# European Multicenter Studies of a Porous Tantalum-Titanium Implant: One-Year Interim Results

**Markus Schlee, DDS, DMD,[1] Peter van der Schoor, DDS,[2] Hai Bo Wen, PhD,[3] Shilpa Kottalgi, BDS, MS,[3] Martin Dinkel, PhD[3]**

[1]Private Practice, Forchheim, Germany; [2]Private Practice, Garderen, the Netherlands; [3]Zimmer Dental Inc., Carlsbad, CA, USA

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## 1 Background

For nearly half a century, numerous attempts have been made to augment osseointegration through changes in implant design and surface modifications. Recently, a combination titanium and tantalum dental implant was developed by replacing the medial threads of a conventional tapered endosseous implant design with highly porous tantalum midsection (Figure 1A). The tantalum material simulates the structure and elasticity of trabecular bone and its open network of pores enables vascularized bone formation inside the material.[1,2] This paper reports the preliminary 1-year follow-up results from two prospective multicenter clinical studies.

## 2 Objectives and Study Design

Both studies are conducted under the auspices of the local institutional review board of each country, and have enrolled subjects with partially edentulous posterior jaw(s). Each patient was treated with up to two Trabecular Metal™ (TM) dental implants.

**Immediate loading study** (**IL Study**): The primary study objective was to clinically evaluate immediately loaded implants over 3 years of clinical function in a controlled population enrolled in 2 clinical sites. Study subjects were healthy with sufficient bone volume and whose implants achieved an insertion torque value of 35 Ncm or greater. Smokers and Type IV bone[3] cases were excluded. Within 48 hours of placement, implants were provisionalized out of occlusion with definitive abutments. Definitive restorations in occlusion were delivered within 2 weeks of implant placement.

**Longitudinal Data Collection Program** (**LDCP Study**): In this prospective observational 5-year study, investigators in 23 clinical sites were required to follow the implant's Instructions for Use (IFU), but use their own clinical judgment in patient selection and treatment. The LDCP was designed to evaluate the clinical outcomes of implants placed in a normal, uncontrolled population that presented in routine clinical practices.

**Table 1.** Summary of patient demographics, implant size, collar design and location, and bone density classifications.

| | | IL | LDCP |
|---|---|---|---|
| **Age (years)** | *Average* | 45.47 | 54.76 |
| | *Minimum* | 19 | 20 |
| | *Maximum* | 73 | 81 |
| **Gender** | *Male* | 11 | 51 |
| | *Female* | 19 | 54 |
| **Implant** | *Diameter (mm)* | 4.7, 6.0 | 4.1, 4.7, 6.0 |
| | *Length (mm)* | 10, 11.5, 13 | 10, 11.5, 13 |
| | *Collar Surface Finish* | Machined (Figure 1A) | machined or fully microtextured |
| **Location** | *Maxilla* | 10 implants | 50 implants |
| | *Mandible* | 27 implants | 91 implants |
| **Bone Density Classification[3]** | *Type I* | | 17 implants |
| | *Type II* | 23 implants | 61 implants |
| | *Type III* | 14 implants | 43 implants |
| | *Type IV* | | 20 implants |



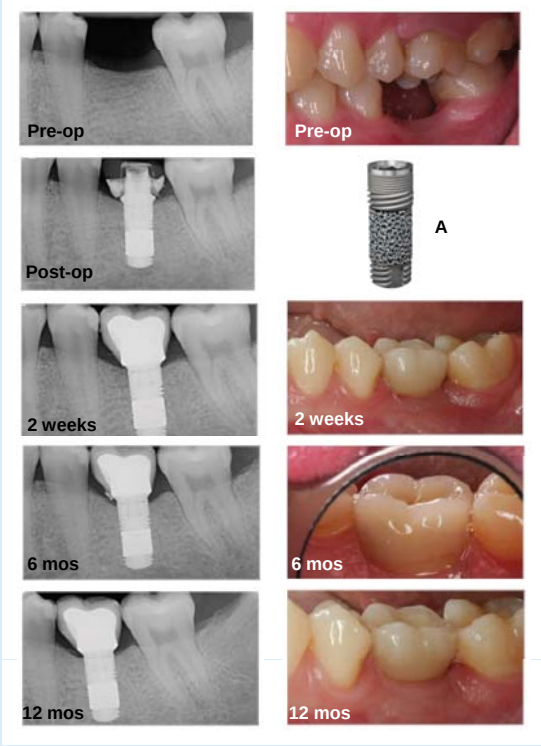


**Figure 1.** The study device (A) included a porous tantalum midsection supported by a threaded titanium body. Radiographs (left) and clinical views (right) of a female patient in the IL study presented with a healed edentulous space in the mandibular left first molar area (pre-op) for placement and immediate provisionalization (post-op) of a TM dental implant *(4.7mmD x 10mmL)*. After two weeks of soft tissue healing, sutures were removed and the definitive restoration was delivered. The fully functional implant maintained soft tissue levels and exhibited no complications 6 months after implant placement. One year after placement, the implant was stable and fully functional with minimal (0.19 mm) crestal bone loss. (Case contributed by Dr. Markus Schlee)

## 3 Results

**IL Study:** 41 subjects with 55 sites were enrolled and 54 implants were placed (1 excluded site required grafting). Of these, 11 subjects/17 implants were withdrawn for protocol violations (insertion torque <35Ncm, Type 4 bone, grafting needed), and 30 subjects/37 implants (Table 1) were treated per protocol. At 6 months, 1 subject/1 implant was lost to recall, 1 implant failed to integrate (survival: 97.2%, n=35/36), and marginal bone loss was 0.42mm from time of placement. No additional failures (n=28/28) at 1 year for implants continuing a 3-year evaluation. The mean marginal bone loss of these implants was 0.52 mm which was not statistically different from their corresponding value (0.45mm) measured at 6 months (P>0.05).

**LDCP Study:** Of the enrolled subjects, 110 patients/150 implants have completed 1-year follow-up. Five implants failed to integrate (survival =96.7%, n=145/150), and 5 subjects/9 implants were excluded for IFU violations (uncontrolled diabetics, substance abusers/mentally unstable subjects, heavy smokers >20 cigarettes/day). The remaining 105 subjects /141 implants (Table 1) exhibited 97.9% survival at 1 year. In this uncontrolled population, 41% (n=43/105) of the subjects with 41% (n=58/141) of all implants placed had risk factors that could adversely influence implant survival and/or bone loss rates (smoking, osteoporosis, bruxism, acute dental/periodontal infections, chronic corticosteroid use, recent heart attack). The implant survival rate was 100% for fresh extraction (n=19/19) and Type IV bone[3] cases (n=20/20) and 98.4% (n=60/61) for the bone augmentation cases. The potential effects of bone augmentation, implant collar surface finish as well as other local and systemic risk factors on crestal bone maintenance are currently undergoing analysis.

## 4 Discussion

The LDCP study anticipated that subjects still harboring risk factors that led to their edentulous state may likely constitute a high percentage of implant candidates that clinicians encounter in daily practice. Diseases and lifestyle choices are often the leading causes of tooth loss. Although the root cause for the single implant failure in the IL pilot study was unclear, the 3 failures in the LDCP at 1-year were not directly related to the study device: 1) preexisting infection, 2) systemic infection induced by sinusitis, 3) iatrogenic disruption of implant healing in a site with simultaneous bone augmentation by a non-sterile probe.

## 5 Significance

Study implants achieved survival rates >97% in both IL and uncontrolled LDCP subjects treated according to the implant's Instructions for Use.

## 6 References

[1] Levine BR, *et al.*, *Biomaterials* 2006;27:4671-4681.

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[3] Lekholm U, Zarb GA. In: Brånemark PI *et al. Tissue-Integrated Prostheses. Osseointegration in Clinical Dentistry*. Chicago: Quintessence Publishing Co., Inc. 1985:199-209.

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