One-year interim report from a multicenter study evaluating Porous Tantalum Trabecular Metal (TM) Dental Implants

Shilpa Kottalgi[1], Wolf-Ullrich Mehmke[2], Guillermo Pradies[3], Arnaud Beneytout[4], Peter van der Schoor[5], Marco Ronda[6], Martin Dinkel[1], Hai Bo Wen[1]
[1]Carlsbad, CA, [2]Chimnitz, Germany, [3]Madrid, Spain [4] Bordeaux, France, [5] Garderen Netherlands, [6]Genova, Italy

1 Background

The Trabecular Metal™ (TM) Dental Implant is a combination titanium and tantalum dental implant where the threads of a conventional tapered endosseous implant is replaced with highly porous tantalum midsection. 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]. The tantalum sleeve may supplement the anchorage through a combination of bone ingrowth and ongrowth, termed as osseoincorporation.[3]

The longitudinal data collection program (LDCP) is an ongoing study to evaluate the long term success and survival of a TM implants. The LDCP was designed to evaluate the clinical outcomes of implants placed in a typical population that presented in routine clinical practice.

2 Objectives and Study Design

A 5 year, international, prospective, multi-center study was undertaken to evaluate the clinical survival and success of TM dental implants in a normal patient population. The study was conducted in 5 countries across 22 sites including university settings and private practices. The study complies with the declaration of Helsinki and the ICH-GCP and is being conducted under the auspices of the local institutional review boards and ethics committees.

Subjects over the age of 18 years, meeting the inclusion criteria were invited to participate in the study. Medical and dental histories including their smoking status, oral habits like bruxism, presence of systemic diseases, history of drug intake were recorded. Subjects who smoked >20 cigarettes/day and with reported surgical complications were excluded from the study.

Each subject received up to two TM dental implants in the maxilla and/or mandible. The LDCP study enrolled subjects with concomitant heath conditions and elevated risk for implant placement including smoking, history of heart disease, periodontal disease and bruxism, intake of systemic steroids and Type 4 bone. Investigators were required to follow the implant's instructions for use (IFU) and their own professional judgment in patient selection and treatment.

3 Results

The study enrolled 304 patients over 24 months, with 35 implants in 27 patients excluded due to IFU contraindications (heavy smokers, substance abuse) and iatrogenic surgical complications. The remaining 277 patients were treated with 393 implants.

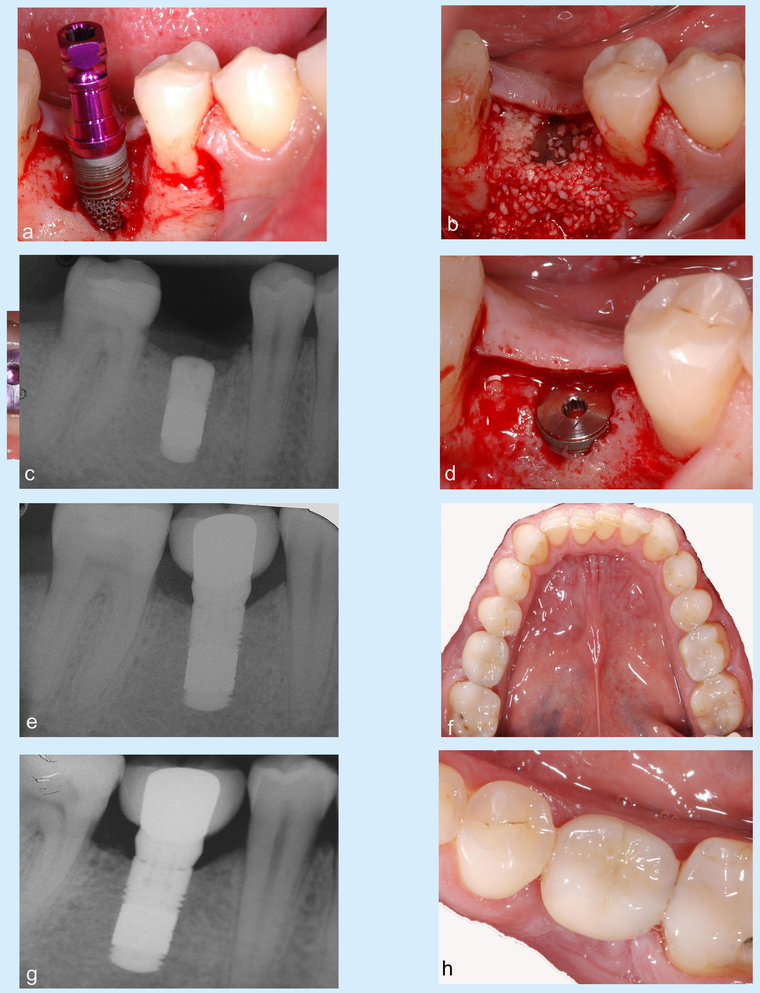

Figure 1: Clinical and radiographic views of a male patient who reported smoking 70 cigarettes/week. A TM dental implant was used to replace the mandibular right first molar. The implant was placed with simultaneous augmentation with an allograft(a, b, c). Figure (d) shows the implant at re-entry. A cement-retained final restoration was placed at 6 months(e, f). The implant was stable and without complications at the 1 year follow up appointment. The average change in marginal bone level from surgery to 1 year was 0.24mm (g, h). Case courtesy of Dr Sergio Spinato, Italy.

Table 1 Demographics

Age	Mean: 52.04 years Min: 22 years Max: 81 years
Gender	129 Males (180 Implants) 148 Females (213 Implants)
Implant Location	167 in Maxilla 226 in Mandible
Soft Tissue Biotype*	288 Thick and 101 Thin
Bone Density[4]*	Type 1: 40 (10.4%) Type 2: 169 (43.8%) Type 3: 104 (26.9%) Type 4: 73 (18.9%)

** Missing data points*

Of these, 133 (48.01%) patients had concomitant conditions that could adversely affect the long term survival and/or bone maintenance around the implant. The average time to final restoration in the maxilla and mandible was 8 (range: 0.5-27.9) months and 5.5 (range: 0.9-30.5) months respectively. 39.1% (n=154/393) of the sites presented with ridge deficiencies and were augmented either prior (n=43) to placement or simultaneously (n=111) with 9.5% (n=37) of the cases placed with sinus grafts.

To date, of the 393 implants, 377 completed 1-year follow up, with 16 implants (10 patients) lost to follow up. Twelve implants failed due to loss of integration (n=6), systemic or peri-implant infection (n=6). The survival rate of TM implants at 1-year is 96.8% (n=365/377). The survival rate was 97.3% (n=144/148) in augmented cases and 100% (n=37/37) in sinus grafts. Table 2 lists the survival rate of TM dental implants in sub groups which presented with and without elevated risks for bone loss and/or implant failure.

Table 2 Survival rates of TM implants in sub groups with and without elevated risks for bone loss and/or implant failure

Sub Group	Number of Implants*	Survival Rate
Implants placed in patients without risk factors	200	97.0% (n=194/200)
Implants placed in patients with one or more of the following risk factors: history of periodontal disease, smokers, history of osteoporosis, para functional habits and Type 4 bone.	177	96.6% (n=171/177)
Smokers*	74	95.9% (n=71/74)
Periodontal Disease*	37	97.3% (n=36/37)
Soft bone (Type 4 only)*	70	97.1% (n=68/70)

** There are overlaps between these groups*

4 Conclusion

Within the limitations of this study TM dental implants were clinically effective, under various clinical conditions, in a cross section of patients with and without concomitant risk factors.

5 References

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