

Preliminary outcome in consecutively treated case series with Trabecular Metal implants

Carlo Maria Soardi*, Hom-Lay Wang**, Emanuele Clozza***,
Davide Zaffe****, Luigi Checchi*****

Objective: The aim of this study was to illustrate the successful use of Trabecular Metal (TM) implants placed in posterior maxilla following maxillary sinus augmentation. **Methods and Materials:** Twelve TM implants were placed after maxillary sinus augmentation using mineralized human bone allograft (MHBA) in 6 patients. At second stage procedure, 3 months after TM implants installation, the outcome measures evaluated were implant success and removal torque test. **Result:** At second stage procedure, the implant success rate was 100%. No evidence of peri-implant marginal bone loss was noted clinically and all implants successfully tolerated a 25 Ncm torque test. **Conclusion:** The favorable outcome of the treatment described suggests that the rehabilitation of atrophic posterior maxillary region can be achieved by the placement of TM implants in sites augmented with MHBA.

Key Words: Allograft, Bone regeneration, Sinus floor augmentation, Tantalum, Implants 3.

INTRODUCTION

The use of human bone for the regeneration of osseous defects has significantly changed implant dentistry in the past 20 years¹. Autologous bone has been considered the material of choice for bone grafting procedures because it possesses osteoconductive, os-

teoinductive, osteogenic and properties². However, the harvesting of bone from patients presents many disadvantages, including morbidity of the donor site and high risk of severe complications³. Moreover, the supply of autologous bone graft may be limited³. As a consequence, alternative grafting materials resembling the properties shown by autologous bone were developed and favorable outcomes were reported by systematic reviews in terms of the survival rate of implants placed into augmented maxillary sinuses^{4,5}.

Recent advancements have led to the development of a new Trabecular Metal (TM) implant (Zimmer Dental Inc., Carlsbad, CA.) in tantalum. Tantalum possesses characteristics that confer significant advantages over traditional implant materials: it is chemically stable and biocompatible, and can be manufactured with a three-dimensional architecture similar to that of bone trabeculae⁶. In addition, it presents favorable strength even in its trabecular form⁶. Pre-clinical and clinical studies have reported that bone ingrowth occurred into the trabecular bone holes⁷⁻¹⁰. Remarkably, the use of tantalum in orthopedics is recommended in regions where the bone quality is questionable^{11,12}.

Shifting this paradigm from orthopedics to implant dentistry, the use of TM implant should be considered

- * Private Practice, Brescia, Italy.
- ** DDS, MSD, PhD, Professor and Director of Graduate Periodontics, Department of Periodontics and Oral Medicine, School of Dentistry, University of Michigan, Ann Arbor, MI, USA.
- *** Resident, Department of Periodontology and Implant Dentistry, New York University College of Dentistry, New York, NY, USA.
- **** PhD, ScMBiol, Associate Professor, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Italy.
- ***** Professor and Chairman of Periodontology and Orthodontics, Department of Periodontology and Implantology, University of Bologna, Bologna, Italy.

Correspondence:

Emanuele Clozza
New York University College of Dentistry
Ashman Department of Periodontology and Implant Dentistry
345 East 24th Street, Suite 3W, New York, NY 10010, USA
Telephone Number: +1(212)992-7040
FAX Number: +1(212)995-3961
E-mail: leleclo@libero.it

a feasible treatment approach in augmented sites and successfully loaded in the early phase of maturation, where the bone quality might not resemble the characteristics of native bone.

Therefore, the aim of this preliminary report was to illustrate that TM implants can be successfully employed for the rehabilitation of edentulous posterior maxilla after maxillary sinus augmentation with mineralized human bone allograft (MHBA).

MATERIALS AND METHODS

Study design

Six patients (5 females and 1 male, between 35 and 71 years of age) were selected from a pool of subjects requiring maxillary sinus augmentation for the placement of delayed posterior implants (Table 1). All patients were partially or totally edentulous and in need of unilateral maxillary sinus augmentation. The recruitment and active treatment period was February 2011 to January 2013 and carried out by the same operator (C.M.S) in a private dental office in Brescia, Italy. Patients were systemically healthy; they did not neither smoke and nor take any medications. Clinical examinations, panoramic radiographs and cone beam computed tomographies (CBCTs) scan were used for pre-operative evaluation (Fig 1a). Patients agreed to the intervention and signed a written consent form, according to the Helsinki protocols.

Surgical procedures

Maxillary sinus augmentation and post-operative care was performed transcristally (Figs 2a and 2b), as described in previous publications¹³. Monthly follow-up was scheduled to check the wound healing up to implant insertion. A CBCT scan was taken 6 months after sinus augmentation (Fig 1b). The 3D radiographic examination revealed the presence of an adequate amount of bone in all the regenerated sites, thus allowing a proper prosthetically driven implant planning. At the time of implant installation (6 to 11 months after sinus augmentation) a significant amount of newly formed bone gain was noted clinically in all the implant sites. A surgical guide was fabricated to dictate the position of initial osteotomy. Next, a trephine drill (external diameter of 4 mm; internal diameter of 3 mm; Stroma GmbH, Emmingen-Liptingen, Germany) was utilized to collect bone cores at 600 rpm under a saline jet prior implant insertion.

The implant platform was positioned at the same level of the bone crest. A total of 12 TM fixtures were placed (Fig. 6d and Table 1). Flaps were repositioned and secured with single interrupted sutures (Gore-Tex 5.0, W. L. Gore & Associates, Flagstaff, AZ) to achieve primary closure. A second-stage procedure was performed three months later to uncover the fixtures (Figs 3a and 3b). The reverse torque testing (Implantmed ,W & H, Bürmoos, Austria) at 25 Ncm (Fig 3c) confirmed the osseointegration implants. Healing abutments were attached to the implants (Figs 3d and 3e). Finally, the rehabilitation on

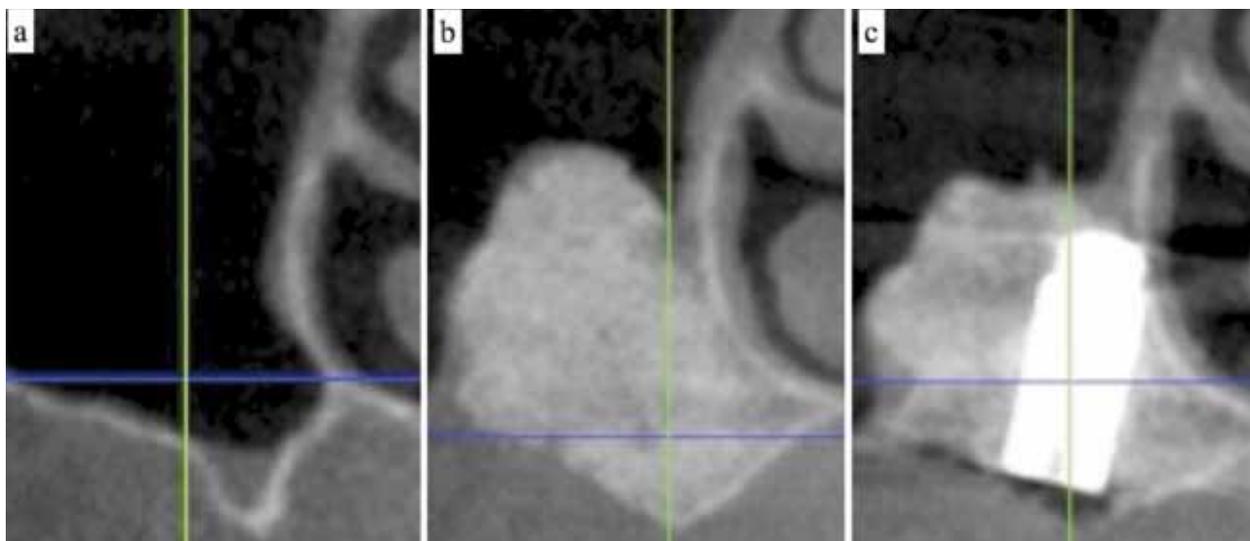


Fig 1 (a) Preoperative CBCT. (b) Six months after sinus augmentation. (c) CBCT taken immediately after implant placement.

implants (Fig 3f) was finalized as described in Table 1. The criteria for implant success were chosen according to Albrektsson et al.¹⁴ and included: absence of implant mobility, absence of peri-implant radiolucency, absence of persistent subjective complaints (dysesthesia, foreign body sensation and pain) and absence of peri-implant infection with suppuration.

Histologic preparation

Bone core biopsies were fixed, embedded in polymethyl methacrylate (PMMA) and sectioned as described by Soardi et al.¹⁵ Microradiographs, toluidine

blue or trichrome Gomori staining of 5- μ m-thick sections, photographs, and bone and graft amount evaluations were performed as previously reported¹⁵.

RESULTS

Clinical results

Primary wound closure was obtained in all surgeries and no complaint or adverse effects were observed during the follow-up. All the 12 implants healed sub-

Table 1 Demography, implant site and sizes, timing of implant procedures and type of prosthesis delivered

Patient No.	Age (years)	Sex	Implant site	Implant diameter (mm)	Implant length (mm)	Timing (months)		Prosthesis delivered
						Implant positioning	Stage-two surgery	
1	35	F	27	4.7	11.5	10	3	CC
2	51	F	26	6	11.5	6	3	FSPD
			24	4.1	11.5			FSPD
			16	4.7	11.5			FSPD
			14	4.1	11.5			FSPD
3	45	F	16	4.7	11.5	8	3	CC
			26	4.7	11.5			CC
4	62	M	16	4.7	11.5	11	3	CC
5	71	F	16	4.7	11.5	7	3	CC
6	68	F	14	4.1	11.5	6	3	FSPD
			16	4.7	11.5			FSPD
			26	4.7	11.5			FSPD
			24	4.1	11.5			FSPD

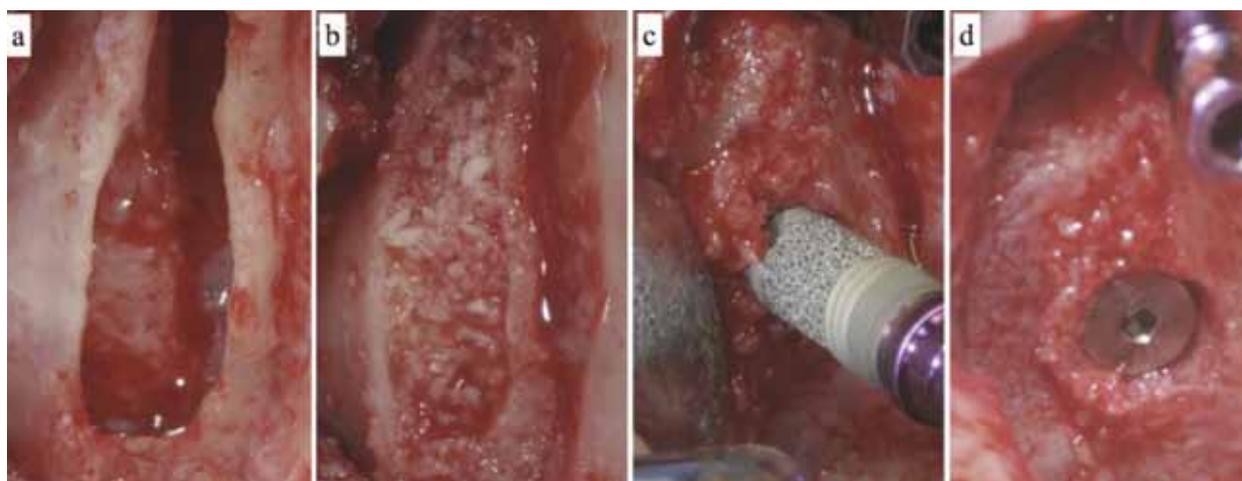


Fig 2 (a) Crestal window approach. (b) Sinus augmentation with MHBA particles. (c) Placement of two TM implants. (d) The implant platform was positioned at the same level of the bone crest.

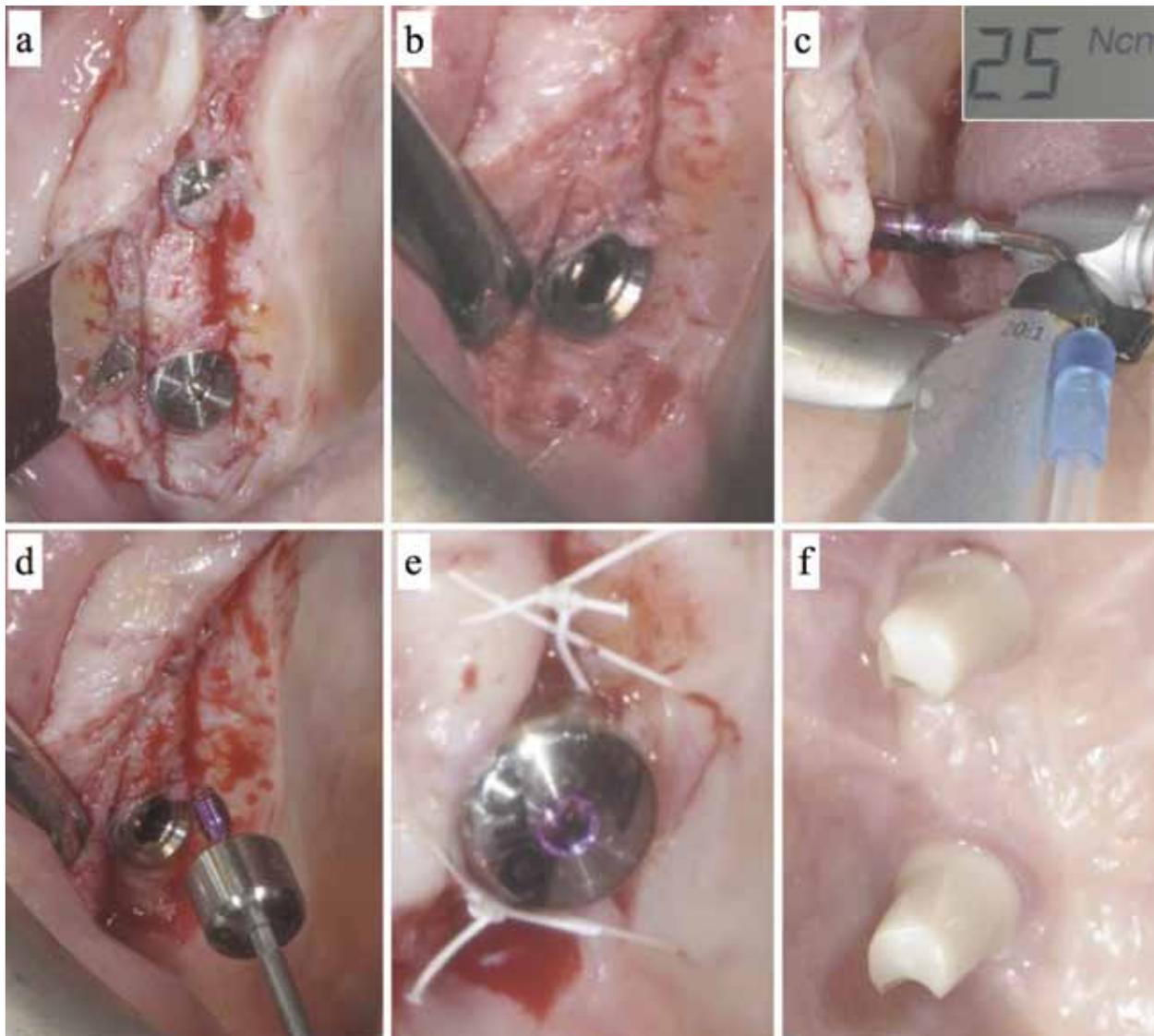


Fig 3 (a) Second stage procedure. (b) Removal of the Cover screw. (c) Reverse torque testing performed at 25Ncm. (d) Placement of the healing abutment. (e) Flap sutured. (f) Cementation of zirconia abutments.

merged without exposure. All the implants were integrated, retained and functional up to the time of the completion of this manuscript. At second stage procedure, no evidence of peri-implant marginal bone loss was noted clinically and all implants successfully tolerated a 25 Ncm torque test.

Histologic results

Six to eleven months after grafting, biopsies showed the presence of newly formed trabecular bone were in intimate contact with residual allograft particles. Limited presence of pristine bone was found in all samples. The histomorphometric evaluation of the amount of

vital bone per tissue volume of all biopsies ranged from 17.8% to 25.3%.

DISCUSSION

This descriptive study illustrated that TM implants could be successfully employed to rehabilitate posterior maxilla previously augmented by allografts.

The crestal approach was chosen to enter the sinus cavity as this technique according to a preliminary report¹³ seemed to minimize dramatically the rate of implant failure.

The histologic analysis revealed that the TM were placed in almost purely augmented bone. The amount of newly formed bone reported in the present study was almost similar to that described by Soadi et al.¹⁵.

At second stage procedure, all 12 TM implants fulfilled the criteria for implant success introduced by Albrektsson et al.¹⁴, thus highlighting the positive performance of these implants whether placed in bone of questionable quality.

A number of devices and techniques have been developed to assess primary and secondary stability¹⁶. In the present study, we verified the osteointegration of TM implants using the reverse torque test. This method is based on unscrewing (the opposite of cutting torque) the implant from bone by the application of a counter-clockwise torque up to 20 Ncm at second-stage surgery¹⁷. While osseointegrated implants will resist a reverse torque at this level, osseointegration failure with fibrous encapsulation will lead to an unscrewing¹⁸. We demonstrated that all 12 implants successfully withstand the 25 Ncm reverse torque test three months after implant placement.

A higher value of rotational force was applied in our protocol, as we argued the TM implant configuration could have yielded additional resistance to reversal rotational force, given that bone ingrowth into the mid-section of the implant. This phenomenon was and also extensively documented in orthopedic literature^{6,7}.

CONCLUSIONS

Based on the favorable results gathered by this clinical study, we propose that the rehabilitation of atrophic posterior maxillary region can be achieved by the placement of TM implants in sites augmented with MH-BA. The conclusions drawn from this case series need to be verified in more rigorously designed studies.

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