellent bone ingrowth within porous tantalum structures [1,3,5,6] and that the material was chemically stable and biocompatible [7,8]. Porous tantalum trabecular metal has excellent biocompatibility and high frictional characteristics, which make it conducive to biologic fixation [1,2], and it has been

used in clinical applications for orthopedics for several decades. PTTM has been recently added to titanium dental implants as an enhancement to titanium implant surfaces [2].

As originally described by Bencharit et al., using PTTM as an enhancement for dental implants can potentially provide multiple advantages, including rapid endothelial budding, as well as ingrowth and endothelial neovascularization, both of which are critical for promoting new osseous tissue formation [2]. Based on the extensive prior clinical use of PTTM in orthopedics, a titanium alloy dental implant with a PTTM midsection was developed (Trabecular Metal Dental Implant, Zimmer Dental Inc., Carlsbad, CA, USA). The TM dental implant is manufactured from a combination of titanium alloy and trabecular metal and designed for integration into hard tissue through a process of bone apposition to the threaded implant surface and by bone ingrowth into the porous surface. These dental implants are indicated for delayed and immediate restoration.

There has been limited clinical research on TM dental implants, with a maximum of 1-year follow-up results reported. In 2013, the authors of the current report published the 1st year results of a 5-year descriptive, pilot study to evaluate TM dental implants which were immediately restored with a provisional restoration and fully loaded within two weeks. Their evaluation showed that during the first year of the study, PTTM-enhanced titanium dental implants had a 97.3% cumulative implant survival rate and appeared to be able to withstand the clinical demands of immediate loading [4]. The authors noted that longer-term follow-up was needed to better evaluate the performance and clinical characteristics of the TM dental implant. The present report describes the 5-year survival results and crestal bone loss associated with immediately-provisionalized and fully loaded (within two weeks) TM dental implants in a descriptive 5-year pilot study.

## 2. Materials and Methods

### 2.1. Study Design and Eligibility Criteria

This was a prospective, two-center, 5-year, nonrandomized, descriptive pilot study. Enrollment was open to all qualifying male or female patients of at least 18 years of age with adequate bone volume to support an implant in the posterior jaw. Other inclusion criteria included having residual facial and palatal/lingual plates at least 1.5 mm thick after osteotomy preparation, having a healed extraction site greater than six months post-extraction (with or without grafting), being able to provide informed consent, and ability to attend evaluation visits.

Exclusion criteria for enrollment into the study included bruxism, fresh extraction sites, smokers, uncontrolled systemic disease, bleeding disorders, use of biphosphonates, and pregnancy. At the time of surgery, an additional exclusion criterion was employed; patients with type 4 bone or implants with <35 Ncm of insertion torque were also excluded. After a patient was deemed medically, dentally, psychologically, functionally, and anatomically to be a good candidate for dental implant therapy, informed consent was obtained, and the patient was enrolled. Up to 40 patients from two sites (one in Germany and one in the Netherlands) were planned for enrollment.

### 2.2. Data Collection

Before implant surgery, patient demographics, and medical and dental conditions were recorded. During the implant surgery, insertion torque values, implant size, and bone density were recorded. Radiographs were taken to evaluate mesial and distal bone levels. All data requested for this study were collected using electronic case report forms (eCRFs). Data collection and management were performed by the Sponsor.

### 2.3. Implant Procedure

Pre-operative photographs and radiographs were taken with an individualized imaging holder (Figure 1). All patients received pre-operative oral antibiotic therapy with either clindamycin or amoxicillin [9]. At the time of the surgical implant placement, the subject was administered anesthesia. As described in an earlier publication, implants of either

4.7 mm or 6.0 mm diameters were placed in either premolar or molar sites, in either jaw [4]. Implants were TM dental implants with a 0.5 mm machined collar, microtextured (MTX) surface, and microgrooves, and were placed according to the surgical manual using a one-stage (nonsubmerged) technique. Implant insertion torque and resonance-frequency analysis values were recorded at the time of placement. As noted earlier, if it was discovered that a patient had type 4 bone at the implant site, they were excluded from the study. Appropriate analgesics and postoperative physical therapy were prescribed as needed. Post-implantation antibiotic therapy was not prescribed unless indicated for infection. After the implant placement, a final impression was taken and sent to the dental lab for fabrication of the final restoration.



**Figure 1.** An individualized imaging holder was made and stored for each patient during the 5-year study period.

#### 2.4. Immediate Provisional and Final Restoration

A standard contoured abutment was placed as the final abutment with 30 Ncm preload, as recommended. This was the abutment for both the provisional and final crown. A non-occluding single acrylic crown provisional prosthesis was immediately delivered and the soft tissues were sutured around the provisional restoration. All immediate provisional restorations were placed within 48 h of surgery. The provisional prosthesis was in place for 7 to 14 days to allow adequate time for soft tissue healing. Periapical radiographs were taken. Seven to 14 days after the implant procedure, the provisional prosthesis and sutures were removed. If the implant appeared stable, the final restoration was delivered (Figure 2). The final restorations were fully occluding, single-tooth ceramometal restorations. Any final occlusal adjustments were made at this visit.



**Figure 2.** Shows the intraoral photos and periapical radiographs taken pre-operatively, at final restoration, and at 5-years follow-up. This female patient with missing posterior mandibular first and second molars received two TM implants (diameter 6.0 mm and length 10 mm for both). Final restoration was completed 13 days after implant placement consisting of two cement-retained crowns. The 5-year follow-up showed good soft tissue health and bone maintenance.

### 2.5. Follow-Up Visits

Subjects were scheduled to be re-evaluated at 1 month, 3 months, 6 months, and for annual visits for 5 years after delivery of the provisional restoration. During each follow-up visit, the study investigator took photographs in the facial, occlusal, and lingual views, assessed for any clinical complications, and took standardized periapical radiographs (Rinn, Dentsply, York, PA, USA) (Figure 1). An individualized imaging holder was made and stored for each patient during the 5-year study period. When mobility was suspected, opposing force from two hand instruments was applied to the post and any overt indication of mobility was recorded as a failure.

### 2.6. Study Endpoints

The primary endpoint was implant survival after 5 years of occlusal loading. Implant failure was defined as the presence of persistent pain, mobility, or loss or removal of the implant.

The secondary study endpoint was change in crestal bone level; mesial and distal levels were determined radiographically and a mean (per implant site) was calculated. Crestal bone loss was summarized as the mean of radiographic mesial and distal changes in bone height from baseline (implant surgery) values. Mean crestal bone loss served as the secondary endpoint, and was computed by averaging the mean bone loss per implant.

All periapical radiographs were evaluated by an independent radiologist using high-resolution uncompressed image files. As described in an earlier paper, crestal bone levels were measured by calculating the distance from the implant shoulder to the first bone-to-implant contact [4]. Both mesial and distal measurements were made on each periapical radiograph, and the mean value was used in the analyses. The known height of the implant's tantalum section (4.8 mm) was used as the standardized dimension for calibration. The height of the tantalum section was measured on the image in pixels, and the ratio between the length in pixels and tantalum height of 4.8 mm was calculated. Because the two study sites used different radiographic image sensors, each site was calibrated differently: 0.0234 mm/pixel (4.8 mm/205.5 px = 0.0234 mm) for the first site (Germany) and 0.0349 mm/pixel (4.8 mm/137.5 px = 0.0349 mm) for the second site (the Netherlands). Bone height values measured in pixels were then multiplied by the calculated calibration factors to arrive at the final data values in millimeters. Each image was opened using US FDA-cleared image analysis software (OsiriX MD, Pixmeo SARL, Bernex, Switzerland) on a personal computer [4]. Measurements were recorded in a spreadsheet (Excel, Microsoft Corp., Redmond, WA, USA).

### 2.7. Statistical Analyses

Descriptive statistics (N, %, mean  $\pm$  SD, min, max, median) were used to summarize the data. The implant was the unit of analysis, except for patient demographics. Implant survival was summarized through the characterization of failure over time, using the Kaplan–Meier method. Cumulative survival of the implants was estimated at each time of assessment, with corresponding 95% confidence intervals. A paired *t*-test was performed to analyze the initial bone loss from implant placement/immediate provisional restoration to 6 months of follow-up, and the additional bone loss was analyzed by comparing crestal bone loss between annual follow-up values and the 6-month value. Statistical significance was declared if the 2-sided *p*-value was <0.05.

Because this was a descriptive pilot study with no control group and no prior hypothesis, no formal sample size calculations were conducted. This pilot study was conducted to gather initial, exploratory data; the sample size was not selected according to any statistical power calculation. Instead, the sample size was determined according to feasibility and was thought to provide sufficient exploratory results to inform the development of future confirmatory studies. Analyses were performed using SAS 9.4 TS (SAS Institute Inc., Cary, NC, USA) or Minitab 18 (Minitab, LLC, State College, PA, USA).

### 2.8. Human Subjects Protections

The research was conducted in compliance with applicable regulations, and according to the principles of the Declaration of Helsinki. The pilot study was conducted in accordance with the respective government regulatory authorities and the local regional Institutional Review Boards for two study sites in Germany and the Netherlands (Protocol CSU2010-07D Freiburger Ethik Kommission—an independent Ethics Committee-28 June 2010). All patient data were fully anonymized to safeguard patient confidentiality. All materials and procedures complied with local and international health and safety standards and good clinical practices. This report is structured in alignment with the Consolidated Standards of Reporting Trials (CONSORT) [10].

### 3. Results

After obtaining informed consent and verifying that potential subjects met the inclusion/exclusion criteria, 30 patients (37 implants) were treated per protocol. Each patient received one or two TM implants in premolar or molar sites (Figure 2). The mean patient age was 45.5 years (range 19 to 73 years), and the majority of patients were female (63.3%). Twenty-nine of the 30 patients were White, one patient was Asian. The most common comorbidity was hypersensitivity reactions/allergies (40%), followed by hypertension/hypotension (30%). Most of the implants (70.3%) were placed in the mandible. Regarding bone density, most implants (62.2%) were placed in type 2 bone, with the remaining placed in type 3 bone. The most common (and smallest) implant diameter that was used was 4.7 mm (64.9%), and the most common length was 10 mm (45.9%). The majority of implants (91.9%) received a provisional restoration on the final abutment at the time of surgery (Table 1). There were no surgical complications across the study cohort.

**Table 1.** Patient Demographics and Surgical Information.

Demographic and Surgical Information	
Age, mean (SD), years	45.5 (15.1)
Female, n (%)	19 (63.3)
Most Common Comorbid Conditions, N (%)	
Hypersensitivity Reactions/Allergies	12 (40.0)
Blood Pressure Disorder (Hypertension or Hypotension)	9 (30.0)
Thyroid Disorders	5 (16.7)
Bone Density Classification * at Surgery, n (%)	
Type 2	23 (62.2)
Type 3	14 (37.8)
Final Insertion Torque, n (%)	
30–44 Ncm	8 (21.6)
45–59 Ncm	25 (67.6)
>60 Ncm	4 (10.8)
Provisional Restoration at Surgery, n (%)	
No	3 (8.1)
Yes	34 (91.9)
Implant Site, n (%)	
Posterior Maxilla	11 (29.7)
Posterior Mandible	26 (70.3)
TM Implant Diameter, n (%)	
4.7 mm	24 (64.9)
6.0 mm	13 (35.1)
TM Implant Length, n (%)	
10 mm	17 (45.9)
11.5 mm	13 (35.1)
13 mm	7 (18.9)

SD = standard deviation. \* Subjectively assessed by the clinician based on radiographic evaluations and tactile sensations during implant placement.

Radiographic evaluations of mean crestal bone levels over time (from baseline time of implant placement/provisional restoration to the 5-year follow-up evaluation) showed an initial bone loss of 0.40 mm in the first 6 months, after which there were no statistically significant changes in crestal bone level over time (Table 2). The mean crestal bone value levels changed minimally ( $\leq 0.05$  mm) from 6 months to any of the annual follow-up visits. Repeated Measures Analysis of Variance with Tukey Pairwise Comparison confirmed there is no statistical difference among the crestal bone level values of the 6-month and annual follow-up visits (details not shown). There was also no statistically significant difference in crestal bone level changes between those who had received 4.7 diameter versus 6 mm diameter implants (data not shown). Additionally, no implants were observed to have pain, mobility, or peri-implant radiolucency.

**Table 2.** Changes in Crestal Bone Levels Over the 5-Year Follow-Up Period.

Evaluation Timepoint	Crestal Bone Level	Mean $\pm$ SD Value in mm	<i>p</i> -Value <sup>1</sup>
Surgery/Provisional (N = 34)	Mean Bone Level	0.51 $\pm$ 0.49	
6 Months (N = 31)	Mean Bone Level Change from Provisional	-0.40 $\pm$ 0.48	<i>p</i> = 0.00
1 Year (N = 25)	Mean Bone Level Change from 6 Months	-0.05 $\pm$ 0.23	<i>p</i> = 0.28
2 Year (N = 25)	Mean Bone Level Change from 6 Months	-0.01 $\pm$ 0.34	<i>p</i> = 0.89
3 Year (N = 25)	Mean Bone Level Change from 6 Months	-0.03 $\pm$ 0.33	<i>p</i> = 0.69
4 Year (N = 22)	Mean Bone Level Change from 6 Months	-0.05 $\pm$ 0.36	<i>p</i> = 0.56
5 Year (N = 22)	Mean Bone Level Change from 6 Months	-0.01 $\pm$ 0.36	<i>p</i> = 0.85

<sup>1</sup> Analyses were conducted using a paired *t*-test. The study population for the bone loss value dataset had several missing values from follow-up visits, which is why there is a slight inconsistency in sample size between the crestal bone level dataset and the survival analysis dataset.

At the end of the 5-year follow-up period, 25 patients remained for evaluation (Table 3). The Kaplan-Meier cumulative survival rate of all implants in the study was 97.2% at the 3-month, 6-month, 1-year, 2-year, 3-year, 4-year, and 5-year evaluation visits; one implant failed to osseointegrate. The patient with a failed implant was a 46-year-old White male who had received a 6  $\times$  10 implant in a mandibular molar site. The implant was placed into type 2 bone without complications. The implant failed to integrate and was removed 30 days after the implant surgery. The patient took no concomitant medications (outside of post-surgical analgesics) and had no recorded comorbidities.

**Table 3.** Kaplan-Meier Survival Analysis: 5-Years of Follow-Up.

Month of Follow-Up	No. of Implants at Risk	No. of Failed Implants	Survival Estimate	95% CI Survival Estimate <sup>1</sup>
1 Month	37	0	1.000	(1.0000, 1.0000)
2 Month	36	1	0.9722	(0.8187, 0.9960)
3 Month	35	0	0.9722	(0.8187, 0.9960)
6 Month	35	0	0.9722	(0.8187, 0.9960)
12 Month	31	0	0.9722	(0.8187, 0.9960)
18 Month	30	0	0.9722	(0.8187, 0.9960)
24 Month	30	0	0.9722	(0.8187, 0.9960)
36 Month	28	0	0.9722	(0.8187, 0.9960)
48 Month	26	0	0.9722	(0.8187, 0.9960)
60 Month	25	0	0.9722	(0.8187, 0.9960)

<sup>1</sup> The Kaplan-Meier method was used to calculate cumulative implant survival. One implant failed within 2 months after loading.

There were no other failures. All 25 implants that completed 5-years of follow-up were surviving and clinically stable, with no indicators of pain, mobility, radiolucency, or clinically meaningful crestal bone loss.

#### 4. Discussion

The results from this descriptive pilot study of 37 implants showed that immediate provisional restoration (out of occlusion, with final restoration and loading within two weeks) of titanium dental implants with surfaces enhanced with PTTM were clinically effective, with a 5-year survival rate of 97.2%. As a comparison to non-TM systems, a recent systematic review and meta-analysis of 18 dental (non-TM) implant studies evaluated the 10-year survival of contemporary, two-piece titanium systems; the summary estimate for 10-year survival at the implant level was 96.4% (95% CI 95.2–97.5%) [11].

Professional consensus in dental implantology affirms that the success of implants is dependent on the presence and preservation of surrounding bone, particularly in the crestal area; however, a primary challenge of dental implant treatment is the bone resorption, particularly saucerization, that occurs after insertion [12]. Results from the present study showed an initial mean bone loss of 0.40 mm (SD = 0.48) after 6 months and minimal bone level changes over time up to 5 years in function. While the small sample size of this uncontrolled study limits direct comparisons to findings in other studies, these findings suggest that crestal bone loss around TM implants is lower than traditional titanium implant systems [13,14], and that the unique properties of PTTM may foster enhanced vital bone and surrounding tissue ingrowth and potentially reduce the amount of bone remodeling which occurs during the first year following implant surgery [15].

A recent 1-year retrospective case-control study by Edelmann et al. reported a 0.28-mm mean bone gain in a TM implant cohort, and multivariate logistic regression analysis demonstrated that the odds of having bone loss were 64% less in a TM group compared to a non-TM implant control group [16]. Another recent study by Bencharit et al. compared osteogenesis gene expression in a small group of patients who had received both TM and non-TM implants; the authors found that, compared to traditional titanium alloy, trephine samples from the TM implant group displayed higher expression of genes specific to neovascularization, growth factors, and osteogenesis [17].

To further contextualize these crestal bone level changes when compared to non-TM implants, contemporary literature was surveilled for studies with similar sample sizes and follow-up periods. An analysis by Payer et al. found that a cohort of 24 patients with 40 screw-type (non-TM) implants that were immediately provisionalized in molar and premolar sites experienced an overall survival rate of 95% at 5 years, with significant marginal bone loss (1.06 mm) in the first year [18].

To compare the crestal bone findings in this report with historical standards, longitudinal studies on the original Brånemark implant showed that one year after abutment connection, crestal bone loss frequently extended 1.5 mm to 2 mm below the implant-abutment junction [19]. This became the unofficial industry standard for acceptable crestal bone loss because most major implant systems experienced a similar bone loss phenomenon during the early years of their products. However, more contemporary implant surfaces typically include a rougher surface to foster better osseointegration, as improving the roughness of an implant surface has been correlated with less peri-implant bone loss [2]. Additionally, because the abutment was immediately placed with no intention of removal during the follow-up period, essentially the “one abutment/one-time” method was used in this study. The abutment was secured not only by the fixation screw, but also with a friction-fit connection. This type of “one-piece” implant has been shown to have less initial bone loss [20].

The TM implants used in this study have a PTTM shell that begins about 4.5 mm apical to the implant platform. A recent report by Fraser et al. compared osteogenic activity between titanium and TM-coated implants in a nonclinical study of rabbits. The authors reported higher vertical bone growth around TM implants compared to titanium implants,

and increased activity in upregulation of key osteogenic genes. Furthermore, TM implants had greater bone-implant contact at 4, 8, and 12 weeks and significantly greater removal torque at 8 and 12 weeks [21]. It is not yet fully known how the TM shell impacts peri-implant bone healing and remodeling at the cervical aspect, though the current study shows promising results. The current clinical pilot study showed no statistically significant bone loss after the initial healing, which may in part be due to the high porosity and modulus of elasticity of the TM surface, which has similar properties to human cancellous bone. Prior studies have shown that these surface properties facilitate bone ingrowth and increased regions of bone-to-implant contact, potentially reducing stress on the coronal aspect of the implant due to rapid ingrowth of bone in the TM shell, though further confirmatory research with larger sample sizes is needed [1,3,5]. Taken together, these promising findings of increased osteogenesis indicators and crestal bone stability around TM implants warrant further study with larger study populations.

In this study, TM dental implants were clinically effective when fully loaded within two weeks in a small population with a variety of health risk factors that may be typically encountered in routine clinical practice.

#### *Limitations*

Patients were followed for 5 years post-restoration; during that interval, the number of evaluable implants went from 37 to 25, an attrition rate of 32%. This is an unfortunate challenge when obtaining long-term survival data, and may lead to a bias in the results [10]. Although the study investigators were aware of several patients moving away from the study site area, the reasons for other patients being lost-to-follow-up was unknown, as were their outcomes, which could potentially bias the study results and conclusions.

Additionally, because implants in this study were only placed in type 2 and 3 bone, the clinical response to TM implants in other bone types is unknown, possibly reducing the generalizability of the results.

#### **5. Conclusions**

Immediate provisional restoration (with final restoration within two weeks) of titanium dental implants with surfaces enhanced with PTTM were clinically effective in a small study population, with a 5-year survival rate of 97.2% and minimal crestal bone loss. These findings of potentially increased osteogenesis indicators and crestal bone stability around TM implants warrant further study with larger study populations.

**Author Contributions:** Conceptualization, P.v.d.S., M.S. and H.-B.W.; methodology, P.v.d.S., M.S. and H.-B.W.; investigation, P.v.d.S. and M.S.; data curation, P.v.d.S. and M.S.; writing—original draft preparation, P.v.d.S., M.S. and H.-B.W.; writing—review and editing, P.v.d.S., M.S. and H.-B.W.; project administration, P.v.d.S. and M.S. All authors have read and agreed to the published version of the manuscript.

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**Institutional Review Board Statement:** The study was conducted in accordance with the Declaration of Helsinki and approved by an independent Ethics Committee (Freiburger Ethik Kommission) for two study sites in Germany and the Netherlands (Protocol CSU2010-07D, 28 June 2010).

**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** The data presented in this study are not publicly available but can be requested from the corresponding author.

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