Original article

Clinical evaluation with 18 months follow-up of new PTTM enhanced dental implants in maxillo-facial post-oncological patients

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Summary

Aim. **The aim of this study is to present 18 months follow-up results of porous tantalum trabecular metal-enhanced titanium dental implant (PTTM) in implant supported prosthesis in post-oncological patients.**
Materials and methods. **A total of 25 PTTM implants were placed in each jaw of 6 patients that met specific inclusion and exclusion criteria. Resonance Frequency Analysis (RFA) was conducted and Implant stability was recorded in ISQ values (Osstell ISQ, Osstell AB, Goteborg, Sweden) at implant placement and after 2,4,6,12 and 18 months of functional loading.**
Mean bone loss was also evaluated at the same interval of time on each periapical radiographs, bone levels were calculated by measuring the distance from the implant shoulder to the first bone to implant contact.
Results. **Cumulative implant survival rate is 100% (n=25/25) to date and mean ISQ values recorded were: 72.14±5.61 (range= 50-81) at surgery, 64.39±8.12 (range=44-74) after 2 months, 74.26±7.14 (range=44-74) after 4 months, 76.84±7.65 (range=60-83) after 6 months, 78.13±4.14 (range=64-84) after 12 months and 80.22±6.23 (range=68-89) after 18 months of functional loading.**
Mean crestal marginal bone loss was 0.19±0.25 mm after 2 months of functional loading on periapical radiographs, 0.22±0.4 mm at 4 months, 0.3±0.46 mm at 6 months, 0.57±0.62 at 1 year and 0.64±0.60 mm after 18 months.
Conclusions. **The results of this study, even if limited by the number of implants placed indicate that PTTM dental implants have a clinical efficacy in prosthetic rehabilitation of post-oncological patients, due to trabecular structure of the porous Ta metal that increases bone-implant connection values.**

Key words: trabecular metal, PTTM dental implants, oral cancer, prosthetic rehabilitation.

Introduction

The treatment for patients with a malignant neoplasia of the oral cavity requires the cooperation of a team of different specialists that follow the patient through the phases of diagnosis, therapy and oral rehabilitation.
Ablative surgery is followed by a reconstructive phase after which the patient may need to undergo radiotherapy, a condition that may compromise the success of oral rehabilitation (1-3).
Radiotherapy side effects may include mucositis, xerostomia, damage of the salivary glands and osteoradionecrosis, which could lead the surgeons to proceed to a partial jaw resection (4-6). Chemotherapy side effects are similar to those of radiotherapy and, usually, is possible to perform dental surgery safely before and after chemotherapy if the patient is not further compromised by also undergoing bisphosphonate drug therapy (7, 8).
The options for a prosthetic rehabilitation are either the tooth-supported prosthesis or implant-supported overdenture (4, 5). However, deformation to the oral structures, by surgical treatments, may prevent a proper osseointegration and result in failure and also conventional tissue-supported restorations may lead to soft tissue management problems (6, 9-13).
Over the years numerous implant surfaces and coatings have been utilized to try to maximize on-growth potential and secondary stability, increasing bone to implant connection values (BIC).
Improvement in surface roughness can be achieved by using Microtextured, Acid Etched, Sand Blasted/Acid Etched, Phosphate Enriched, Hydoxyapatite (HA), Titanium Plasma Spray (TPS), or Nanotexturized implant surfaces.
These surfaces promote the adherence of platelets from the initial clot that releases platelet-derived growth factors (PDGFs), which are chemotactic and

mitogenic for mesenchymal cells and osteoblast progenitor cells (14).
The current implant surface treatment seems to improve osteoblastic activities and reduces peri-implant bone loss, however 100% Bone to Implant Contact is not achievable because gaps and voids may occur along the surface.
A porous tantalum trabecular metal (PTTM), known commercially as Trabecular Metal Material (Trabecular Metal Technology, Zimmer Inc., Parsippany, NK, USA), used since 1998 in orthopaedic reconstructions, has been adapted for dental implant use to achieve higher BIC values and bone ingrowth (15-18).
The aim of this study is to evaluate the clinical efficacy of porous tantalum trabecular metal-enhanced titanium dental implant (PTTM) in implant-supported prosthesis in oral-maxillofacial post-oncological patients.

Materials and methods

This study was open to all patients that met specific inclusion and exclusion criteria (Tab. 1) and that signed informed consent, according to the World Medical Association's Declaration of Helsinki.
Six patients were enrolled in this study, 4 female (66,66%) and 2 male (33,34%) with a mean age of 55±25,45 years (age range 37-74), they were all post-oncologic patients treated for oral cancer (Tab. 2).
The inclusion criteria did not distinguish between patients receiving radiotherapy and non-irradiated patients, when radiotherapy was used it was included in the medical record.
A total of 25 PTTM implants were placed in a period between June and July 2012. Each subject was treated with a number of implants based on their clinical need, bone quantity and quality (Tabs. 3, 4).
For prophylaxis, one hour before surgery antibiotics were given to the patients: 2 g of amoxicillin and clavulanic acid (Augmentin®, Roche S.p.A., Milan, Italy). Chlorhexidinedigluconate 0,12% mouth wash (Dentosan® Collutorio Trattamento Mese, Recordati S.p.A., Milano, Italy) was prescribed every day for 7 days after surgery. Patients were provided with written instructions for oral hygiene and were recommended to follow a soft diet for 4 to 5 days post surgery. Written consent for implant treatment was signed by all patients prior to the study. Medical examinations were scheduled respectively 7,14 and 28 days after surgery and then once a month (1/30 days) for the following 18 months.
The definitive restorations were made in a period between 2 and 3 months post surgery.
Resonance Frequency Analysis (RFA) was conducted and Implant stability was recorded in ISQ values (Osstell ISQ, Osstell AB, Goteborg, Sweden) at implant placement and after 2,4,6,12 and 18 months of functional loading.
Standardized (Rinn, Dentsply, York, PA, USA) periapical radiographs were taken for each implant at placement and after 2, 4, 6, 12 and 18 months of functional loading.
Mean bone loss was also evaluated with the same time interval on each periapical radiograph, bone levels were calculated by measuring the distance from the implant shoulder to the first bone to implant contact.

Table 1. Patient inclusion criteria.

Inclusion	Male or female at least 18 years of age Benefit from the implant prosthesis Insertion torque >35 Ncm
Exclusion	Subjects with bruxism or clenching parafunctional habits Mental disorders Uncontrolled systemic disease Untreated oral pathologies Pregnancy Use of Bisphosphonates

Results

Cumulative implant survival rate is 100% (n=25/25) to date and all implants had at least 18 months of clinical follow-up after functional loading (Figs. 1, 2, 3).
No serious complications or adverse reactions were reported and all implants were stable and well osseointegrated.
Mean ISQ values recorded were: 72.14±5.61 at surgery, 64.39±8.12 after 2 months, 74.26±7.14 after 4 months, 76.84±7.65 after 6 months, 78.13±4.14 after 12 months and 80.22±6.23 after 18 months of functional loading (Tab. 5).
Mean crestal marginal bone loss was 0.19±0.25 mm after 2 months of functional loading on periapical radiographs, 0.22±0.4 mm at 4 months, 0.3±0.46 at 6 months, 0.57±0.62 at 1 year and 0.64±0.60 after 18 months (Tab. 6).

Discussion

ISQ results showed an optimal primary stability of the PTTM dental implants thanks to the trabecular structure of the porous Ta metal, which is similar to cancellous bone. High initial ISQ results remained constant over time, while lower initial ISQ values increased more once osseointegration was stabilized (Tab. 5).
Measurements of the distance from the implant shoulder to the first bone to implant contact on periapical radiographs demonstrated a minimal crestal bone loss compared to the conventional titanium alloy dental implants (Tab. 5). PTTM manufacturing process is extremely complex. It utilizes a chemical vapour deposition process (CVD), which deposits elemental tantalum (Ta) onto a substrate and therefore creates a nanotextured surface topography to build the Trabecular Metal Material.
Ta is a transitional metal often extracted from the mineral tantalite, its atomic number is 73, it's highly biocompatible and corrosion resistant (16). Ta is deposited onto a vitreous carbon skeleton to reproduce the

Table 2. Patient medical history.

Patient	Diagnosis	Treatment	Implant placement	Prosthetic Rehabilitation
D.S. Woman 52 year old	Squamous cell carcinoma of the right edge of the tongue	Anterolateral thigh flap	Six months later two submerged PTTM-dental implants (4.1 x 10 mm) in the right inferior canine and premolar locations	Six months later provisional acrylic resin fixed partial denture with a distal cantilever for second premolar occlusion. After one month temporization, a definitive ceramometal restoration
L.T. Woman 37 year old	Unicystic ameloblastoma of the right mandibular quadrant	Radical resection of the right posterior mandible and simultaneous reconstruction with iliac crest flap	Six months later two submerged PTTM-dental implants (4.1 x 10 mm, 4.1 x 11.5 mm) in the right posterior mandible	Five months later provisional fixed partial denture, definitive ceramometal restoration one month later
A.L. Woman 74 year old	Left floor-of-mouth cancer (FOM)	Partial mandibulectomy from the lower left second premolar to the lower right lateral incisor END levels I-IV Simultaneous anterolateral thigh free flap Radiotherapy	One year after radiotherapy, seven submerged PTTM-dental implants in the mandible (2 each 4.1 x 10 mm, 2 each 4.1 x 11.5, two 4.7 x 11.5 mm and one 4.1 x 13 mm)	Six months later definitive, screw-retained prosthesis
T.G. Man 56 year old	Right FOM cancer	Segmental mandibulectomy in the right posterior mandible Simultaneous pectoralis major flap Radiotherapy	One year after radiotherapy, four PTTM- dental implants were placed (2 each 4.1 x 10 mm and 2 each 4.7 x 11.5 mm)	Tissue-supported overdenture retained by ball abutments after 6 months from implant placement
P.D. Man 45 year old	Osteosarcoma of the jaw located in the anterior region of the maxilla	Partial maxillectomy Simultaneous fibula free flap reconstruction	Seven months later six submerged PTTM- dental implants (3 each 4.1 x 10 mm, 2 each 4.1 x 11.5 mm, 1 each 4.7 x 11.5 mm)	Five months later fixed implant-supported prosthesis
C.E. Woman 56 year old	Multicystic ameloblastoma of the upper jaw	Maxillectomy performed from the right canine to the second left molar Simultaneous fibula free flap reconstruction	Six months later four PTTM- dental implants (2 each 4.1 x 10 mm, 2 each 4.1 x 11.5 mm, 4.7 x 11.5 mm)	Six months later a bar-retained overdenture

Table 3. Trabecular metal dental implants inserted.

Lenghts (mm)	Diameters (mm) ø		
	4,1 mm	*4,7 mm*	Implants
10 mm	12	0	12
11,5 mm	5	6	12
13 mm	1	0	1

Table 4. Treatment sites.

Maxillary locations	Lateral Incisor	1
	Canine	1
	First premolar	1
	Second premolar	1
	First molar	6
	Second molar	4
Mandibular locations	Lateral Incisor	1
	Canine	5
	First premolar	1
	Second premolar	2
	First molar	1
	Second molar	1

trabecular bone structure and its properties. Prof. Branemark was the first to use Ta in the implantology field however due to its production costs and difficulty of extraction it was quickly abandoned.

Trabecular Metal material is a porous biomaterial with up to 80% interconnected porosity. It has an open-cell three-dimensional dodecahedrical shape, that resembles trabecular bone and its 12 interconnecting hexagonal pores. These pores have an average size of 440 μm to allow vascularized bone ingrowth, which requires a minimum size of 300 μm (19).

PTTM enhanced titanium dental implants (Trabecular

Figure 1. Trabecular metal dental implant.

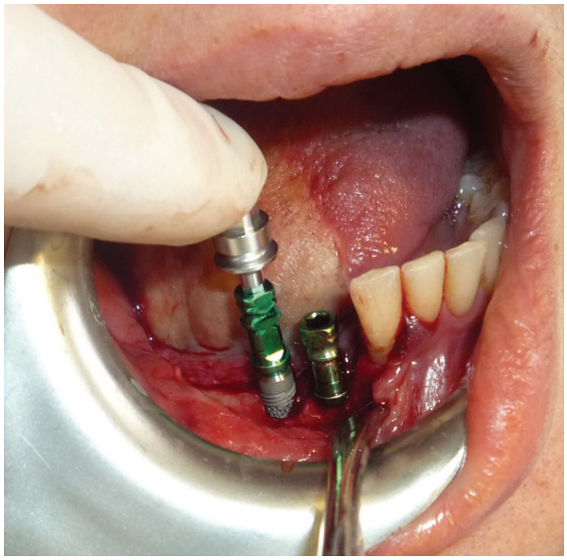

Figure 2. Trabecular metal dental implants placements.

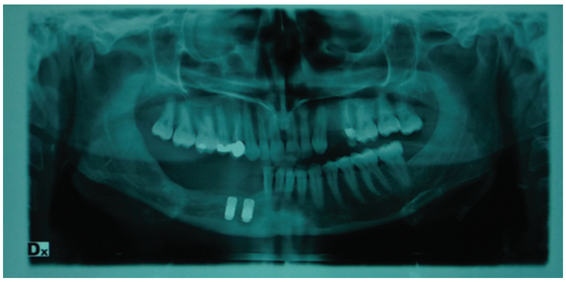

Figure 3. Post-surgical orthopantomography.

Table 5. Resonance frequency Analysis (RFA).

Interval	ISQ Values	Range
Surgery	72.14±5.61	50-81
2 Months	64.39±8.12	44-74
4 Months	74.26±7.14	52-80
6 Months	76.84±7.65	60-83
1 Year	78.13±4.14	64-84
18 Months	80.22±6.23	68-89

Table 6. Crestal bone loss (mm).

Interval	Measurement Location	Mean Bone level (mm)	Range
Surgery	Mesial	0.5±0.48	0.07-1.8
	Distal	0.62±0.70	0.03-2.3
	Average	0.56±0.48	0.03-2.3
2 Months	Bone loss Mesial	0.21±0.46	-0.65-1.1
	Bone loss Distal	0.18±0.23	-0.48-0.94
	Bone loss Average	0.19±0.25	-0.48-1.1
4 Months	Bone loss Mesial	0.24±0.48	-0.9-1.4
	Bone loss Distal	0.20±0.22	-0.8-1.5
	Bone loss Average	0.22±0.4	-0.8-1.5
6 Months	Bone loss Mesial	0.28±0.49	-1.06-1.2
	Bone loss Distal	0.33±0.48	-0.8-0.96
	Bone loss Average	0.3±0.46	-0.8-1.2
1 Year	Bone loss Mesial	0.55±0.71	-0.78-2.09
	Bone loss Distal	0.59±0.53	-0.41-1.89
	Bone loss Average	0.57±0.62	-0.78-2.09
18 Months	Bone loss Mesial	0.62±0.73	-0.84-2.20
	Bone loss Distal	0.66±0.52	-0.70-1.99
	Bone loss Average	0.64±0.60	-0.70-2.20

Metal Dental Implant, Zimmer Dental Inc., Carlsbad, CA, USA) were introduced in 2012. They are composed of a PTTM material midsection added to a titanium multi threaded self-tapping endosseous dental implant (Tapered Screw-Vent Implant, Zimmer Dental Inc., Carlsbad, CA, USA). These dental implants consist of a titanium cervical and internal core section covered by a trabecular metal shell and joined by a Ti apical section. The tapered titanium alloy (Ti-6Al-4V grade 5) used in the cervical and apical sections provides the strength of traditional dental implants, while titanium alloy and PTTM components are produced separately and laser welded.

This structure allows to achieve Osseoincorporation, a combination of osseointegration and bone in growth into the porous structure as demonstrated by *in vivo* (20-22) and *in vitro* (23) studies and by histologic testing in transcortical canine (24, 25) and human (26) models.

With respect to the conventional titanium alloy implants (27-31), the Secondary Stability is increased in PTTM dental implants, which leads to achieve better results in critical situations such as maxillofacial trauma, cleft and lip palate (32, 33) and post-oncologic patients.

This study represents the first clinical trial of PTTM dental implants in post-oncological patients and our preliminary results indicate that PTTM dental implants could have a clinical efficacy in prosthetic rehabilitation of these patients.

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