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# Prospective clinical evaluation of 273 modified acid-etched dental implants: 1- to 5- year results

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# ABSTRACT

**Aim** The aim of this study was to evaluate the implant survival and the implant-crown success of implants with surface treated with organic acids.

**Materials and methods** A total of 273 implants (Implus®, Leader-Novaxa, Milan, Italy) were inserted in 63 patients, from June 2006 to June 2010, in a single clinical centre. In each annual follow up session, clinical, radiographic and prosthetic parameters were evaluated. The implant-crown success criteria included the absence of pain, suppuration and clinical mobility, a distance between the implant shoulder and the first visible bone contact (DIB) <2.0 mm from the surgery and the absence of prosthetic restorations at the implant-abutment interface. Prosthetic restorations were 32 fixed partial prostheses, 48 single crowns and 16 fixed full arches.

**Results** the cumulative survival rate was 95.70% (93.81 maxilla, 98.24% mandible). Among the surviving implants, the implant-crown success was 96.07%. At the 5-year control, the mean DIB was 1.2 mm ( $\pm$  0.5).

**Conclusion** Implants with surface treated with organic acids seem to represent a good solution for the prosthetic rehabilitation of partially and completely edentulous patients.

KEYWORDS Dental implants; Implant surface; Implant survival; Organic acids; Surface geometry.

# **INTRODUCTION**

The high, medium and long-term success rates of prosthetic rehabilitations supported by osseointegrated

implants in partially and totally edentulous subjects has confirmed the correctness of the principles at the basis of the biological process of osseointegration, as defined by the international scientific community (1–3).

In a 5-year study on 1583 implants with different prosthetic indications, Davarpanah et al. (1) reported a cumulative implant survival of 96.5%, with a mean crestal bone loss of  $0.2 \pm 1.7$  mm. Similar results were reported by Naert et al. (2) with implants supporting fixed partial prostheses, and an implant success rate of 95% after a mean follow-up period of 6 years (2). In a recent systematic review on the 5-year survival rates of implants supporting single crowns, Jung et al. (3) reported a survival rate of 96.8%.

Titanium has excellent biocompatibility and mechanical properties, and for this reason it is the material of choice in bone implant surgery (4). After the insertion of a titanium implant, performed in respect of tissue biology and primary implant stability, the related tissue response is ankylotic with subsequent *de novo* bone formation around the alloplastic device (4, 5). This condition influences the healing processes giving a direct bone-to-implant contact with no fibro-connective tissue interposition.

Over the recent years, it has been demonstrated that the bone apposition on implant surfaces can be influenced by surface macro- and micro-topographical features, and by implant surface roughness (6, 7). The presence of a rough surface is able to accelerate the process of bone healing and promote osseointegration (6, 7). Microrough surfaces show an increased absorption of functional biomolecules from external environment and seem able to modify the cell response supporting the deposition of new bone on the implant (6-8). Many different histological studies unequivocally demonstrated that microrough implant surfaces are able to promote a greater apposition of new bone on the implant surface, promoting a rapid ostseointegration, when compared to smooth implant surfaces (8). The results of these De Franco M. et al.

histological studies were confirmed by the clinical results obtained with microrough implant surfaces, showing excellent long-term survival and success rates (1, 2, 8). Among the modern implant surfaces there are blasted or etched ones (6-9). Acid etched surfaces were introduced in order to avoid some problems caused by blasting, such as the contamination of the titanium by particles used during the blasting procedure, the different homogeneity on the blasted surfaces and the potential risk of material loss from the blasted implant, that could jeopardize the long-term clinical results (9). In general, the acid etching is obtained either with a mix of hydrochloric and sulphuric acid (HCI/H<sub>2</sub>SO<sub>4</sub>) or using a mix of hydrofluoric and nitric acid (HF/HN<sub>2</sub>) (6-9). To obtain blasted and etched implants, surfaces are first treated with materials that produce a macro-rough surface and then immersed into an acid solution producing micro-irregularities with subsequent increase of the implant surface area (6-8). A treatment option for the implant surface is represented by etching with organic acids, such as ossalic and maleic acids (9-12). This procedure results in a surface with a specific geometry represented by a sequence of repeated concavities of homogeneous and controlled dimensions (9-12). Histomorfometrical studies with organic acid etched implants on baboons showed a substantial bone apposition after a healing period of 3 months, with high bone-to-implant contact values, regardless the loading protocol (immediate loading or submerged healing) (10). In a previous comparative study on humans and baboons, the surface treated with organic acids revealed a higher bone-to-implant contact, when compared to a smooth surface (11). The presence of a repeated sequence of superficial concavities seems to be linked to the excellent results in terms of new bone apposition on the implant surface obtained by organic acid treatment (10-12).

The aim of this clinical study was to evaluate the survival and implant-prosthetic success of implants with a modified acid-etched surface obtained by organic acids treatment.

#### **MATERIALS AND METHODS**

#### Patient selection

Between June 2006 and June 2010, all patients who referred to one single clinical centre for fixed prosthetic restoration supported by dental implants were selected to take part in the present prospective clinical study. Inclusion criteria were adequate bone height and width for the placement of an implant of at least 3.3 mm in diameter and 8.0 mm in length. Exclusion criteria were: poor oral hygiene, active periodontal infections, uncontrolled diabetes, bruxism, heavy smoking habit (more than 10 cigarettes/day).

All the selected patients were fully informed about the study and signed an informed consent form for implant treatment.

Sixty-three patients (25 males and 38 females, aged between 31-78 years; average: 54.5 years) were enrolled in this study. Two-hundred and seventy three implants were placed. A total of 160 implants were inserted in the maxilla, while 113 implants were inserted in the mandible. Fifty-two implants were placed in the maxillary anterior region, while 108 implants were placed in the maxillary posterior region; 35 implants were placed in the mandibular anterior region and 78 in the mandibular posterior region. The distribution of implants by length and diameter is shown in Table 1. The most frequent indication was the restoration of partially edentulous patients, while the least frequent indication was the treatment of single tooth gaps. The prosthodontic restorations comprised 32 fixed partial prostheses (FPPs), 48 single crowns (SCs) and 16 fixed full-arch prostheses (FFAs). Each fixed full-arch prosthesis was supported by 8 implants.

#### **Implant surface**

The new BOAT implant surface (Biological Organic Acid Treatment, Implus<sup>®</sup>, Leader-Novaxa, Milan, Italy) was obtained after an organic acid treatment with a mixture of organic acids (oxalic acid/maleic acid), according to the following procedures:

- sonic bath in distilled water at a temperature of 25°C for 5 minutes to remove residuals deriving from manufacturing;
- immersion in NaOH (20 g/L) + H<sub>2</sub>O<sub>2</sub> (20 g/L) at a temperature of 80°C for 30 minutes;
- > sonic bath in distilled water at a temperature of 25°C for 5 minutes;
- acid etching in an organic mixture of 50% oxalic acid and 50% maleic acid at a temperature of 80°C for 45 minutes;
- > washing in distilled water and sonication for 5 minutes;
- > immersion for 30 minutes in a solution of 65% nitric acid and distilled water with a volumetric range of 1 to 1 at a temperature of 100°C;
- > washing in distilled water.

The organic acid treatment provided an implant surface with the mean of absolute values average of all profile points (Sa), root-mean-square of the values of all points (Sq) and the average value of the absolute heights of the five highest peaks and depths of the five deepest valleys (Sz) of 0.9, 1.1, 6.9  $\mu$ , respectively.

#### **Pre-operative examinations**

A complete examination of the oral hard and soft tissues was carried out for each patient. Panoramic radiographs formed the basis for the primary investigation, together with periapical radiographs using a Rinn alignment system (Rinn<sup>®</sup>, Dentsply, Elgin, IL, USA) with a rigid filmobject-X-ray source coupled to a beam-aiming device in order to achieve reproducible exposure geometry; where necessary, computed tomography (CT) scans were used

#### **Implant placement**

Local anaesthesia was obtained by infiltrating articaine (4%) containing 1:100.000 adrenaline (Ubistesin<sup>®</sup>, 3M Espe, St. Paul, MN, USA). A midcrestal incision was made at the sites of implant placement. The mesial and distal aspects of the crestal incision were connected to two releasing incisions. Full thickness flaps were reflected exposing the alveolar ridge, and the preparation of implant sites was carried out with spiral drills of increasing diameter (2.6 mm to place an implant with 3.3 mm diameter; 2.6 and 3.2 mm, to place an implant with 3.75 mm diameter; 2.6, 3.2 and 3.8, to place an implant of 4.5 mm diameter; an additional 4.8 mm drill was used to prepare the site for 5.5 mm diameter implants), under constant irrigation. Implants were positioned at the bone crest level. Finally, sutures were performed (Supramid<sup>®</sup>, Novaxa Spa, Milan, Italy).

#### **Post-operative treatment**

All patients received oral antibiotics, 2 g each day for 6 days (Augmentin<sup>®</sup>, Glaxo-Smithkline Beecham, Brentford, UK). Postoperative pain was controlled by administering 100 mg nimesulide (Aulin<sup>®</sup>, Roche Pharmaceutical, Basel, Switzerland) every 12 hours for 2 days, and detailed instructions about oral hygiene were given, including mouthrinsing with 0.12% chlorhexidine (Chlorexidine<sup>®</sup>, OralB, Boston, MA, USA) administered for 7 days. Suture removal was performed after 8-10 days.

# **Healing period**

A two stage technique was used to place the implants. The healing time was 2-3 months in the lower jaw and 3-4 months in the upper jaw. Second-stage surgery was conducted to gain access to the underlying implants and healing abutments were placed. In all fixed prosthetic rehabilitation protocols (fixed partial prosthesis, FPPs; fixed full arches, FFAs; single crowns, SCs), the abutments were placed and activated 2 weeks after the second surgery. Acrylic resin provisional restorations were used to monitor implant stability under a progressive load and to obtain good soft tissue healing around the implant before fabrication of the definitive restorations. The temporary restorations remained in situ for 2-3 months, and after this period definitive restorations were placed and cemented with zinc phosphate cement (Harvard<sup>®</sup>, Richter & Hoffmann, Berlin, Germany).

# Clinical and radiographic evaluation

At each annual follow up session, for each single implant, the following clinical parameters were investigated:

- > presence or absence of pain and/or sensitivity (13);
- > presence or absence of suppuration and/or

exudation;

> presence or absence of implant mobility, tested manually using the handles of two dental mirrors (13).

Moreover, intraoral periapical radiographs were taken for each implant, using a Rinn alignment system (Rinn<sup>®</sup>, Dentsply, Elgin, IL, USA) with a rigid film-object-X-ray source coupled to a beam-aiming device in order to achieve reproducible exposure geometry. Radiographs were taken at baseline (immediately after implant insertion) and at each annual follow up session, for two purposes:

- to evaluate the presence/absence of continuous peri-implant radiolucencies;
- > to measure the distance between the implant shoulder and the first visible bone contact (DIB) in mm, at the mesial and distal implant site (13). For this measurement, crestal bone level changes were recorded as changes in the vertical dimension of the bone around the implant, so that an evaluation of peri-implant crestal bone stability over time was obtained. In order to control the dimensional distortion in the radiographs, the apparent dimension of each implant (directly measured on the radiograph) was compared with the real implant length, introducing the following proportion:
  - Rx IMPLANT LENGTH : REAL IMPLANT LENGTH = Rx DEFECT : REAL DEFECT. In that way it was possible to establish, with adequate precision, the eventual amount of vertical bone loss at the mesial and distal site of the implant (13).

# **Prosthesis function**

To test prosthesis function, at each annual scheduled check, static and dynamic occlusion were evaluated, using standard occluding papers (Bausch articulating paper<sup>®</sup>, Bausch inc, Nashua, NH, USA). Careful attention was dedicated to the analysis of prosthetic complications at the implant-abutment interface (abutment loosening, abutment fracture).

#### Implant survival and implant-crown success criteria

Implants were basically divided into two categories: "survived" and "failed" implants. An implant was classified as a "survived implant" when it was still in function at the last follow up session. Indeed, implant losses and implants presenting pain upon function or clinical mobility were all included into the "failed" categories. The conditions for which implant removal could be indicated included the failure of osseointegration or infection, recurrent peri-implantitis, or implant loss due to mechanical overload. Statistical analysis was carried out with the life-table analysis described by Cutler and Ederer (14).

Among the survived implants, an implant was classified in the implant-crown success group when it fulfilled all the following clinical, radiographic and prosthetic success criteria (15):

DIAMETER LENGTH							
	8.00	10.0	11.5	13.0	Total		
3.30	14	6	4	4	28		
3.75	23	43	16	34	116		
4.50	19	32	15	32	98		
5.50	8	10	5	8	31		
Total	64	91	40	78	273		

TAB. 1 Implant distribution by length and diameter (in mm).

MAXILLA								
Months	Implants	Drop-outs	At risk	Failures	Survival	Cumulative		
0-12	160	1	159	6	96.23%	96.23%		
12-24	142	2	140	2	98.58%	94.81%		
24-36	101	1	100	1	99.00%	93.81%		
36-48	65	-	65	-	100.0%	93.81%		
48-60	20	1	19	-	100.0%	93.81%		

TAB. 3 Cumulative survival rate in the maxilla.

- > absence of pain or sensitivity;
- > absence of suppuration or exudation;
- > absence of clinically detectable implant mobility;
- > absence of continuous peri-implant radiolucency;
- > DIB < 2.0 mm from the implant insertion ;
- > absence of prosthetic complications at the implantabutment interface.

The implant-crown success was defined by all these conditions, otherwise implants were classified in a second group, defined as the compromised survival.

## RESULTS

#### Implant survival

At the end of the study, the overall cumulative implant survival rate was 95.70%, with 262 implants still in function (Table 2). In the maxilla, the cumulative survival rate was 93.81%, with 9 implants failed and removed (Table 3). In the mandible, the survival rate was 98.24%, with 2 implants failed and removed (Table 4). With regard to the position of the failed implants, 7 were in the posterior maxilla, 2 in the anterior maxilla and 2 in the posterior mandible. Eight implants failed during the first year after insertion. Among these, 6 implants were classified as "early failures", showing clinical mobility due to lack of osseointegration (4 implants) or recurrent infections with pain and suppuration (2 implants) before the connection of the abutment. Five implants were classified as "late failures", after the abutment connection, 3 showed untreatable recurrent peri-implant infections, and 2 failed because of progressive bone loss due to mechanical overloading, without clinical signs of peri-implant infection (Table 5).

OVERALL LIFE-TABLE							
Months Implants Drop-outs At risk Failures Survival Cumulative							
0-12	273	1	272	8	97.06%	97.06%	
12-24	246	3	243	2	99.18%	96.24%	
24-36	186	2	184	1	99.46%	95.70%	
36-48	96	-	96	-	100.0%	95.70%	
48-60	32	1	31	-	100.0%	95.70%	

TAB. 2 Overall life-table analysis for implant survival.

MANDIBLE							
Months	Implants	Drop-outs	At risk	Failures	Survival	Cumulative	
0-12	113	-	113	2	98.24%	98.24%	
12-24	104	1	103	-	100.0%	98.24%	
24-36	85	1	84	-	100.0%	98.24%	
36-48	31	-	31	-	100.0%	98.24%	
48-60	12	-	12	-	100.0%	98.24%	

TAB. 4 Cumulative survival rate in the mandible.

FAILURES				
Months	Mobility	linfection	Bone loss	Total
0-6	4	2	-	6
6-12	-	2	-	2
12-24	-	1	1	2
24-36	-	-	1	1
36-48	-	-	-	-
48-60	-	-	-	-
Total	7	2	2	11

TAB. 5 Overall failures during the healing and follow-up period

#### Implant-crown success

Two-hundred and sixty-two implants were still in function at the end of the study. Three patients (7 implants), however, failed to attend the annual recall visits and were classified as drop-outs. Among 255 checked implants, 245 (96.07%) were classified in the implant-crown success group. All these implants did not show pain or clinical mobility, suppuration or exudation, with a DIB <2.0 mm, and did not have any prosthetic complication at the implant-abutment interface. Only 10 implants (3.93%) were classified in the second group, among the compromised survival implants. These implants did not show any pain, suppuration, or mobility, but they had a DIB >2.0 mm; 2 of these implants had a history of exudation. At the 5-year follow up recall, the radiographic evaluation of the implants revealed a DIB of  $1.2 \text{ mm} (\pm 0.5).$ 

No complications were observed at the implant-abutment connection.

# DISCUSSION

This prospective study aimed at evaluating the implant survival and implant-crown success of implants with a surface obtained by treatment with a mixture of organic acids (oxalic acid and maleic acid). The clinical results of the present study are consistent with those reported in the literature on modern osseointegrated implants (1-3, 5-9), and support the evidence emerged in a previous work on systems with a BOAT surface (16), showing how the use of systems with surface treated with organic acids can be a safe and successful procedure. The present clinical results seem also to support previous histological and histomorphometric studies in animal models and humans, where a substantial apposition of new bone on surfaces treated with a mixture of organic acids, with high values of contact between bone and implant, regardless of the loading protocol applied (immediate loading or submerged healing) was shown (9-12). Indeed, several studies have shown, in terms of success, the high clinical predictability of implantsupported rehabilitations (1-3,5-7).

Implant survival in the international literature varies between 96% and 97% and the success rate of implantsupported rehabilitations varies between 87% and 97% after 5 years of functional loading (17). The implant survival and success criteria generally used in clinical studies are those proposed by Albrektsson in 1986 (18) and then resumed in 1989 by Smith and Zarb (19). These criteria can still be considered valid even if, more recently, additional parameters were proposed for evaluating the success of implants (20). Originally, it was perceived that an implant system could be considered valid and reliable when the overall success rate was at least 85%, 5 years after implant placement (18, 19). Subsequently, Misch has modified this percentage into 90% (5 years) and 85% (10 years) (21); finally, the same author reported that the expected implant survival and implant-crown success should be of approximately 90% (10 years) (22).

The present study shows similar results to those reported by Misch in 2005 (22), with a 95.70% cumulative overall implant survival rate.

In order to obtain a successful implant-supported prosthetic restoration, it is mandatory to consider several variables, including biological and biomechanical features at different levels, i.e. bone-implant interface, implant-abutment connection, abutment-prosthesis interface (20-22).

The literature has suggested that the implant surface geometry may affect the basic steps of osseointegration, such as fibrin clot extension (23, 24) and the creation of a favourable microenvironment for the osteoblastic activity, which is essential for osseointegration (25, 26). Implants treated with a mixture of organic acids present a surface with a peculiar geometry, characterised by a homogeneous and uniform micro and macroconcavities. This geometric structure is able to support and sustain the rapid growth of new bone, starting from the concavities (25-32).

# **CONCLUSION**

In the present clinical study, implants with surface treated with organic acids seem to represent a good solution for the prosthetic rehabilitation of partially and completely edentulous patients.

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