Placement of Implants with Highly Porous Midsections into Grafted Maxillary Sinuses: Interim Results from a Prospective, Multicenter Study in an Uncontrolled Population

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1 Introduction

Dental implant placement in the posterior maxilla can often be complicated by pneumatization of the sinus, alveolar ridge resorption and the presence of low-density bone.[1] The resulting lack of available bone for implant placement can be overcome by subantral augmentation (sinus lift) procedures.[1] Trabecular Metal™ (TM) Dental Implant (Zimmer Dental Inc., Carlsbad, CA) is a tapered, multi-threaded implant with a modified midsection of highly porous tantalum material, to augment anchorage through osseoincorporation, a combination of conventional osseointegration and bone ingrowth and neoformation inside its network of interconnected pores.[2] To evaluate the long-term clinical performance of TM implants, a 5-year, multicenter, Longitudinal Data Collection Program (LDCP) is currently being conducted in Europe. Many of the enrolled subjects have presented with elevated risks for bone loss or implant failure: smoking, history of periodontal disease, implant placement in sinus grafts, controlled systemic diseases and Type IV bone.

Since implant placement in sinus grafts has been reported in the dental literature as a potential risk factor for implant failure, the current interim analysis was undertaken to determine early outcomes of TM dental implants in sinus grafts from the LDCP study.

2 Methods

The study is being conducted in 22 sites that include both university settings and private practices in 5 countries. Study oversight is provided by local institutional review boards and ethics committees, and complies with the declaration of Helsinki and good clinical practices specified by the International Congress on Harmonization (ICH-GCP). Subjects over 18 years of age who met the inclusion criteria were invited to participate in the study (Table 1). Medical and dental histories, personal habits (such as smoking and bruxism), and oral health status were reviewed. 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 judgments in patient selection and treatment (Fig. 1a-l). Subjects with IFU violations were excluded from the study.

Table 1. **Demographics and Implant Design Summary**

Patient Age (years)	Average	55.78
	Minimum	38
	Maximum	77
Patient Sex	Male	11
	Female	16
Implant Design	Diameter (mm)	4.1, 4.7, 6.0
	Length (mm)	10, 11.5, 13
	Collar Surface Finish	Machined or Fully Microtextured

3 Results and Discussion

Results are summarized in Table 2. A total of 38 implants were placed in grafted sinuses of 28 patients. From this group, 1 subject with 1 implant was excluded for implant placement in a heavy smoker (>140 cigarettes per week), which was an IFU violation.

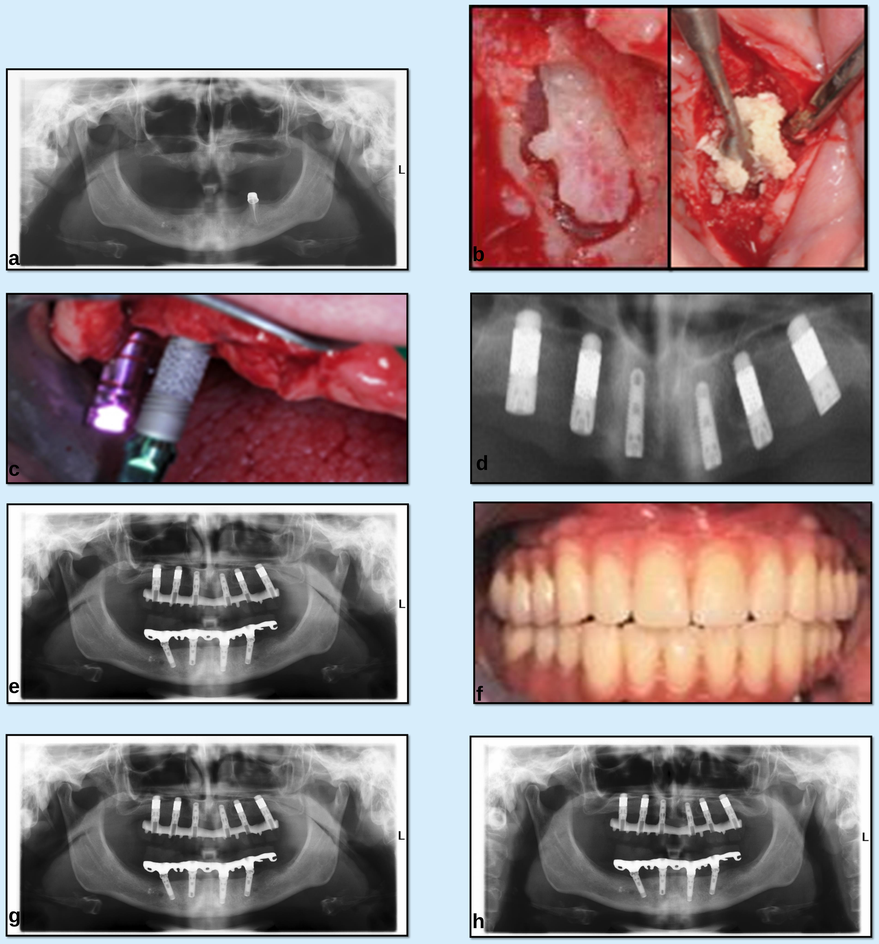

Figure 1. Preoperative views show an edentulous maxilla with <1mm ridge height (a). A crestal window was made bilaterally, followed by augmentation with a composite graft of 80% cortical and 20% allogenic bone chips (Puros®, Zimmer Dental Inc.) (b). Implants were placed after a healing time of 6 months; the study implants were placed in relation to the maxillary right first premolar and molar (c,d). After 6 months of submerged healing, the implants were restored (e,f). Implants were stable and without complications at the 1 and 2 year follow up appointments (g,h). The mean marginal bone level change from surgery to 1 year was 0.34mm and from surgery to 2 years was 0.53mm. *Case contributed by Dr Carlo Maria Soardi.*

The remaining study group of 11 males and 16 females ranged in age from 38 to 77 (mean = 55.78) years. In 10 patients, 11 implants were simultaneously placed at the time of sinus augmentation using either a crestal (n = 7 implants, 7 patients) or lateral (n = 4 implants, 3 patients) approach for graft placement. The remaining 26 implants were placed into healed sinus grafts of 17 patients. The average time to implant placement from grafting for the delayed group was 5.9 months. After implant placement, mean time to implant loading was 6.3 months for simultaneous placement group and 5.3 months for the delayed placement group. Implants were placed into sinuses grafted with anorganic bovine mineral (Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland) (n = 13), solvent-dehydrated cortical and cancellous (80:20) allograft mix (Puros, Zimmer Dental Inc.) (n = 21), or autogenous bone chips (n = 3). Most (n = 33/37) implant sites were Type IV bone. There were no adverse events and implant survival was 100% at 1 year follow up.

Table 2 **Summary of Patients and Implant Outcomes**

Category	Patients (n)	Implants	
		Number	Percentage
Patients Enrolled	28	38	100
Patients Excluded	1	1	2.63
Final Study Group	27	37	100
Simultaneous implant placement and grafting*	10	11	29.7
Delayed implant placement after grafting*	17	26	70.3
Failed implants	0	0	0
Surviving implants	27	37	100

*Implant level calculations

4 Conclusions

Within the limitations of this study, placing Trabecular Metal Dental Implants into grafted sinuses resulted in a high level of predictability.

5 References

1. Altintas NY, et al. Comparative radiological analyses of newly formed bone after maxillary sinus augmentation with and without bone grafting. J Oral Maxillofac Surg 2013; 71:1520-1530
2. Schlee M, van der Schoor WP, van der Schoor ARM. Immediate loading of Trabecular Metal-enhanced titanium dental implants: interim results from an international proof-of-principle study. Clin Implant Dent Relat Res 2013;Jul 30. doi: 10.1111/cid.12127. [Epub ahead of print].

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