

Survival of Hybrid Titanium and Porous Tantalum Implants in Low Density (Type IV) Maxillary Bone:

1- Year Interim Results

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1 Background

The efficacy of osseointegrated implant therapy in the treatment of fully and partially edentulous patient is well established. Success rates of over 90% in the mandible and over 80% in the maxilla have been historically reported.¹ However, failure rates were much higher in sites which presented with an insufficient quality and/or quantity of bone, i.e., Type IV bone.^{1,2}

The Longitudinal Data Collection Program, is an ongoing study in Europe to evaluate the clinical term survival and success of a novel hybrid titanium and porous tantalum dental implant, Trabecular Metal™ (TM) Dental Implant. Among the enrolled subjects, many presented with elevated risks for implant failure, such as, smoking, periodontal disease, parafunctional oral habits, controlled systemic diseases and Type IV bone. This report is focused on the subgroup analysis of TM implant survival in sites which presented with Type IV bone.

2 Materials and Methods

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.

Age (years)	Average	55.35
	Minimum	22
	Maximum	79
Gender	Male	17
	Female	31
Implant	Diameter (mm)	4.1, 4.7, 6.0
	Length (mm)	10, 11.5, 13
	Collar Surface Finish	Machined or Fully Microtextured

Table 1. Summary of demographics and implant design

Each patient was allowed to receive up to 2 TM dental implants as part of the study. Investigators were required to follow the implant's instructions for use (IFU) and their own professional judgment in patient selection and treatment. Subjects who smoked >20 cigarettes/day and with reported surgical complications were excluded from the study. For this sub group analysis, sites presenting with Type IV bone in the anterior and posterior maxilla were selected. The clinician evaluated the quality of bone using both radiographs

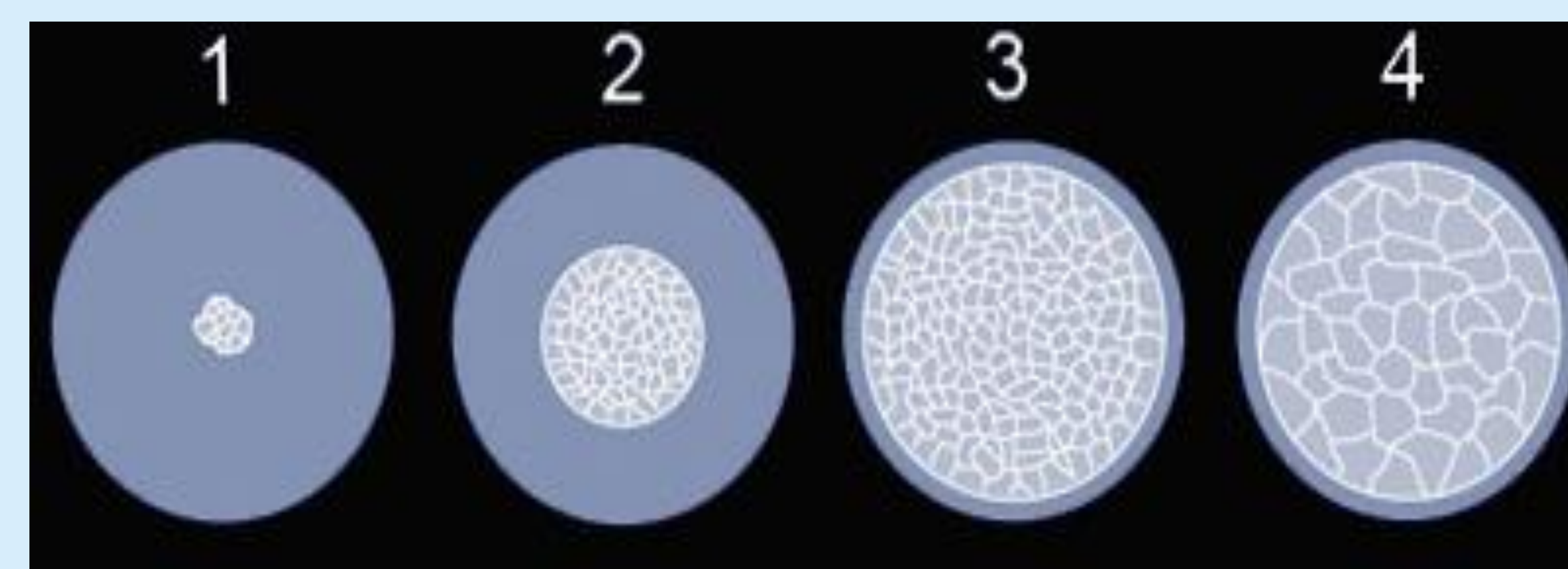


Figure 1. Bone Density Classification (Lekholm and Zarb)³
(1) Type I bone
(2) Type II bone
(3) Type III bone
(4) Type IV bone

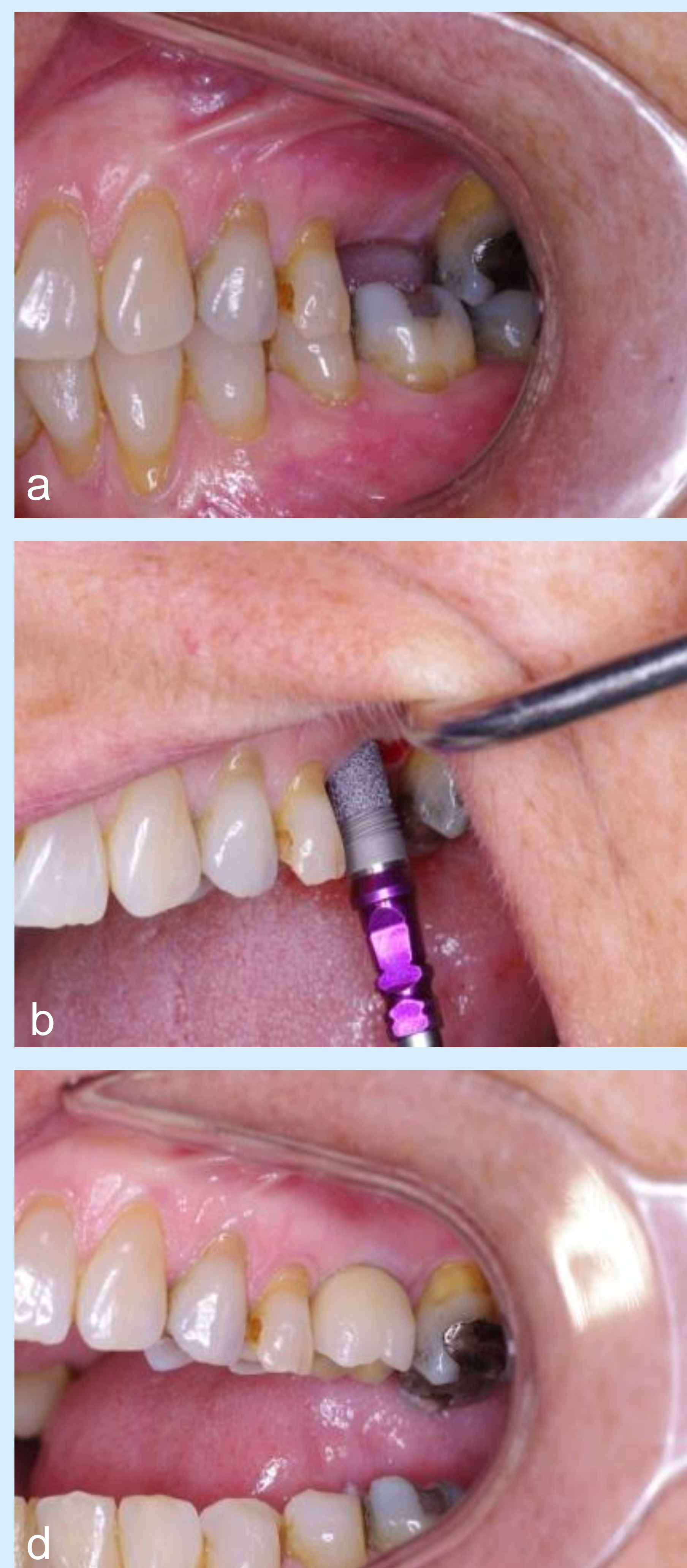


Figure 2. Radiographic and clinical views of a 53 year old female subject in the LDC study who presented to the clinic with a missing left first molar and received a TM implant. (a) preoperative view of missing left first molar; (b) TM implant placement; (c) post-op radiograph; (d) final restoration at 4 months; (e) radiograph at 1 year post restoration

and tactile sensation of cutting resistance and force during preparation of the osteotomy and classified the bone type according to the Lekholm and Zarb criteria (Figure 1).³ The importance of correlating tactile feedback with evidence from diagnostic imaging is underscored by Trisi and Rao⁴ who reported that clinicians could tactilely distinguish between Types I and IV bone, but not Types II and III bone.

Statistical Analysis: Continuous data were summarized by descriptive statistics of sample size N, average, and range. Categorical data were summarized by descriptive statistics of frequency and percentage.

3 Results and Discussion

To date, 64 implants, placed in the maxillary anterior and posterior jaws of 48 subjects (17 men and 31 women) with Type IV bone, have completed 1 year of follow up (Table 1). Of the 64 implants, 47 were placed in the maxillary molar regions (73.5%); 15 in the pre molar region (23.4%) and 2 in the maxillary anterior region (3.1%). 76.5% (n=49) of the implants placed were 4.7mmD; 14.1% (n=9) were 4.1mmD and 9.4% (n=6) were 6.0mmD TM implants. 34 implants were fully microtextured and 30 had machined collars. 96.8% (n=62) of the implants were placed using a soft bone protocol with over 50% of those implants attaining a final insertion torque between 30Ncm to 60Ncm.

Of the 48 subjects in this group, 25% (n=12 subjects) had one or more concomitant health conditions or risk factors in addition to the Type IV bone: Smoking, periodontal disease, osteoporosis, history of heart disease and parafunctional habits like bruxism. At 1 year after placement, 2 implants failed to osseointegrate. The cumulative implant survival rate in Type IV bone was 96.88% (n=62/64).

4 Conclusion

Within the limitations of this subgroup analysis, TM Dental Implants demonstrated clinical efficacy in Type IV bone at 1 year after implant placement.

5 References

1. Fugazzotto PA, Wheeler SL, Lindsay JA. J Periodontal 1993; 64:1085-1087.
2. Truhlar et al. J Oral Maxillofac Surg; 55:38-45, 1997, Suppl 5.
3. Lekholm U, Zarb GA. In Branemark P-I et al.: Tissue integrated Prosthesis: Osseointegration in clinical Dentistry. Chicago; Quintessence Publishing Co Inc., 1985;199-209..
4. Trisi P, Rao W. Clin Oral Impl Res 1999;10;1-7.

Note: Trabecular Metal™ is a trademark of Zimmer, Inc.