Immediate Loading of Trabecular Metal-Enhanced Titanium Dental Implants: Interim Results from an International Proof-of-Principle Study

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[Correction added on August 12, 2013, after first online publication: Author first name Armvander corrected to Alexandra]

ABSTRACT

Objectives: A 3-year proof-of-principle study was initiated to evaluate the clinical efficacy of immediately loading titanium dental implants with surfaces enhanced with porous tantalum trabecular metal (PTTM). First-year interim results are presented.

Materials and Methods: Healthy, partially edentulous patients ($n = 30$) were enrolled and treated per protocol (minimum insertion torque: ≥35 Ncm) with 37 implants placed in one or two premolar or molar locations in either jaw (study group). Implants were immediately provisionalized out of occlusion with single acrylic crowns. After 7 to 14 days of soft tissue healing, implants were definitively restored in occlusion with ceramometal crowns. Because most study group implants (54.1%, $n = 20$) had less than 1 year of clinical follow-up, this interim analysis was limited to the first 22 consecutively placed implants in 17 subjects (10 women and 7 men) who completed 1 year of clinical follow-up to date (focus group).

Results: To date, one implant failed to integrate in the study group (survival = 97.3%, $n = 36/37$). Focus group implants achieved 100% ($n = 22/22$) survival with 0.43 ± 0.41 mm of mean marginal bone loss. There were no serious complications.

Conclusion: Early clinical findings indicated that immediate loading of PTTM implants was safe and effective under the controlled study conditions.

KEY WORDS: bone ingrowth, osseoincorporation, porous tantalum, trabecular metal

INTRODUCTION

A variety of porous coatings developed to enhance the integration of orthopedic implants[1,2] have been adapted for dental implant use.[1,3,4] The degree of achievable bone ingrowth has greatly varied, however, according to the porosity, pore size, and thickness of the coatings.[1,5–9] While a pore size of 100 µm is conducive for bone ingrowth,[7] 150 µm pores are needed for osteon formation inside a porous material,[8] and pores greater than 300 µm are required to support vascularized bone ingrowth.[9] Because pore sizes tended to be irregular and porosity extremely limited in applied surface coatings, orthopedic researchers took a biomimetic approach in developing a highly porous tantalum trabecular material (PTTM) (Trabecular Metal Material, Zimmer TMT, Parsippany, NJ, USA) that simulated the trabecular structure[10–17] and more closely approximated the elastic modulus (2.5–3.9 GPa) of both cancellous (6.8 GPa) and cortical (13–17 GPa) bone than the titanium (106–115 GPa), cobalt chromium (210 GPa), or stainless steel (230 GPa) surgical metals used for orthopedic implants.[17–19]

PTTM is fabricated by coating a vitreous carbon skeleton (~2%) with elemental tantalum (~98%) through a chemical vapor deposition process.[10,11,13] The finished material is a nanotextured, osteoconductive framework[20] that forms a network of interconnected pores in highly regular sizes (~440 µm) and shapes.[13,14,21] PTTM has been applied to titanium alloy orthopedic

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implants and used for hip, knee, and spine reconstructions since 1997.[12–14,16–18] The biocompatibility and corrosion resistance of the three combined biomaterials (titanium, vitreous carbon, tantalum) used in the implant design have been extensively documented[22–24] and clinically evaluated through corrosion testing and more than 15 years of orthopedic implant use. In dentistry, each of these materials has also been used individually in various dental implant designs.[22–25] Based on the extensive clinical use of PTTM in orthopedics, a titanium alloy dental implant with a PTTM midsection (Trabecular Metal Dental Implant, Zimmer Dental Inc., Carlsbad, CA, USA) (Figure 1) was developed to achieve biologic anchorage through osseoincorporation,[26] a combination of osseointegration (bone ongrowth) and bone ingrowth into the PTTM material.

Building on earlier reports[27,28] that bone fused directly to titanium, Brånemark and colleagues[29] researched and documented the processes for predictably achieving and maintaining osseointegration in the dental environment. During the 1980s and much of the 1990s, Brånemark's[29] experimental two-stage surgical protocol was deemed axiomatic for achieving and maintaining osseointegration. Historically, however, immediate implant loading with or without initial occlusal contacts had been used with varying success rates by several root-form dental implant systems since 1939.[30–35] With continued evolution in implant designs and surgical techniques, renewed interest in immediate and early implant loading has arisen in recent years. It was unknown, however, if the initial stability and design of the new PTTM dental implant could effectively withstand the clinical demands of immediate loading.

With reported long-term survival rates of 90% or greater already documented for conventionally osseointegrated implants,[36–38] the question arises as to what clinical advantages osseoincorporation may provide. Although the present proof-of-principle (PoP) study cannot answer the question because of its small size and the short duration of this interim clinical follow-up, prior studies[18,38,39] of PTTM can help to answer the question. First, the trabecular structure of PTTM-enhanced dental implants can improve osseointegration by increasing the area of bone-to-implant contact in a three-dimensional manner that mimics the natural osseous structure.[26,39] In preclinical research on PTTM, two studies documented bone growth inside the porous tantalum structures.[18,40,41]

Figure 1 Example of the study implant with a porous tantalum trabecular metal midsection and textured cervical microgrooves.

In the first study, porous tantalum cylinders were implanted, and subsequent histologic and mechanical testing was performed at follow-up intervals in a transcortical canine model.[18,40] In samples that had an average pore size of 430 μm, new bone occupied 42% of the pores at 4 weeks, 63% at 16 weeks, and 80% at 1 year.[18,40] Histologic examination revealed increasing regions of bone-implant contact over time and evidence of haversian remodeling inside the porous material.[18,40] Mechanical testing demonstrated minimum shear fixation strength of 18.5 MPa at 4 weeks, significantly higher ($p = .004$) than that of sintered beads and several other

porous metals (9.3–12.1 MPa).[18,40] This increase in shear strength was attributed to the greater porosity of the porous tantalum cylinders compared with other porous surfaces, which led to a higher volume of bone occupying the pores for any given percentage filled.[18,40] The study concluded that porous tantalum is an effective scaffold for relatively complete osseoincorporation, with new bone ingrowth by 16 weeks and little change after 1 year in dogs.[18,40]

In the second preclinical study, 22 cementless PTTM components were studied in a canine model for a period of 6 months.[18,41] Stable bone-implant interfaces were detected histologically and radiographically and when examined by electron microscopy.[18,41] The depth of ingrowth ranged from 0.2 to 2.0 mm and was found in all 22 components.[18,41] The mean bone ingrowth for all sections was 16.8%, whereas the periphery averaged 25.1%.[18,41]

Positive outcomes have been generally reported for immediate loading of dental implants in selected patients.[42–44] For such cases, clinical implant stability is essential at the time of loading to prevent micromovements that could inhibit osseointegration and result in fibrous tissue interface encapsulation of the implant.[45,46] The patient's bone density,[47] the clinician's surgical technique,[48–50] and the implant's insertion torque,[50,51] macro design,[48,50,51] and surface texture[47,48] have all been reported to directly affect implant micromotion and survival rates.[47–51] Because the external threads were removed from the midsection of the PTTM implant design, it was unknown if the implant could achieve adequate clinical stability for immediate loading.

This paper reports on the 1-year interim results of a 3-year international PoP study that evaluated immediate loading of PTTM dental implants in humans.

MATERIALS AND METHODS

The PoP 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. All materials and procedures complied with local and international health and safety standards and good clinical practices and adhered to the patient privacy rules of the US Health Insurance Portability and Accountability Act of 1996. The study was open to all qualifying patients who met specific inclusion criteria (Table 1) and were deemed as suitable study participants according to the professional judgments of the treating clinicians. Patients were

TABLE 1 Patient Selection Criteria

Inclusion	Male or female at least 18 years of age
	Ability to understand what is involved in the study, including follow-up visits requirements
	Benefit from the implant prosthesis
	Adequate bone volume to support an implant without additional augmentation
	Residual facial and palatal/lingual plates at least 1.5 mm thick after osteotomy preparation
	Vertical bone volume to extend at least 2.0 mm apical to the implant after implant placement
	Healed extraction site
	Insertion torque of ≥35 Ncm for immediate loading
Exclusion	Subjects with bruxism or clenching parafunctional habits
	Fresh extraction sites
	Grafted sites with <6 months of healing by the implantation date
	Smokers
	Sites with a previously failed dental implant
	A history of mental instability that could hinder participation in the study
	Uncontrolled systemic disease (e.g., uncontrolled diabetes)
	Severely compromised immune system
	Untreated oral pathologies
	Pregnancy
	Bleeding disorder or use of anticoagulants
	Use of bisphosphonates
	Other conditions the investigator may feel would inhibit the patient from being a good candidate for this study

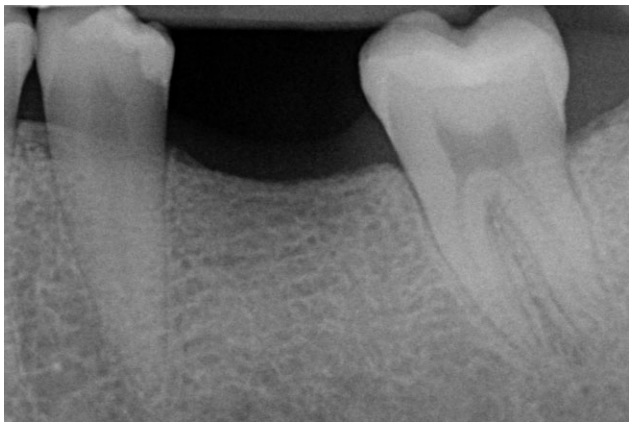

Figure 2 Preoperative: radiograph of a missing mandibular left first molar.

enrolled after providing signed informed consent in accordance with the World Medical Association's Declaration of Helsinki.[52]

Study Design

The original study design was to clinically evaluate immediately loaded PTTM dental implants during 6 months of clinical function in a controlled population; however, the research protocol was later amended to extend the study through 3 years of clinical monitoring. Study candidates were limited to healthy, partially edentulous subjects with at least 6 months of healing after tooth extraction or bone grafting (Figures 2 and 3). An implant insertion torque value of 35 Ncm or greater was deemed as adequate primary stability for immediate loading based on the findings of earlier studies.[53–55] Patients with type 4[56] bone and/or implants with <35 Ncm of insertion torque were excluded from the study. After 6, 12, 24, and 36 months of functioning, subjects were reappointed for evaluation. Study end points included implant survival rates, changes in marginal bone levels on standardized periapical radiographs evaluated by an independent clinician, and changes in oral health[57–59] indices. At all monitoring appointments, subjects completed a patient questionnaire to assess their functional, psychological, emotional, and esthetic satisfaction with treatment.

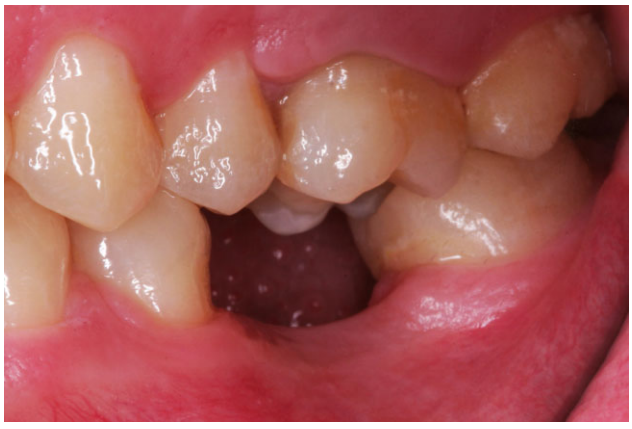

Figure 3 Preoperative: clinical view of the edentulous space.

Clinical Procedures

Implants smaller than 4.7 mm in diameter were not yet released for clinical use at the time of surgeries, so implant placement was limited to mandibular and maxillary first premolar to second molar jaw locations bilaterally. It was felt that ridge widths in those areas could accommodate the 4.7 or 6.0 mm–diameter implants available at the time without compromising the required 1.5 mm of residual facial and lingual/palatal ridge widths after osteotomy preparation. Each subject was treated with one or two implants based on the patient's clinical needs. At the time of surgery, the subject was administered anesthesia and one dose of oral prophylactic antibiotics, either clindamycin (Pharmacia & Upjohn, Bridgewater, NJ, USA) (600 mg one tablet) or amoxicillin (GlaxoSmithKline, Brentford, UK) (2 or 3 g one tablet), prior to dental implant placement. Further antibiotic treatment was not indicated unless other medical conditions or the presence of infection required further antibiotic treatment. Implants were placed according to the protocol provided by the manufacturer and utilized a one-stage (nonsubmerged) surgical protocol. Implant insertion torque, measured in newton-centimeters (Ncm), and resonance frequency analysis (RFA) values, measured in the unit's (Osstell ISQ, Osstell AB, Göteborg, Sweden) proprietary implant stability quotient (ISQ) were recorded at implant placement.

Within 48 hours of implant placement, an abutment was attached to the implant, and a nonoccluding provisional prosthesis was luted to the abutment with temporary cement (TempBond, Kerr Corp., Orange, CA, USA, or Premier Implant Cement, Plymouth Meeting, PA, USA). Excess cement was carefully removed along the crown margins, and the soft tissues were sutured around the provisional restoration (Figure 4). Investigators prescribed routine analgesics according to their professional judgments. The

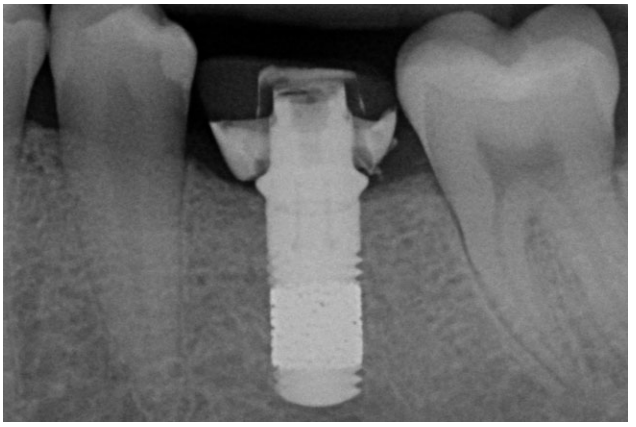

Figure 4 Postoperative (within 48 hours): radiograph of the provisional prosthesis in place.

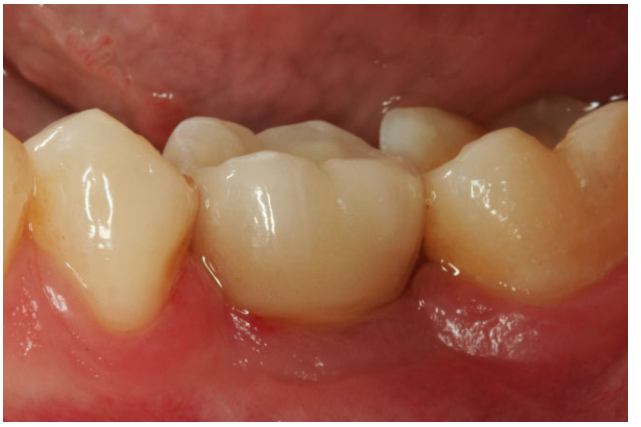

Figure 6 Postoperative (2 weeks): clinical view of the definitive restoration in place.

provisional prosthesis was in place for approximately 7 to 14 days to allow adequate time for soft tissue healing, then the provisional prosthesis and sutures were removed. If there was no change in provisional and definitive abutments (i.e., "one abutment, one time" technique) and if the implant appeared clinically stable, a definitive prosthesis was luted onto the final abutment (Durelon, 3M ESPE, St. Paul, MN, USA, or Premier Implant Cement) and the restoration was placed in occlusion. For other subjects, the provisional abutment was removed, and implant stability was evaluated both clinically and with RFA. The definitive abutment (Figure 5) and prosthesis were then similarly delivered in occlusion (Figures 6 and 7). Final occlusal adjustments were made. Subjects were reappointed at 1, 3, and 6 months, and again at 1, 2, and 3 years for clinical monitoring and annual hygiene prophylaxis (Figures 8–12).

Calculation of Bone Levels

After initial patient evaluations, standardized (Rinn, Dentsply, York, PA, USA) periapical radiographs were

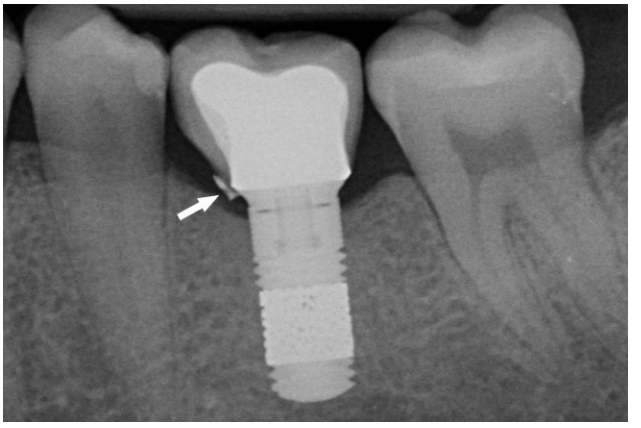

Figure 7 Postoperative (2 weeks): radiographic view of the definitive restoration in place. Note the cement fragment (*arrow*), which was subsequently removed.

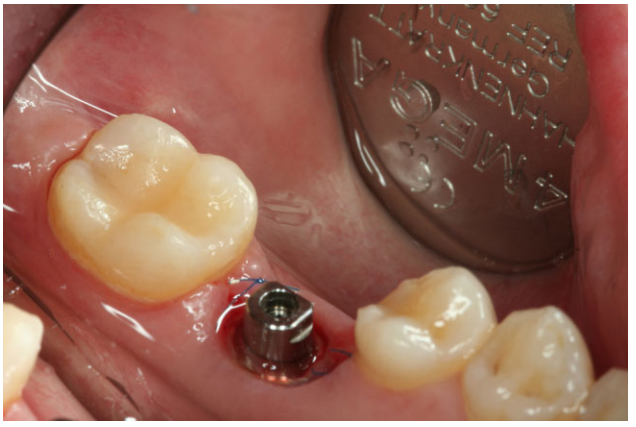

Figure 5 Postoperative (within 7–14 days): clinical view of the definitive abutment in place at suture removal.

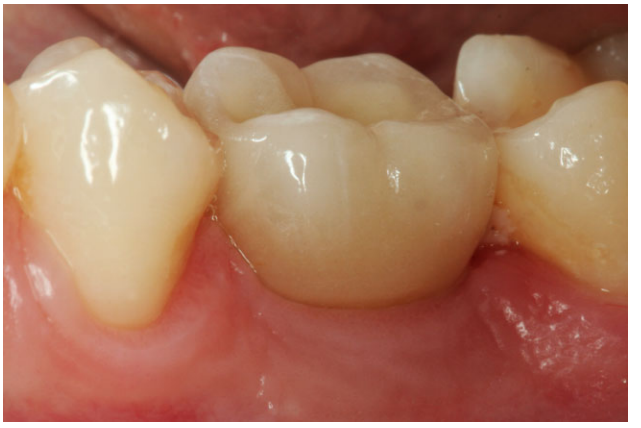

Figure 8 Postoperative (1 month): definitive restoration shows no change in the gingival margin.

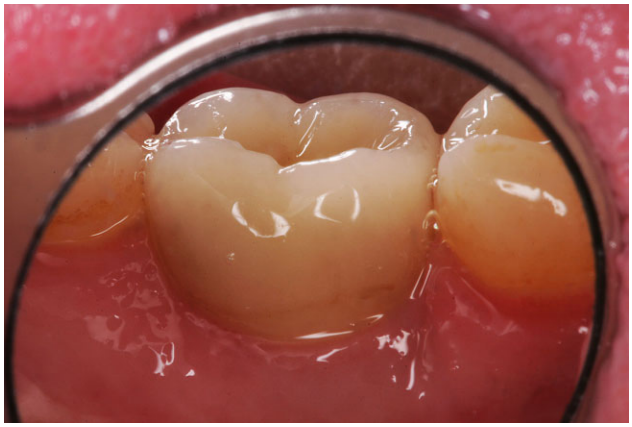

Figure 9 Postoperative (1 month): lingual view of the definitive restoration.

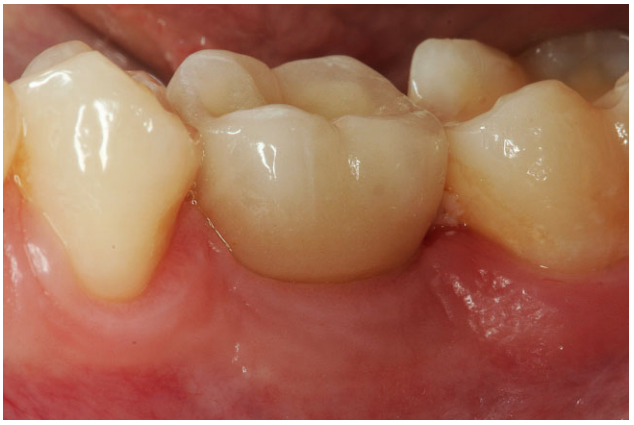

Figure 11 Postoperative (1 year): clinical view shows stable gingival margins and healthy tissue.

taken for each implant at provisionalization (baseline) and after 6, 12, 24, and 36 months of functioning. All periapical radiographs were provided to an independent radiologist in high-resolution (minimum 300 dpi) JPEG format. Each image was opened using US Food and Drug Administration – cleared image analysis software (OsiriX MD, Pixmeo SARL, Bernex, Switzerland) in a personal computer (Apple Mac Pro, Apple Inc., Cupertino, CA, USA). Bone levels were measured by calculating the distance from the implant shoulder to the first bone-to-implant contact. Both mesial and distal measurements were made on each periapical radiograph. 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. Measurement data were entered into a digital spreadsheet (Excel, Microsoft Corp., Redmond, WA, USA). Saved screen captures with the measurements were pasted into digital documents (Word, Microsoft Corp.) and saved as source documents for the study.

Statistical Analysis

Descriptive statistics (*N*, %, mean ± SD, *N*, min, max, median) were used to summarize the data. Changes in crestal bone levels were summarized at the patient level

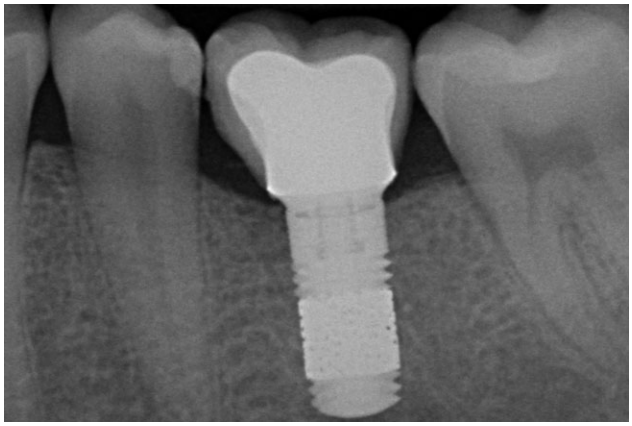

Figure 10 Postoperative (6 months): radiograph shows little or no change in marginal bone levels.

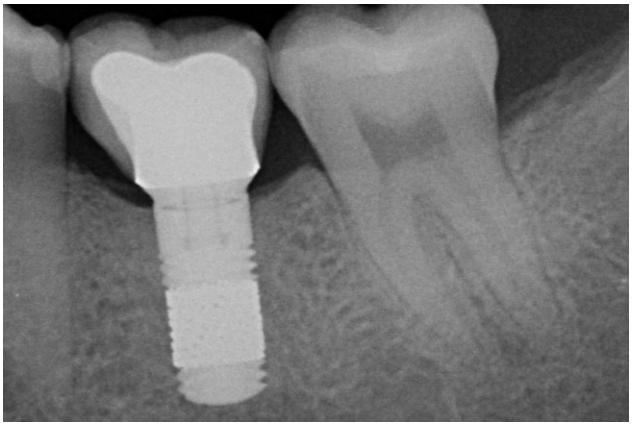

Figure 12 Postoperative (1 year): radiograph shows stable crestal bone levels.

by averaging distal and mesial measurements and then averaging across different implants at the patient level. Patient satisfaction surveys were summarized as continuous variables. The primary null hypothesis, H_0: $P_e - P_c \leq -0.65$ and H_1: $P_e - P_c > -0.65$, where P_e is the survival rate of PTTM implants and P_c is the survival rate of historical control implants,[60] was tested. The secondary hypothesis, H_0: $\mu_e = \mu_c$ and H_1: $\mu_e < \mu_c$, where μ_e is the mean marginal bone loss amount of PTTM implants and μ_c is the mean marginal bone loss amount of historical control implants,[60] was tested.

RESULTS

The final study group consisted of 30 subjects who were treated per protocol with 37 implants. Within this initial group, one implant failed to osseointegrate, which resulted in a 97.3% ($n = 36/37$) cumulative implant survival rate to date; however, the majority of these implants (54.1%, $n = 20$) currently had less than 1 year of clinical follow-up. For this reason, the present interim evaluation was limited to the first consecutive 17 subjects (10 women, seven men) in the study who completed the first year of clinical follow-up. Patient and treatment data are summarized in Table 2. Nine (52.9%) of these subjects reported eight medical conditions as part of their health histories: hypertension ($n = 3$), unspecified thyroid disease ($n = 3$), allergies ($n = 3$), halitosis ($n = 1$), osteoarthritis ($n = 1$), unspecified circulatory system disease ($n = 1$), deep periodontal pockets ($n = 1$), and unspecified gastric problems ($n = 1$). Fifteen subjects (88.2%) were taking 10 categories of concomitant medications: antibiotic ($n = 20$), analgesic ($n = 8$), antihypertensive ($n = 6$), anti-inflammatory ($n = 6$), antilipid ($n = 4$), thyroid

TABLE 2 Patient Demographics and Treatment Summary

Patients	Age (Years)	Mean ± SD	46.6 ± 16.4
		Range	19–73
	Sex	Male	7
		Female	10
Implants	Diameters	4.7 mm (N)	13
		6.7 mm (N)	9
	Lengths	10 mm (N)	13
		11.5 mm (N)	7
		13 mm (N)	2
	Surfaces	Cervical collar	Machined
		Implant body (Ti-6Al-4V)	Microtextured
		Implant body (TM)	Nanotextured
Treatment sites	Maxillary locations	First premolar (N)	2
		Second premolar (N)	2
		First molar (N)	1
	Mandibular locations	First premolar (N)	1
		Second premolar (N)	1
		First molar (N)	10
		Second molar (N)	5
	Bone density classification[57] by implant site*	Type II (N)	18
		Type III (N)	4
	Residual plate thickness after osteotomy preparation (mm)	Facial plate (Mean ± SD)	1.6 ± 0.2
		(Range)	1.5–2.0
		Lingual plate (Mean ± SD)	1.6 ± 0.2
		(Range)	1.5–2.0
	Final implant insertion torque	35–44 Ncm	5
		45–59 Ncm	16
		>60 Ncm	1

*Subjectively assessed by the clinician based on radiographic evaluations and tactile sensations during implant placement.

hormone ($n = 3$), antiplaque ($n = 2$), anticoagulant ($n = 1$), psychotropic ($n = 1$), and antacid ($n = 1$).

There were 61 protocol procedural violations but no significant device-related violations: appointment outside of the designated time frame ($n = 37$), minor documentation error ($n = 22$), and missed intermediate follow-up appointment ($n = 2$). Patients reported mild levels of pain from implant surgery through the first month of functioning with the definitive prosthesis, then an absence of pain until the 1-year follow-up, when one subject reported mild pain.

A total of 34 adverse events were reported in 11 patients, three of which were reported as being of uncertain relationship to the implant: one patient with excessive generalized crestal bone loss (>1.0 mm) that stabilized after adjusting the prosthesis, one case of mild patient-induced pain after biting hard on the implant, and one case of mesial bone loss that stabilized after adjusting the prosthesis (Table 3). Two adverse events were reported as being probably related to the implant: one case of bleeding attributed to iatrogenic causes and one case of abutment loosening that was resolved by retightening the abutment screw (see Table 3). The remaining 29 adverse event reports (85.29%) were listed as being not directly related to the implant (see Table 3). Most (76.47%, $n = 26$) of these adverse events were concentrated in four subjects (AAX120, AAS118, AAA101, and AAO114). The first subject (AAX120) had 10 adverse events: cement failure, which necessitated crown recementation (Durelon, 3M ESPE) once in the maxillary right first premolar and twice in the mandibular left first molar locations; one abutment screw that loosened and had to be retightened; one case of allergic reaction unrelated to the implant; one report of pain caused by food impaction around a crown with an inadequate emergence profile; pain in the maxillary left first premolar tooth caused by a systemic condition; and single episodes of pain were reported in both the mandibular left second molar and mandibular right first molar teeth, both of which were unrelated to the study implants.

The second subject (AAS118) had nine adverse event reports: the maxillary right first molar implants had two reports of bone loss and one report of pain after the patient chewed on hard substances; the maxillary right first molar implant had two reports of the loose crowns being swallowed by the patient, one case of excess cement that was removed, and one episode of abutment loosening; a crown fractured in the mandibular left first molar area; and the maxillary first premolar tooth exhibited pain unrelated to the implants.

TABLE 3 Summary of Adverse Events

Category	Description	*N* (%)
Type	Prosthetic complication	20 (58.82)
	Nonprosthetic complication	9 (26.47)
	Allergic reaction not related to the implant	1 (2.94)
	Infection	1 (2.94)
	Soft tissue dehiscence	1 (2.94)
	Fractured prosthesis	1 (2.94)
	Loose abutment	1 (2.94)
Cause	Unknown	20 (58.82)
	Patient induced	5 (14.71)
	Iatrogenic	3 (8.82)
	Systemic	3 (8.82)
	Residual tooth root	1 (2.94)
	None listed	2 (5.88)
Intensity	Mild	29 (85.29)
	Moderate	5 (14.71)
Relationship to the implant	Not related	29 (85.29)
	Uncertain	3 (8.82)
	Probably related	2 (5.88)
Treatment	Prosthodontic treatment	19 (55.88)
	Nonprosthodontic treatment	8 (23.53)
	Repaired prosthesis	4 (11.76)
	Oral hygiene prophylaxis	1 (2.94)
	Tightened abutment screw	1 (2.94)
	Tightened prosthesis screw	1 (2.94)
Outcome	Resolved	21 (61.76)
	Tolerated	9 (26.47)
	Ongoing	4 (11.76)

The third subject (AAA101) had five adverse events associated with the mandibular left second molar implant: one report of crown loosening, one case of bleeding attributed to iatrogenic causes, one report of a crown defect, one case of crown chipping, and one report of proximal food impaction that was attributed to iatrogenic causes. The fourth subject (AAO114) had two reports of pain caused by food impaction around the mandibular right first molar implant.

Three adverse events were reported as being of uncertain relationship to the implant: one patient with excessive generalized crestal bone loss (>1.0 mm) stabilized after adjusting the prosthesis, one case of mild patient-induced pain after biting hard on the implant, and one case of mesial bone loss that stabilized after

TABLE 4 Periodontal Health Indices

		Final Restoration		6 Months		1 Year	
Metric	Score	*N*	%	*N*	%	*N*	%
Plaque Index[58]*	0	20	90.91	19	86.36	19	86.36
	1	0	0.00	3	13.64	0	0.00
	2	2	9.09	0	0.00	3	13.64
	3	0	0.00	0	0.00	0	0.00
Gingival Index[59]†	0	20	90.91	21	95.45	17	77.27
	1	2	9.09	1	4.55	4	18.18
	2	0	0.00	0	0.00	1	4.55
	3	0	0.00	0	0.00	0	0.00

*0 = no plaque; 1 = a film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface; 2 = moderate accumulation of soft deposits within the gingival pocket or on the tooth and gingival margin that can be seen with the naked eye; and 3 = abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

†0 = absence of inflammation; 1 = mild inflammation; slight change in color and little change in texture; 2 = moderate inflammation; moderate glazing redness edema and hypertrophy; bleeding on pressure; and 3 = severe inflammation; marked redness and hypertrophy; tendency toward spontaneous bleeding; ulceration.

adjusting the prosthesis (see Table 3). Two adverse events were reported as being probably related to the implant: one case of bleeding attributed to iatrogenic causes and one case of abutment loosening that was resolved by retightening the abutment screw (see Table 3).

There were few serious periodontal health issues (Table 4) and no reports of peri-implant radiolucency or damage to the hard or soft tissues. All implants remained stable, with mean ISQ values of 76.86 ± 7.71 (range = 48–83) at surgery ($n = 22$) and 78.94 ± 3.91 (range = 69–83) at definitive restoration ($n = 17$). In the focus group, implant survival was 100% ($n = 22/22$) and mean crestal bone loss from immediate provisionalization to the 1-year follow-up was 0.43 ± 0.41 mm (Table 5). In comparison, the historical control study[60] that used the same protocol with fully threaded implants reported 98.04% ($n = 50/51$) implant survival and 1.05 mm (range = 0.38–2.69 mm) ($n = 50$) of mean cumulative bone loss.

DISCUSSION

Mean implant bone loss rates were 0.43 ± 0.41 mm for PTTM implants ($n = 36$) in the present PoP study and 0.98 ± 0.67 mm for the fully threaded implants ($n = 50$) in the historical control study.[60] Based on these data, a p value of <.001 was obtained by the Satterthwaite t-test. Thus, the null hypothesis was rejected at a .05 significance level, and it was claimed that the mean marginal bone loss amount of PTTM implants was significantly less than the mean marginal bone loss amount of the historical control[60] implants. A 95% two-sided confidence interval for the difference in mean marginal bone loss amounts between fully threaded implants in the historical control study[60] and PTTM implants in the present PoP study were estimated as (0.3176, 0.7824).

The single implant failure to date in the full PoP study database was a failure to integrate, which occurred from unknown causes in a subject who took no concomitant medications and who had no history of medical or dental risk factors for implant failure. This finding underscores the fact that dental implant failure is often a complex, multifactorial process that cannot always be explained by empirical clinical factors, such as smoking, aging, systemic diseases, or peri-implantitis.[61] In contrast, there were no implant failures in the present analysis of the first 37 implants in 17 patients with at least 1 year of clinical follow-up, despite patient histories of deep periodontal pockets (≥4 mm) and/or use of concomitant medications. The immediately loaded implant-supported restorations in the present study remained clinically stable and continued to function after 1 year of service.

In comparative animal studies, researchers[62–64] have reported that immediately loaded dental implants developed significantly denser peri-implant bone than implants subjected to delayed loading. A limitation in the present human study was that use of the historical

TABLE 5 Crestal Bone Response (mm)

Interval	*N*	Measurement Location		Mean ± SD	Range
Provisional	22	Baseline bone level*	Mesial	0.51 ± 0.54	0.06–1.9
			Distal	0.64 ± 0.67	0.04–2.4
			Average (mesial + distal)	0.58 ± 0.58	0.09–1.87
6 months	21	Mesial	Bone level*	0.82 ± 0.37	0.15–1.58
			Change from provisional	0.3 ± 0.51	−1.08–1.18
	22	Distal	Bone level*	0.92 ± 0.5	0.26–2.53
			Change from provisional	0.29 ± 0.45	−0.9–0.94
	21	Average	Bone level*	0.88 ± 0.36	0.25–1.69
			Change from provisional	0.29 ± 0.45	−0.99–1.0
1 year	20	Mesial	Bone level*	0.86 ± 0.36	0.19–1.46
			Change from provisional	0.37 ± 0.54	−1.14–1.18
			Change from 6 months	0.04 ± 0.31	−0.79–0.78
	19	Distal	Bone level*	0.95 ± 0.39	0.39–1.72
			Change from provisional	0.41 ± 0.44	−0.68–1.03
			Change from 6 months	0.07 ± 0.29	−0.81–0.5
	19	Average	Bone level*	0.91 ± 0.34	0.29–1.59
			Change from provisional	0.43 ± 0.41	−0.51–1.1
			Change from 6 months	0.06 ± 0.25	−0.47–0.67

*Measured from a common reference point on the implant to the point of first bone contact with the implant surface.

control[60] precluded any direct radiographic comparisons with implants subjected to delayed loading. Thus, the question of how bone ingrowth into the porous PTTM material may affect the density of the periimplant bone could not be answered by the present data.

The study implants differed from the historical control[60] implants by a lack of threads in the midsection of the implant where the PTTM material was placed and the addition of circumferential microgrooves and microtexturing in the cervical region of the implant that extended to within 0.5 mm of the coronal platform. In comparison, implants in the historical control study[60] were fully threaded with traditional machined (turned) surfaces and no microgrooves in their cervical regions. The clinical efficacy of milled cervical microgrooves and microthreads on marginal bone preservation has been debated in the literature.[68–70] In a randomized clinical trial, Tan and colleagues[68] reported that implant collars with 1 mm of microtextured surface maintained significantly higher bone levels than implant collars without microtextured surfaces. In another randomized clinical study, den Hartog and colleagues[69] reported that implants with microgrooves preserved significantly more crestal bone than implants with machined surfaces. In a systematic review of the literature, however, Bateli and Strub[70] found that the current literature provides insufficient evidence about the effectiveness of different implant neck configurations in the preservation of marginal bone. The authors[70] concluded that more long-term randomized controlled studies are needed to elucidate the effects of such modifications.

Immediately after implant placement and immediately before delivery of the definitive restoration, RFA was conducted, and implant stability was recorded in ISQ values (Osstell ISQ, Osstell AB), which ranged from 1 (least stable) to 100 (most stable). Mean ISQ values recorded at surgery (76.86 ± 7.71, range = 48–83) ($n = 22$) and at provisional restoration (78.94 ± 3.91, range = 69–83) ($n = 17$) in the present study fell within the range of implant stability (55–80 ISQ) (Osstell ISQ, Osstell AB) deemed by some clinicians[65] as acceptable for immediate loading. High initial ISQ values (Osstell ISQ, Osstell AB) of 70 and above tend to not increase in measureable stability over time but may experience a small drop in stability 2 to 3 weeks postimplantation, and then level out over time.[65] In contrast, lower initial ISQ values (Osstell ISQ, Osstell AB) at implant placement have been reported to normally increase during bone remodeling processes.[65] Because the implants in the present study were definitively restored within 14

days of implant placement, ISQ values (Osstell ISQ, Osstell AB) could not be recorded beyond that time to determine if PTTM implants experienced a similar drop[66,67] and leveling out of ISQ values 2 to 3 weeks after implant placement.

While the small number of cases in this 1-year interim report may reduce the weighted value of the clinical findings, results suggest that the biocompatibility, similarity to cancellous bone in porous structure and mechanical properties, and the ability to achieve vital bone and blood vessel ingrowth may provide PTTM-enhanced titanium dental implants with a good prognosis for long-term clinical predictability. Larger, long-term, clinical studies will help to better elucidate the clinical characteristics of this new treatment modality.

Within the parameters of the present study, it is concluded that Trabecular Metal Dental Implants (Zimmer Dental Inc.) may be immediately loaded out of occlusion in selected patients and definitively loaded in occlusion after 7 to 14 days of soft tissue healing.

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