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# Article in The International journal of oral & maxillofacial implants · July 2017

DOI: 10.11607/jomi.5578

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# Assessment of Long-Term Survival of Immediately Loaded Tilted Implants Supporting a Maxillary Full-Arch Fixed Prosthesis

Tiziano Testori, MD, DDS<sup>1</sup>/Fabio Galli, MD, DDS<sup>2</sup>/Luca Fumagalli, DDS<sup>2</sup>/Matteo Capelli, DDS<sup>2</sup>/ Francesco Zuffetti, MD, DDS<sup>2</sup>/Matteo Deflorian, DDS<sup>2</sup>/ Andrea Parenti, DDS<sup>2</sup>/Massimo Del Fabbro, MSc, PhD<sup>3</sup>

**Purpose:** To analyze the long-term outcome of fixed prostheses supported by six implants, two of which were tilted, placed in the maxilla and immediately loaded more than 10 years earlier. Materials and Methods: A retrospective review of implants placed between May 29, 2003 and February 12, 2005 and used to support immediately loaded fixed dental prostheses in the maxilla was conducted. The features of failed implants were analyzed. In the most recent follow-up visits, survival of individual implants and prostheses was verified, and modified Plaque Index as well as modified Sulcular Bleeding Index were assessed. Patients also filled out a questionnaire requiring graded responses from 0 (poor) to 10 (excellent) that was designed to assess their quality of life. Results: A total of 162 implants were placed between May 29, 2003 and February 12, 2005 to support immediately loaded maxillary fixed prostheses of 27 totally edentulous patients (19 female, 8 male). Three patients (1 male, 2 female) dropped out, so 144 implants were followed up. Seven of the 144 original implants failed, corresponding to a survival rate of 95.1% over 10 years. All the failures occurred within 2 years after surgery. Patients' responses to the questionnaire produced an average score of 8.4 to 8.8, showing a relevant degree of satisfaction. Conclusion: Based upon this study of 27 patients who received immediately loaded maxillary full-arch fixed implant-supported prostheses supported by two tilted and four axial implants, it appears that this is a reliable procedure with a high long-term survival rate and a high level of patient satisfaction. INT J ORAL MAXILLOFAC IMPLANTS 2017;32:904-911. doi: 10.11607/jomi.5578

Keywords: immediate loading, maxilla, tilted implants, 10-year follow-up

The use of osseointegrated implants to support prostheses in partially or totally edentulous patients is an established practice.<sup>1</sup> The rehabilitation of the edentulous maxilla, nevertheless, is associated with anatomical problems due to reduced bone volume, especially in the premolar/molar zone. Among

**Correspondence to:** Dr Tiziano Testori, IRCCS Istituto Ortopedico Galeazzi, Via R. Galeazzi 4, Milan 20161, Italy. Fax: + 39 02 50319960. Email: Tiziano.Testori@unimi.it

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the possible surgical techniques utilized to overcome this problem is maxillary sinus floor elevation carried out via the crestal or lateral approach. However, this procedure is increasingly refused by patients for its invasiveness and high biologic cost.<sup>2</sup>

To maintain an acceptable level of quality of life, avoiding psychological and functional issues, patients with completely edentulous maxillae have a compelling need for the restoration of esthetics and function. For this reason, the present authors have adopted an "all-on-6" type of rehabilitation protocol for the last 12 years, which is characterized by the placement of four axial implants in the anterior region and two posterior implants inserted with a distal angulation so as to exploit the residual bone. Such configuration eliminates the need for bone augmentation and reduces the total treatment time.<sup>3</sup>

Since rehabilitation with implant-supported prostheses is considered a long-lasting treatment, it is fundamental to verify the long-term survival of this type of approach, highlighting potential differences between the survival rates of tilted and axial implants as well as the occurrence of possible complications and adverse events.

<sup>&</sup>lt;sup>1</sup>Head, Section of Implant Dentistry and Oral Rehabilitation, Dental Clinic, IRCCS Galeazzi Institute, Milan, Italy; Department of Biomedical, Surgical and Dental Sciences, University of Milan, Milan, Italy.

<sup>&</sup>lt;sup>2</sup>Research Assistant, Section of Implant Dentistry and Oral Rehabilitation, Dental Clinic, IRCCS Galeazzi Institute, Milan, Italy; Department of Biomedical, Surgical and Dental Sciences, University of Milan, Milan, Italy.

<sup>&</sup>lt;sup>3</sup>Associate Professor, Department of Biomedical, Surgical and Dental Sciences, University of Milan, Milan, Italy; Head of Section of Oral Physiology, IRCCS Galeazzi Institute, Milan, Italy.

It is also interesting to assess the quality of life of these patients more than 10 years after the rehabilitation.

The aim of this study, therefore, was to analyze the survival of both implants and prostheses in patients with maxillary fixed prostheses supported by four axial and two tilted implants and to assess the patients' quality of life after at least 10 years of function.

# **MATERIALS AND METHODS**

In this retrospective study, patients who were rehabilitated using an all-on-6 approach (insertion of six implants with the posterior two implants tilted distally) between March 1, 2003 and March 1, 2005 have been assessed after at least 10 years of function. The detailed surgical procedure has been described in a previous publication<sup>4</sup> and is outlined below.

Patients with the following characteristics were enrolled:

- Males and females of any ethnic origin, over 18 years of age
- Able to understand and sign an informed-consent form to allow the use of their clinical data in a scientific publication
- Physically and psychologically able to tolerate standard implant surgery (ASA-1 or ASA-2 according to the classification of American Society of Anesthesiologists)
- Totally edentulous maxilla
- Treatment plan involving implant placement already decided but reluctance shown to undergo bone volume augmentation
- Maxilla resorbed with at least 4 mm of residual bone height and 6 mm of width in the premolar zone where an intervention would be necessary for bone augmentation to place the implants in the posterior area

Patients with the following characteristics were excluded:

- Signs of inflammation or infection in the chosen sites to place an implant
- Systemic, uncontrolled disease (eg, diabetes)
- Radiation therapy to the head and neck 12 months prior to surgery
- Bruxism and clenching
- Suspected or ascertained pregnancy
- Drug use
- Bisphosphonate therapy
- Poor oral hygiene and motivation

According to the original protocol, all implants should have been placed with a torque  $\ge$  30 Ncm. If this wasn't possible for one or two axial implants,

immediate loading could still have been carried out on the two adjacent, stable implants. Instead, if the primary stability needed for a tilted implant, or three or more axial implants, could not be obtained, immediate loading would not have been carried out, and implants would have been allowed to heal for 2 months before proceeding with prosthesis placement. Those patients, however, were excluded from the study.

In each center, implants were placed by an experienced surgeon. The surgical procedures were of the routine type in all centers and have been described in detail elsewhere.<sup>4</sup> All procedures were carried out while the patient was undergoing antibiotic prophylaxis using amoxicillin and clavulanic acid (Augmentin, Roche). A sedative (Valium, Roche) was administered before the operation to particularly anxious patients. All patients received a local anesthetic injection of articaine 1:100,000 (Ultracain D-S Forte, Aventis Pharma Deutschland). The bone was then exposed by lifting a mucoperiosteum flap. A small antrostomy was also made with a piezoelectric tool (Piezosurgery, Mectron). Six implants were then placed in the maxilla, starting with a distal implant tilted 30 to 35 degrees with respect to the vertical plane parallel to the anterior wall of the sinus. Through the antrostomy it was possible to visually check that implants did not protrude into the sinus. Two implants were then placed axially, oriented toward the premaxillary zone parallel to the median line, starting from the more mesial and positioning the third implant more or less the same distance from the other two implants already placed. It was then checked that the insertion torque was at least 30 Ncm using the information on the surgical handpiece (W&H Elcomed, W&H Dental Werk). In most cases, the implants were placed with the platform at crestal level. The procedure was repeated contralaterally. All the implants were produced by BIOMET/3i (now Zimmer Biomet).

Within 48 hours of surgery, patients were given provisional prostheses screwed to the implants. Definitive prostheses were mounted 3 months after surgery (Figs 1 to 4). Most of the definitive prostheses (20) were porcelain-cemented restorations with a cast mesiostructure connecting all the implants on each side. In four cases, a screw-retained prosthesis fabricated with a titanium framework (CRESCO, Dentsply Implants) with acrylic resin teeth was used instead.

#### **Assessment Criteria**

A prosthesis that was supplied within the planned timeframe and whose function was maintained without complications, including failure, was considered successful; a prosthesis still in function, even with biomechanical complications requiring repairs, was considered survived. A prosthesis that had to be replaced for any reason was considered a failure.

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**Figs 1a and 1b** Preoperative extraoral view and panoramic radiograph of one of the patients included in the study. The prognosis of the remaining teeth was unfavorable. It was decided to extract the remaining maxillary teeth and prepare an immediately loaded fixed prosthesis.



**Figs 2a and 2b** Once the implants were positioned, an impression was taken with a sterile, biocompatible, and radiopaque material; a provisional screw-retained fixed prosthesis was then prepared. Postoperative panoramic clinical and radiograph intraoral view.



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**Figs 4a to 4e** Extraoral and intraoral views, panoramic radiograph, and periapical radiographs at 10 years follow-up. The porcelain incisal edge of the maxillary right central incisor fractured at 7 years; the margin was polished and the prosthesis was kept in place.

Criteria adopted to determine the survival of implants, on the other hand, are those described by Albrektsson et al<sup>5</sup> in 1986.

The peri-implant condition was assessed during routine follow-up undertaken between February 1, 2014 and February 1, 2015. The periodontal indices modified Plaque Index (mPI) and modified Sulcular Bleeding Index (mBI) were measured in the proximity of each implant. Peri-implantitis was defined as the presence of an inflammatory lesion in the peri-implant mucosa associated with plaque, bleeding on probing, and radiographic bone loss around implants exceeding conventional values.

During the observation period, mechanical complications were also recorded. They were divided into minor (chipping of the esthetic coating, loosening of screws, decementation) and major complications (implant or prosthesis fracture).

Each patient was given a questionnaire that was designed by the team (Galeazzi Quality of Life). It consisted of six questions and graded responses from 0 (poor) to 10 (excellent) to assess current quality of life (ability to speak and chew, mouth esthetics), to what degree expectations and final result of treatment correspond, and possible difficulties in carrying out oral hygiene. Patients were also asked if they would recommend the treatment to their friends and relatives, judging by the results obtained.

#### **Statistical Analysis**

Quantitative data were expressed as mean value  $\pm 1$  standard deviation (SD) or as absolute values and percentages. Comparisons were made by parametric or nonparametric tests (Pearson's chi-square), as appropriate. A *P* value of .05 was considered as the significance level.

# RESULTS

#### **Patients Enrolled**

Twenty-seven patients (19 female, 8 male) were enrolled. All implants achieved an insertion torque > 30 Ncm, and all patients were rehabilitated according to the planned protocol. By the end of the observation period, a male patient had died while two female patients had not come to the scheduled follow-ups. In total, three patients dropped out (1 male, 2 female),

Table 1Pathologies EncourMedical Histories	ble 1 Pathologies Encountered in Patients' Medical Histories						
Pathology	No. of cases						
Hypertension	4						
Type 2 diabetes	1						
Osteoporosis	1						
Hiatus hernia	1						
Congenital myopathy	1						
Parkinson's disease	1						
Angina	1						
Mild tachycardia	1						
Moderate mitral insufficiency	1						

Table 2Properties of the Implants Used in the Study							
	No. of i						
Diameter (mm)	Length (mm)	Axial	Tilted				
3.25	11.5	2	0				
4	8.5	1	0				
	10	15	2				
	11.5	19	2				
	13	29	14				
	15	24	25				
	18	0	1				
5	10	2	0				
	13	3	1				
	15	1	2				
6	10	0	1				

Table 3 Types of Implants Used in the Study						
Type <sup>a</sup>	n					
Osseotite NT	80					
Full Osseotite NT	60					
Osseotite XP NT	2					
Osseotite NT Certain	1					
Osseotite Certain IOS	1					

<sup>a</sup>All implants manufactured by Zimmer Biomet.

which reduced the number of patients considered to 24. At the time of surgery, the average age for both genders was 57 years (range: 39 to 69 years for females and 48 to 66 years for males). Interventions on average took place 11.1 years before the last follow-up visit (range: 10.0 to 12.5 years).

At the time of surgery, 16 patients (12 female, 4 male) were classified as ASA1 and 11 (7 female, 4 male)

as ASA2. The pathologies encountered when recording patients' medical histories are reported in Table 1. One patient was found to be allergic to nimesulide, whereas another was allergic to amoxicillin. In these particular cases, a special pharmacologic protocol was devised.<sup>6</sup> In the years that elapsed between surgery and follow-up, one patient had been afflicted by rheumatoid arthritis (2006) and hyperthyroidism (2014). Regarding smoking, 21 patients declared they were not smokers and 3 said they smoked under 10 cigarettes a day. Over the interval from surgery to the last follow-up, 8 patients have quit smoking.

#### **Implants and Prostheses**

For each of the 24 patients, 6 implants were placed to support prostheses in the maxilla, for a total of 144 implants. The diameters of the implants inserted were 3.25 mm, 4 mm, 5 mm, or 6 mm, with lengths of 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, or 18 mm. The most often used were  $4 \times 13$  mm for the straight placement (29 implants) and  $4 \times 15$  mm for tilted placement (25 implants).

The characteristics of the implants are shown in Table 2, and the types of implants placed are shown in Table 3. Of these, seven failed due to implant mobility or peri-implantitis, as specified in Table 4. The overall cumulative implant survival rate beyond 10 years was therefore 95.1%. Three out of seven implants that failed were tilted, representing 6.25% of the tilted implants compared with 4.17% failures for axial implants. Tilted implants did not fail significantly more than axial implants (P > .05).

Two implants in two different patients failed due to peri-implantitis (1.3% of total implants in 8.3% of patients). Five out of seven failures (71%) occurred in smokers and four out of seven (57%) in patients who had declared they smoked 10 or more cigarettes/day. One patient (who smoked more than 10 cigarettes/ day) experienced failure of two implants. Overall, longterm implant survival in 11 patients with smoking habits at the time of surgery was 92.4% (61/66 implants) as compared to 97.4% in 13 nonsmokers (76/78 implants). The difference was not significant on both the implant level (P = .16) and patient level (P = .24).

During the observation period, chipping of the esthetic coating of the prosthesis was noted in eight cases (5.6% of implants and 33.3% of prostheses) resolved with adhesives; prosthesis fracture was observed in one case (4.2% of total prostheses) and was repaired in the laboratory.

In the selected patients, the antagonists in most cases were implants (66.7%), implants in the posterior section and natural teeth from canine to canine (16.7%), or natural teeth (16.7%). In the patients with implant failures, the antagonists were always implants.

Table 4 Failed Implants During the Study Period								
Date of failure	Date of placement	Months	Site	Tilted	Size	Туре	Reason for failure	Smoker at date of failure
6/1/05	2/15/05	3	15	Yes	4  imes 11.5	Osseotite NT	Loosening	Yes, < 10/d
12/21/05	4/20/04	20	23	No	4  imes 15	Osseotite NT	Peri-implantitis	Yes, $\geq 10/d$
1/12/06ª	6/28/05	6	21	No	4  imes 13	Osseotite NT	Loosening	Yes, $\geq 10/d$
5/1/06	2/23/05	14	13	No	4  imes 15	Osseotite NT	Peri-implantitis	No
6/30/06ª	6/28/05	12	25	Yes	4 × 15	Full Osseotite NT	Loosening Not osseointegrated Tooth removed	Yes, $\ge 10/d$
12/19/06	2/21/05	21	13	No	4  imes 15	Full Osseotite NT	Loosening Not osseointegrated	Yes, $\geq 10/d$
06/16/07	10/5/05	20	26	Yes	$4 \times 13$	Full Osseotite NT	Loosening	No

<sup>a</sup>Implants failed in the same patient.

Table 5 Patients' Responses to Questionnaire on Quality of Life							
Question	Mean score	SD					
How do you rate							
your ability to chew?	8.72	0.94					
your ability to speak?	8.84	0.75					
the esthetic outcome of your prostheses?	8.80	0.96					
the ease with which you keep the prostheses clean?	8.80	0.65					
the outcome compared to your initial expectations?	8.36	1.08					
Would you recommend this type of treatment to someone close to you?	Yes (24)/No (0)						

Scores ranged from 0 (poor) to 10 (excellent).

#### Follow-up

The periodontal indices mPI and mBI assessed during follow-up sessions varied between 1 and 3 and between 0 and 2, respectively, according to the following distribution: mPI (0: 0.0%; 1: 73.53%; 2: 25.74%; 3: 0.74%), mBI (0: 69.12%; 1: 22.79%; 2: 8.09%).

#### **Quality of Life**

The assessment of various aspects of patients' quality of life, investigated via their responses to the six questions posed in the questionnaire, are reported in Table 5.

# DISCUSSION

This study verified the long-term (more than 10 years after surgery) results in 24 patients with a totally edentulous maxilla treated using an all-on-6 protocol. Among the criteria employed in similar studies, as detailed by Papaspyridakos et al,<sup>7</sup> implant loosening, bleeding, peri-implant soft tissue, Plaque Index, and prosthetic function were considered.

The long-term survival rate of implants placed only in the maxilla has rarely been reported in the literature, and it is therefore difficult to compare data obtained in the present study with other studies. Nevertheless, a survival of 95.1% obtained in this study can be compared with 98.0% of 968 implants placed in 242 patients treated with all-on-four protocol in the maxilla and evaluated up to 3 or 5 years of function.<sup>8</sup> However, it must be noted that only 24 patients achieved 5 years of follow-up in that study. Other long-term studies reported lower survival rates, such as 93.5% after 10 years in 15 patients (57 implants, of which 29 were placed in the maxilla).<sup>9</sup> In that study, however, after 10 years 50% of implants tested positive to plaque while 61% of cases had bleeding in the peri-implant sulcus. These values are considerably higher than those observed in the present cohort of patients.

Another study reported 82.9% of patients positive to plaque in the case of maxillary rehabilitation of 90 implants in totally or partially edentulous patients followed up for over 10 years.<sup>10</sup> In that study, only 1 out of 121 implants, 24 of which were immediately loaded,

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failed (after 8 years), giving a survival rate of 99.2% after 10 years.

Loosening was the main cause of implant failure in the present study (5 out of 7), which is in line with a study by Schwartz-Arad et al that investigated failure causes of 3,609 implants followed up for 8 years and found loosening to be the cause of failure in 43% of cases.<sup>11</sup> Tilted implants, however, did not fail more often than axial implants, confirming what Del Fabbro and Ceresoli and Chrcanovic et al reported in recent independent meta-analyses.<sup>12,15</sup>

In the present study, radiographic documentation at implant placement and at the last follow-up was available for less than 50% of the patients. Because this did not allow peri-implant bone level changes to be assessed for a consistent number of patients, this outcome was not presented. Other recent studies and systematic reviews have addressed this topic. Del Fabbro and Ceresoli (based on a sample of 19 articles reporting on 716 prostheses supported by 1,494 axial and 1,338 tilted implants) found that tilting of the implants had no effect on marginal bone level change as compared to axially placed implants, and the bone loss in rehabilitations supported by a combination of such implants was very limited, even after 3 or more years of loading.<sup>12</sup> Similar outcomes were reported by Menini et al,<sup>13</sup> Peñarrocha-Oltra et al,<sup>14</sup> and Chrcanovic et al,<sup>15</sup> confirming the good performance of this treatment approach.

The present study again confirmed that smoking is an important risk factor and may lead to implant failure, as also shown in a study by Abt.<sup>16</sup>

Incidence of peri-implantitis in this study was 8.3% at the patient level, well within the wide range (1% to 47%) assessed in literature, but below the 22% incidence found in a recent meta-analysis.<sup>17</sup> The value obtained in the present study is in line with the results previously obtained by the group (3.6%).<sup>18</sup> At the implant level, the rate of peri-implantitis observed in the present study was as low as 1.3% compared with 2.2% in the above-mentioned study.

It is worth highlighting that this study's low percentage of technical complications, ie, chipping or prosthesis fracture, is well under the 66.6% observed by Papaspyridakos et al after 10 years.<sup>19</sup> The reduced rate of both biologic and technical complications was probably due to the strict follow-up regimen adopted, whereby patients were recalled at least every 6 months for a check-up.

The questionnaire responses clearly showed the patients' high level of satisfaction regarding quality of life; the average score for each question was between 8.36 and 8.84. Additionally, all the patients taking part in the study said they would recommend the treatment to someone close to them. Erkapers et

al,<sup>20</sup> who assessed 51 patients treated with maxillary fixed prostheses using the immediate loading procedure, reported similar results based on their patients' responses to the Oral Health Impact Profile 49 (OHIP-49) questionnaire.

# CONCLUSIONS

Based on this study of 27 patients who received immediately loaded full-arch fixed implant-supported prostheses in the maxilla with a total of six implants per patient—two distal implants intentionally tilted toward the posterior and four axial implants—the following conclusions are made:

- Ten-year implant survival was at 95.1%.
- All implant failures occurred within 2 years of surgery.
- Most failures took place in patients who smoked 10 or more cigarettes a day at the time of surgery.
- Tilted implant performance mimicked that of axial implants.
- Patient quality of life was positively affected.
- Patient satisfaction at 10 years remained high.

# ACKNOWLEDGMENTS

The authors wish to thank Dr Daniele Venturoli for his help in data management and in preparing the manuscript. The authors declare they have no conflicts of interest related to this study.

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