Case Series

Immediate Functional Loading of Edentulous Maxilla: A 5-Year Retrospective Study of 388 Titanium Implants

Marco Degidi,* Adriano Piattelli,† Pietro Felice,† and Francesco Carinci‡

Background: *Immediate functional loading is a new surgical-prosthetic technique that can be used extensively in implant placement. Because of a lack of experimental reports regarding edentulous maxilla, we decided to evaluate the survival rate of immediately loaded dental implants in this area.*

Methods: *Forty-three patients (44.4% male) with a median age of 55 years receiving 388 implants (mean 9.0 per case) were enrolled in this study. Cross-arch acrylic provisional restorations were performed in the same stage. Data were analyzed by Kaplan-Meier product limit estimation. Stratification of implants survival was performed for the available variables of interest, and comparisons were analyzed by a log rank test. Cox algorithm was used for multivariable analysis.*

Results: *At 5-year follow-up, the crude survival rate (overall survival not stratified according to any available variable) was 98%. All failures occurred within 6 months from loading. We found differences in survival relating to: 1) implant diameter (99.37% for diameter ≤5.25 mm and 93.75% for diameter >5.25 mm); 2) number of implants (99.29% for ≤10 implants and 96.30% for >10); and 3) gender (97.08% and 99.54% for males and females, respectively). Cox regression analysis showed that diameter of implants adjusted for patient age and gender was associated to an average risk of failure (hazard rate) of 3.13 (*P *value = 0.042, 95% confidence interval 1.04 to 9.43) per mm (from 3 to 6.5).*

Conclusions: *Immediate functional loading is a reliable surgical-prosthetic procedure in edentulous maxillae. Implants with wider diameter are associated with a higher risk of failure.* J Periodontol 2005;76:1016-1024.

KEY WORDS

Dental implants; immediate loading; jaw, edentulous; maxilla; regression analysis.

For several years, submerging dental implants during the healing period was a major prerequisite to obtain implant osseointegration.[1] It was believed that micromovement of implants, due to functional forces at the bone-implant interface during wound healing, could induce the formation of fibrous tissue rather than bone, leading to a clinical failure.[1] In addition, the coverage of an implant was thought necessary to prevent infection and epithelial downgrowth.[2,3] Usually, the second surgical procedure was performed after 3 months in the mandible and 6 months in the maxilla.[4,5]

Recently, several authors have focused on the possibility of an immediate functional loading of dental implants in order to minimize the delay between surgical and prosthetic phases.[6-14] Immediate loading means placing the final or provisional prosthetic restoration immediately or within 48 hours from the surgical procedure.[14] Two types of immediate loading have been proposed: 1) the immediate functional loading (IFL) if the prosthetic crown is in occlusion and 2) the immediate non-functional loading (INFL) if the prosthetic crown is not in occlusion.[14] Several reports have shown that immediate loading can lead to clinical and histological osseointegration.[14-16]

Salama et al.[7] reported two cases in which immediate loading of titanium root-form implants was successfully used to support provisional fixed restorations in the maxilla and the mandible. Surprisingly, all immediately loaded implants were still in place at a 3-year follow-up.

Tarnow and coworkers[17] reported the effects of IFL in six completely edentulous mandible and four maxilla. Sixty-seven out of 69 immediate loaded implants had a successful outcome.

Grunder[18] reported the effect of IFL in 91 implants placed both in mandible and maxilla, 66 of which were placed immediately after tooth extraction. The author reported an overall success rate of 92.31%, after a 2-year follow-up (87.5% for maxilla and 97.26% for mandible).

Misch and Degidi[19] treated 12 edentulous maxillary arches (of which two were immediately loaded and 10 loaded after 2 weeks) inserting 108 implants. After an average follow-up period of 2.6 years, they reported an implant survival rate of 100%.

* Dental School, University of Bologna, Bologna, Italy.
† Dental School, University of Chieti, Chieti, Italy.
‡ University of Ferrara, Ferrara, Italy.

Olsson et al.[20] treated 10 patients with totally edentulous jaws. Implants were loaded after 1 to 9 days. Only four implants were lost in a follow-up period of 1 year. Previously, we evaluated implant survival both in IFL and INFL.[14] That study included 152 patients for a total of 646 immediately loaded implants. There were 422 IFL for totally edentulous patients and 224 INFL for partially edentulous subjects. After a follow-up period of 2 to 60 months, there was a 98.6% and 99% survival in cases of INFL and IFL, respectively. It was concluded in that study that immediate functional and non-functional loading is a technique that gives satisfactory results in selected cases.

Because there is a lack of reports regarding immediately functionally loaded implants in the edentulous maxilla, we decided to evaluate the outcome (expressed as implant survival) of implants immediately loaded with a cross-arch fixed temporary restoration in the edentulous upper jaw in a consecutive study population of 43 patients.

MATERIALS AND METHODS

Study Population

Forty-five patients were consecutively enrolled in this study between 1995 and 1999; all the patients presented with completely edentulous maxilla or with a residual hopeless dentition. There were 20 (44.4%) males and 25 (55.6%) females with a median age of 55 (range 42 to 80). Fifteen patients (33.3%) were smokers. A total of 388 implants were placed by the same surgeon in his private practice (MD) with a mean value of 9 implants per patient.

We chose several different types of implants to verify that the surgical procedure was not related to a specific implant surface, design, and system.

Inclusion criteria were: 1) absence of residual maxilla dentition; 2) the need for a cross-arch fixed implant-supported bridge; 3) the possibility of placing at least six implants, preferably with lengths of ≥10 mm; 4) sufficient primary stability as judged clinically; 5) absence of local inflammation; 6) absence of oral mucosal disease; 7) no history of local radiation therapy; 8) no general or local health-related contraindications for implant surgery; and 9) patient consent to the protocol.

Exclusion criteria included: 1) systemic diseases; 2) severe parafunctions; 3) drug or alcohol abuse; 4) chronic renal or liver diseases; 5) uncontrolled diabetes; 6) hemophilia, bleeding disorders, or anticoagulant therapy; 7) immunocompromised conditions, including HIV; 8) physical or psychiatric handicaps that could interfere with good oral hygiene; 9) pregnancy at time of evaluation; 10) mucosal diseases, such as lichen planus; 11) uncooperative patient; and 12) unrealistic patient expectations.

Data Collection

Before surgery, radiographic documentation was obtained by means of periapical radiography, orthopantomographs, and computerized dental scan.

In each patient, peri-implant crestal bone level was evaluated by a calibrated examination of periapical x-rays. Measures were recorded again after surgery and at each 12-month check-up. The measurements were carried out mesially and distally for each implant, calculating the distance between the edge of the implant and the most coronal point of contact between the bone and the implant and averaged for each implant and each patient. The bone level recorded just after surgery was the reference point for all the other measurements. The measurement was rounded off to the nearest 0.2 mm. A peak scale loupe with a magnifying factor of seven times and a scale graduated in 0.1 mm was used. All the measurements were made by the same examiner (MD). All 388 implants were measured six times (immediately after surgery and every year). We have been able to follow-up every implant. Peri-implant probing was not performed because controversy still exists with respect to the correlation between probing depth and implant success rates.[21,22] Implant survival rate was evaluated according to the following criteria: 1) absence of persisting pain or dysesthesia; 2) absence of peri-implant infection with suppuration; 3) absence of mobility; and 4) absence of crestal peri-implant bone resorption (<1.5 mm during the first year of loading and 0.2 mm/years during the following years).[23] When this study started, there was no available device to record torque value or resonance frequency. A general surgical unit[§] was used in this study to insert the implants.

Surgical and Prosthetic Techniques

All patients underwent the same surgical protocol. Antimicrobial prophylaxis was obtained with mouthrinses of 0.12 % chlorhexidine gluconate solution (three times a day for 7 days starting 3 days before surgery) and antibiotics (2 g per day of clavulanic acid and amoxicillin for 3 days starting 1 hour before surgery). Local anesthesia was induced by infiltration with articaine/epinephrine.

Preoperatively, a set-up of teeth in wax was done and a surgical template was prepared for each case. A cross-arch acrylic temporary empty shell was also prepared. Surgery began with a bone crest incision (sulcular incision in case of immediate extraction and implantation). In the case of post-extraction implants, the sockets were not reduced. Usually, separation beyond the mucogingival junction was avoided and osteoplasty was carried out if necessary. After identification of the implant sites, these

§ KaVo Dental GmbH, Biberach, Germany.

Table 1.

Distribution by Patients and Implants

N Patients	N Implants
2	6
4	7
8	8
15	9
7	10
5	11
2	12
43 (total)	388*

* N patients × N implants inserted per patient.

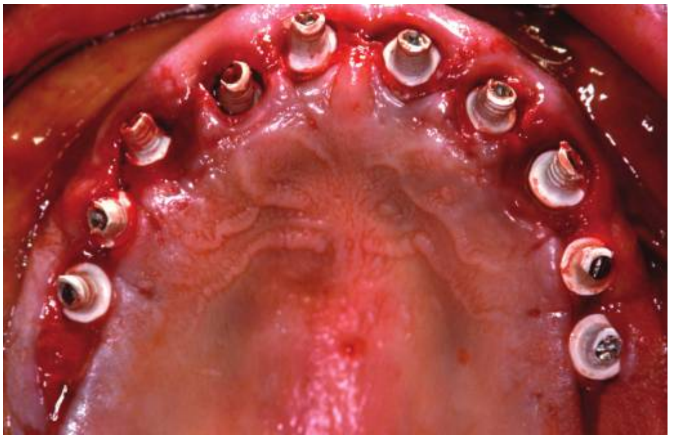

Figure 2.
Temporary abutments in place.

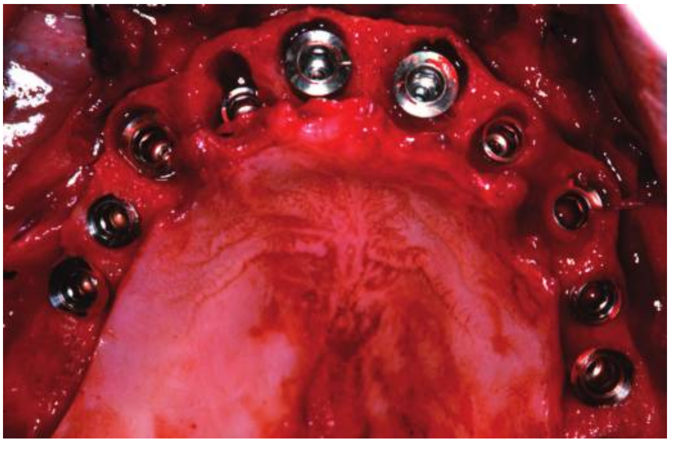

Figure 1.
Immediate extractions, immediate implant insertion.

Figure 3.
Temporary restoration in place.

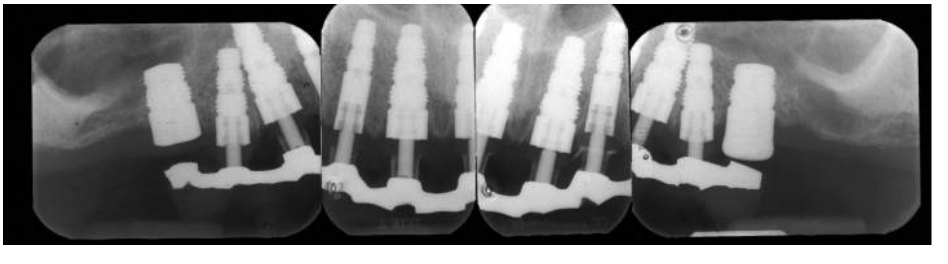

Figure 4.
Peri-apical x-ray, baseline.

were prepared using surgical templates according to protocols of each implant system: in cases of implants with platforms, these were left above the bone crest in the same manner as those implants with a collar. Implants were placed with the widest possible anterior-posterior distribution (six implants was the minimum, while the average was nine) (Table 1). Provisional abutments were then positioned, the previously prepared provisional shell was relined with acrylic, allowed to cure, trimmed, and finally cemented or screwed in place a few hours later (Figs. 1 through 4). A soft diet was recommended for a 3-week period. After a healing time of 4 to 6 months, provisional crowns were removed, implant mobility checked, and final impressions taken. A porcelain fused to metal cement-retained restoration was placed in all cases. All patients were included in a strict recall of 4 and 6 months and were reevaluated after 1, 2, 3, 4, and 5 years. (Figs. 5 through 7).

Figure 5.
Peri-apical x-ray: follow-up 3 years after implant placement.

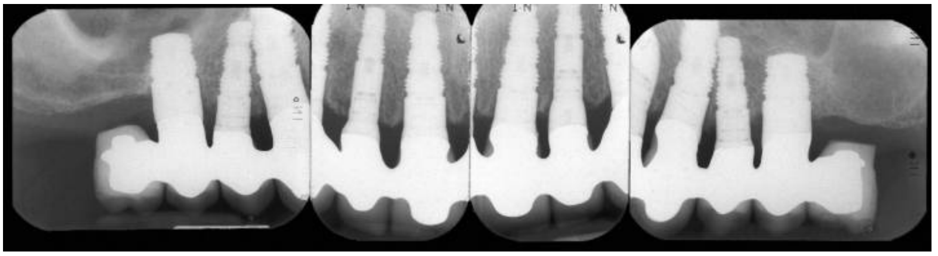

Figure 6.
Peri-apical x-ray: follow-up 5 years after implant placement.

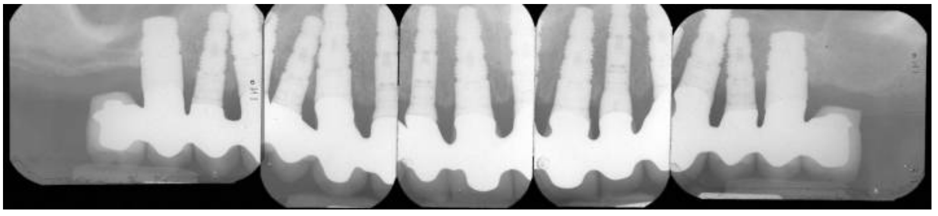

Figure 7.
Peri-apical x-ray: follow-up 8 years after implant placement.

Statistical Analysis

For statistical purposes, the 43 cases were weighted for the number of implants placed, yielding 388 measurements.

Univariate analysis. Implant survival curves were calculated according to the Kaplan-Meier product-limit estimation (Kaplan-Meier algorithm).[24] Time zero was defined as the date of the initial implant placement. Implants which were still properly placed (survived) were included in the total number at risk of failure only up to the time of their last follow-up. Therefore, survival rate changed only when failure occurred. The calculated survival curve was the "most likely" estimate ("maximum likelihood" estimate) of the true survival curve. Log rank test was used to explore the differences among the survival curves stratified for the variable of interest. The implant survival rate was evaluated by life table analysis, by using fixed cut-off points of 1 year each from 0 to 5 years.

Multivariate analysis. Cox regression analysis was then applied to determine the single contribution of covariates on survival rate. Cox regression analysis compared survival data while taking into account the statistical value of independent variables such as age and gender or whether an event (i.e., failure) was likely to occur. If the associated probability was less then 5% (P <0.05), the difference was considered statistically significant. During the regression analysis, hazard rates for each variable and 95% confidence intervals (CI) were calculated. Higher magnitudes of positive coefficients implied fewer probabilities of survival. Confidence bounds did not have to include the value 1.[25]

RESULTS

Three hundred eighty-eight implants were placed and distributed as shown in Table 1. They had a crude survival rate (overall survival not stratified according to any available variable) of 98.45% (Fig. 8).

Twenty of the 43 upper jaws were healed edentulous maxilla, while 25 had some hopeless teeth that needed to be removed. In total, 213 implants were placed in healed sites, and 175 were placed in immediate post-extraction sites.

Six implants failed and were consequently removed during the first 6 months of immediate loading. The clinical profile of failed implants is shown listed in Table 2. Implant survival rate curves were plotted according to the patient gender (Fig. 9). Probabilities of implants to survive 5 years after surgery were 97.08% and 99.54% for males and females, respectively (P value <0.05, log rank test). Figure 10 shows the 5-year survival rates in the studied groups stratified by implants diameter. Survival rates were 99.37% for diameter of implant ≤5.25 mm and 93.75% for diameter >5.25 mm (P value = 0.0009 log rank test).

The 5-year survival rates in the groups stratified by number of loaded implants (≤10 versus >10) was 99.29% and 96.30%, respectively, with an associated P value = 0.0332, log rank test (Fig. 11).

Implant length, implant surface, patient bone quality and placement in post-extraction versus healed

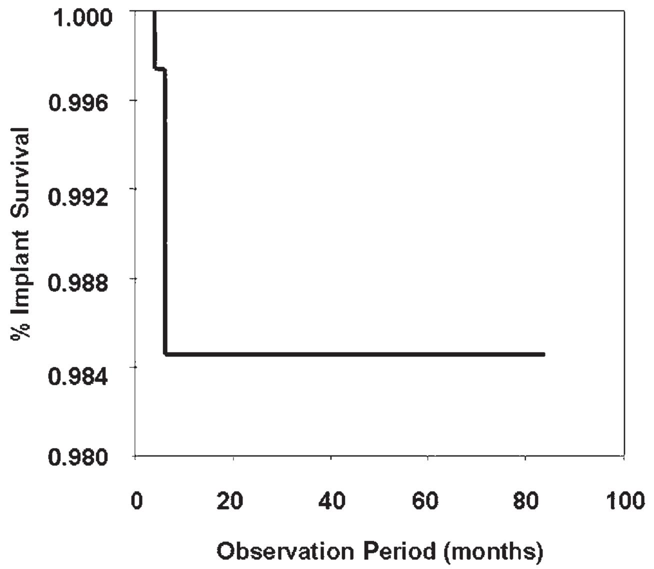

Figure 8.
Implant survival curve according to Kaplan-Meier product limit estimation: number of implants: 382; failures: 6; survival rate: 98.45%.

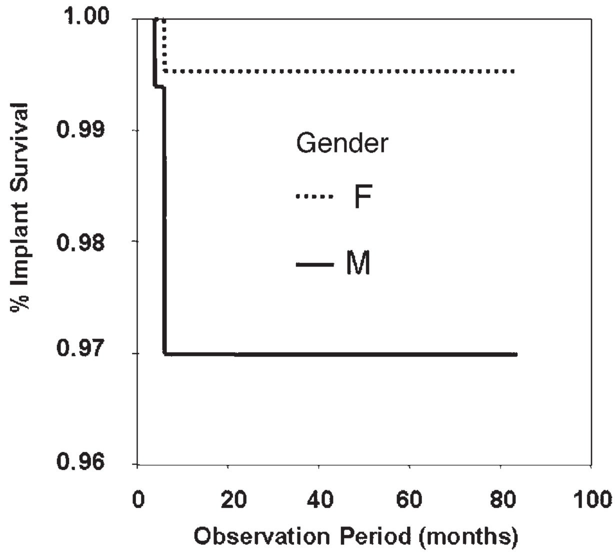

Figure 9.
Implant survival curve according to Kaplan-Meier product limit estimation: distribution for gender; P value: 0.0470, log rank test.

Table 2.
Characteristics of Failed Implant

Patient	Gender	Age	N Implants Failed	Failure Time (months)	Diameter (mm)	Length (mm)	Bone Quality*
1	Male	51	2	6.13	5.50	10	D3
2	Male	48	1	4.07	5.50	13	D3
3	Female	56	1	6.13	5.50	13	D2
4	Male	80	1	6.13	3.80	13	D2
5	Male	80	1	6.13	3.80	13	D3

* D3 = Thin porous cortical on crest, fine trabecular bone within; D2 = thick, dense to porous cortical on crest and coarse trabecular bone within.

sites did not reach significant statistical value in determining a better outcome in immediate functional loading.

Variables associated with a P value <0.05 (i.e., gender, diameter, number of implants) by log rank test were suitable for a multivariate analysis. Life-table analysis (Table 3) for crestal bone loss yielded a survival rate at 5 years of 99.7%. Analysis was performed after eliminating the six failed implants.

Table 4 presents the output of Cox regression. As shown, implant diameter and patient age reached statistically significant contribution on survival rate followed by gender (female patients have a lower risk of failure). In particular, quantitative higher diameter (in mm) and older age (in years) are associated with a poorer outcome.

DISCUSSION

High survival rates for immediately loaded implants were first documented in the middle 1980s,[26] when the one-stage implants protocol gained popularity. Babbush et al.[27] reported a cumulative survival rate of 88% on 1,739 immediately loaded titanium plasma-sprayed implants. Subsequently, many authors have shown the possibility of loading implants immediately after implant surgery with a survival rate similar to the traditional two-stage approach.[7,11,14,15,19,28-30] Over the last several years, clinical and histological results allowed development of guidelines for the long-term survival rate of immediately loaded implants.[8,9,13,14,17,31-34]

Data from the literature suggest that several factors may influence the outcome of immediately loaded implants: 1) surgery-, 2) host-, 3) implant-, and 4) occlusion-related factors.[35] The surgery-related factors comprise several variables such as an excess of surgical trauma like thermal injury,[36] bone preparation,[37] and drill sharpness and design.[38] Bone quality and quantity are the most important host-related factors,[6,8-10,39] while design,[40-42] surface coating,[6,8,43] and length[39] are the strongest implant-related factors. Finally, quality and quantity of force[44,45] and prosthetic design[7,46,47] are the variables of interest among the occlusion-related factors. All these variables are a

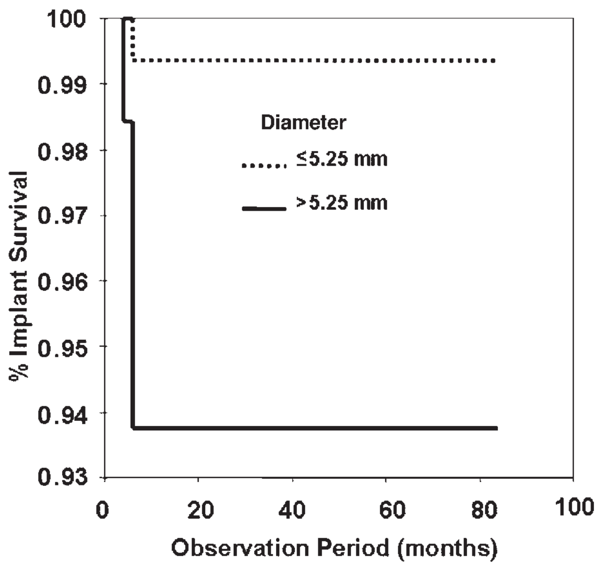

Figure 10.
Implant survival curve according to Kaplan-Meier product limit estimation: distribution for diameter; P value: 0.0018, log rank test.

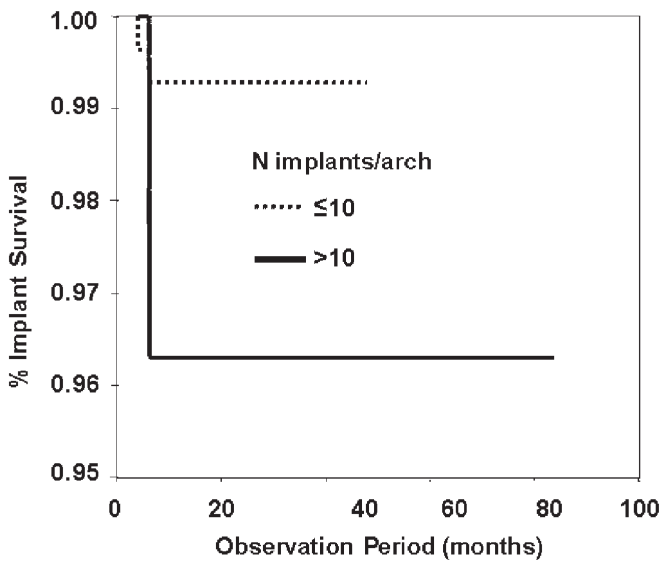

Figure 11.
Implant survival curve according to Kaplan-Meier product limit estimation: distribution for number implant/arch; P value: 0.0332, log rank test.

matter of scientific investigations because they may affect the primary stability in immediately loaded implants.

Immediate loading of implants in post-extraction sites is a current topic of discussion, because few reports have focused on this surgery-related factor. In the present study 388 implants were immediately loaded, of which 213 were inserted in healed bone and 175 in post-extraction sockets. No statistically significant differences were observed. Consequently, the immediate loading of implants inserted in post-extraction sites could be considered a predictable clinical procedure. Similar results were reported by Grunder[18] but with a shorter follow-up.

Bone quality, a host-related factor, is believed to be the strongest predictor of outcome in immediate loading. Misch[48] reported that most immediately loaded implants are placed in anatomical sites with bone quality D1 or D2. According to this author D1 is dense cortical bone, D2 is thick dense to porous cortical bone on crest and coarse trabecular bone within, D3 is thin porous cortical bone on crest and fine trabecular bone within, D4 is fine trabecular bone. It is well known that mandible (especially the interforaminal region) has a better bone quality than the maxilla, and this is probably why several studies report immediately loaded implants inserted in the mandible have a high survival rate.[11,12,26,30,41,49] Also, immediate loading of the totally edentulous maxilla has been reported with promising outcomes.[8,20,50] In this study, we did not find statistically significant differences between mandible and maxilla and we can conclude that also the maxilla is an appropriate site for immediate loading, at least in completely edentulous cases.

Additional host-related factors are age, gender, and smoking. Smoking is not an absolute contraindication for the immediate loading of dental implants, and we did not find a statistically significant adverse effect on long-term survival rate. Instead gender and age influence implant survival. The older the patient, the poorer the result, and males have an higher risk than females (Fig. 2).

Length, surface, diameter, and number are relevant implant-related factors. Tarnow et al.[17] proposed using implants longer that 10 mm in case of immediate loading. In our series, implant length and surface were not critical points for survival. Among our implant failures there were two 10 mm long and four 13 mm long with a mean value of 12 mm (Table 2). Instead, we found a different survival rate according to specific cut-off points for implant diameters (Fig. 10). Four of six failures had a diameter ≥5.25 mm (crude survival rate = 93.75%) while the remaining two had a diameter <5.25 (crude survival rate = 99.37%). These results were confirmed after adjustment for age and gender, which could be confounding factors for survival rate. Cox regression analysis (Table 4) associated a hazard rate of 3.13 as the average increased risk (CI 95%, 1.041 to 9.435) of implant loss estimated for a diameter >5.25 compared to ≤5.25 mm. To the best of our knowledge, this is the first study that associated a calculated risk to specific cut-off implant diameter in immediate loading. Previously, no critical diameter of immediately loaded implants was reported.[35] The reason that wider

Table 3.
Life-Table Analysis according to Number of Survived Implants (382)

Time (year)	N Patients Beginning of Time Interval	N Cases Lost in This Interval	% Terminating in This Time Interval	% Surviving in This Time Interval (success rate)	Cumulative % Surviving at End of Time Interval (cumulative success rate)
1	382	0	0	100	100
2	382	1*	0.26	99.7	99.7
3	381	0	0	100	99.7
4	381	0	0	100	99.7
5	381	0	0	100	99.7

* Patient with bone resorption >1.5 mm after first year of loading and >0.2 mm in subsequent years.

Table 4.
Cox Regression Output

Variable	Hazard Rate	95% CI Lower	95% CI Upper	*P* Value
Age (years)	1.071	1.003	1.143	0.041
Diameter (mm)	3.134	1.041	9.435	0.042
Female gender	0.133	0.016	1.138	0.066

diameter implants have a poorer prognosis is probably related to an inverse correlation between quality of bone and implant diameter.

Number of implants is an additional variable that has to be considered during planning. Our 5-year survival rates in the groups stratified according to number of implants loaded (≤10 versus >10) was 99.29% and 96.30%, respectively, with an associated *P* value = 0.0332, log rank test (Fig. 11). Previously, some authors proposed 10 or more implants for IFL.[18,20] Discrepancy may depend on surgical technique. Implants placed too close to each other may increase the risk of failure because of insufficient quantity of bone per implant, high drilling stress on bone per square cm, and higher probability of transmitted infection among implants. Moreover, the use of many implants increases dramatically the cost of treatment. However, a balanced distribution of implants (and forces) over the long alveolar arch, maximizing the anterior-posterior distance between them is of paramount importance in immediately loaded edentulous maxillae. Our result suggests that immediate/early loading may be considered for patients treated with eight or nine implants (in our case series the mean was 8.6) distributed from second molar to second molar.

Finally, we reported a high survival rate at the 5-year follow-up (Table 3) by using crestal bone loss as a variable. We had just one failure (a patient with bone resorption >1.5 mm after the first year of loading and >0.2 mm from the second year on. Cumulative survival rate at the end of 5 years was 99.7%. We can conclude that IFL gives stable results over time.

In conclusion, in this study we have shown that IFL is a reliable surgical procedure in completely edentulous maxilla. The overall success rate was high and stable over time. Post-extraction IFL is possible and has results comparable with IFL in healed sites. Bone quality and smoke are not major limiting variables, nor is implant length or surface. Diameter cannot always compensate for bone quality, and a precise planning of implant positioning is probably the most critical point for a successful oral rehabilitation.

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Correspondence: Prof. Adriano Piattelli, Via F. Sciucchi 63, 66100 Chieti, Italy. Fax: 39-0871-3554076; e-mail: apiattelli@unich.it.

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