Parallel Screw Cylinder Implants: Comparative Analysis Between Immediate Loading and Two-Stage Healing of 1005 Dental Implants with a 2-Year Follow Up

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ABSTRACT

Background: Recently, several authors have focused on the possibility of an immediate functional loading of dental implants to minimize the delay between surgical and prosthetic phases.

Purpose: The aim of this study was a reevaluation of the XiVE® dental implant (Dentsply-Friadent, Mannheim, Germany) with: (1) a longer follow-up period; (2) a higher number of fixture; and (3) a proper statistical method.

Materials and Methods: In July 2001 and December 2002, 371 patients (180 males and 191 females; ages ranging from 17 to 83; mean age, 53 years) were consecutively enrolled in this study. In 371 patients, a total of 1005 XiVE dental implants were distributed as follows: 484 immediately loaded implants (test group) were inserted in 130 patients, whereas 521 unloaded implants were inserted in 241 patients (control group).

Results: The implant survival was 98.7 and 99.4% in immediate loading and control group, respectively. Univariate analysis showed no statistically significant difference between the two groups.

Conclusion: In a previous report, we showed that immediate loading offered a predictable and reliable procedure also for XiVE implants, at least in the short period. In this study, we confirmed the results of the previous study and added information regarding the survival rate and marginal bone level stability with a 2-year follow up.

KEY WORDS: dental implants, immediate loading, implant failures, implant survival, Kaplan-Meier algorithm

For several years, to submerge dental implants during the healing period was a major prerequisite to obtain implant osseointegration.[1] It was believed that the 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 also 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 (IFL) of dental implants to minimize the delay between surgical and prosthetic phases.[6–14] Immediate loading means to place 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 IFL if the prosthetic crown is in occlusion; and (2) the immediate nonfunctional loading 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]

Immediate loading has been documented to be a successful procedure with several implant system.

In a previous report,[17] we have shown that immediate loading offers a predictable and reliable procedure also for XiVE® dental implants (Dentsply-Friadent,

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Mannheim, Germany), at least in a short period. Because it has been demonstrated that marginal bone level resorption rate is related to the implant type,[18] we therefore decided to reevaluate the XiVE implant with: (1) a longer follow-up period; (2) a higher number of fixture; and (3) a proper statistical method.

MATERIALS AND METHODS

Patients

In July 2001 and December 2002, 371 patients (180 males and 191 females; ages ranging from 17 to 83; mean age, 53 years) were consecutively enrolled in this study. The protocol was approved by the ethics committee of our university and a written informed consent was obtained from each patient.

The inclusion criteria were controlled oral hygiene, the absence of any lesions in the oral cavity, sufficient residual bone volume to receive implants of at least 3.4 mm in diameter and 9.5 mm in length, resonance frequency analysis (RFA) values >60 implant stability quotient (ISQ) recorded at the time of insertion, and implant insertion torque (IIT) >25 Ncm; in addition, the patients had to agree to participate in a postoperative control program.

The exclusion criteria were insufficient bone volume, bone quality type D4, a high degree of bruxism, smoking more than 20 cigarettes per day and excessive consumption of alcohol, localized radiation therapy of the oral cavity, antitumor chemotherapy, liver diseases, blood diseases, kidney diseases, immunosupressed patients, patients taking corticosteroids, pregnant women, inflammatory and autoimmune diseases of the oral cavity, poor oral hygiene, RFA <60, and IIT <25 Ncm.

Data Collection

Before surgery, radiographic examinations were done with the use of periapical radiography, orthopantomograph, and computerized axial tomography scan. In the follow-up period, periapical radiographs were used.

In each patient, the peri-implant crestal bone level was evaluated by calibrated examination of periapical x-rays. Measures were recorded after surgery and after a 12-month time period. The measurements were carried out mesially and distally to each implant, calculating the distance between the edge of the implant and the most coronal point of contact between the bone and the implant. The bone level recorded just after the surgical insertion of the implant was the reference point for the following measurements. The measurement was rounded off to the nearest 0.1 mm. A Peak Scale Loupe® (AP Photo Industries, S.L. Spain) with a magnifying factor of 7× and a scale graduated in 0.1 mm was used. All measurements were made by three independent examiners.

Peri-implant probing was not performed because a controversy still exists regarding the correlation between probing depth and implant success rates.[19,20] The implant success 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 persisting peri-implant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm/year during the following years.[21]

Implants

In 371 patients, a total of 1005 XiVE dental implants (Dentsply-Friadent) were distributed as follows: 484 immediately loaded implants (test group) were inserted in 130 patients, whereas 521 unloaded implants were inserted in 241 patients (control group). One hundred one implants did not meet the inclusion criteria and were therefore excluded (48 in the test group and 53 in the control group).

The implant distribution is reported in Tables 1 and 2. Figures 1–4 show the RFA, ISQ, implant diameter, and implant length of immediately loaded implants, while Figures 5–8 in the control implants.

Surgical and Prosthetic Technique

All patients underwent the same surgical protocol. Antimicrobial prophylaxis was obtained with amoxycillin 500 mg twice daily for 5 days starting 1 hour before surgery. Local anesthesia was induced by infiltration with articaine/epinephrine and postsurgical analgesic treatment was performed with Nimesulide™ (Merck Generics Italy, Milano, Italy) 100 mg twice daily for 3 days. Patients had a soft diet for 4 weeks and oral hygiene instructions were provided.

After a crestal incision, a mucoperiosteal flap was elevated. The implants were inserted according to the procedures recommended[17] (Figures 9 and 10). The implant platform was positioned slightly above the alveolar crest. In case of immediate loading, a temporary

TABLE 1 Distribution of the Immediately Loaded Implants

	Number of Cases	Number of Implants	Number of Failures	Success of Implants (%)	Number of Failures of Prosthetic	Success of Prosthetic (%)
Single		32	1	96.7	1	96.7
Edentulous mandible	19	110	0	100	0	100
Edentulous maxilla	24	187	4	97.8	0	100
Anterior mandible	15	37	0	100	0	100
Posterior mandible	19	63	1	98.4	0	100
Anterior maxilla	7	16	0	100	0	100
Posterior maxilla	14	39	0	100	0	100
Total	130	484	6	98.7	1	99.7

TABLE 2 Distribution of the Control Implants

	Number of Cases	Number of Implants	Number of Failures	Success of Implants (%)	Number of Failures of Prosthetic	Success of Prosthetic (%)
Single	96	96	2	97.9	2	97.9
Edentulous mandible	4	18	0	100	0	100
Edentulous maxilla	3	24	0	100	0	100
Anterior mandible	8	19	0	100	0	100
Posterior mandible	75	204	0	100	0	100
Anterior maxilla	10	27	1	96.3	0	100
Posterior maxilla	45	133	0	100	0	100
Total	241	521	3	99.4	2	99.1

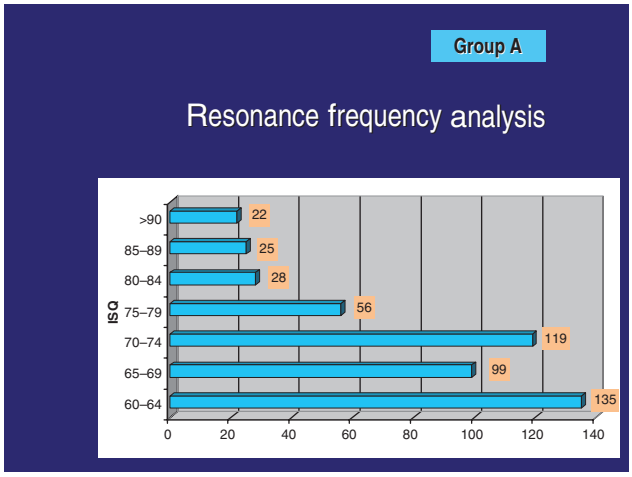

Figure 1 Resonance frequency analysis in immediately loaded implants. ISQ = implant stability quotient.

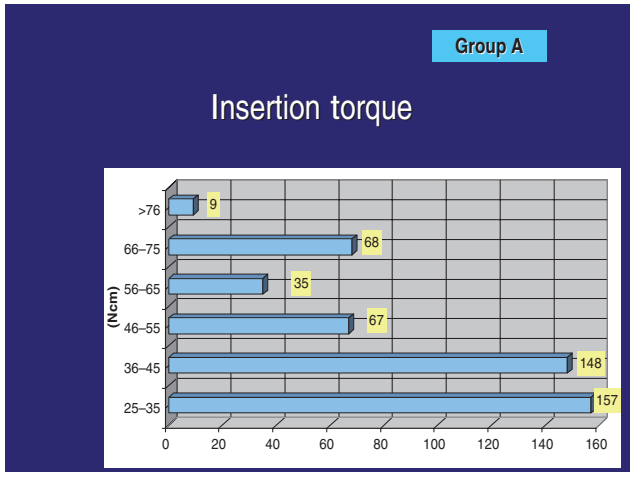

Figure 2 Insertion torque in immediately loaded implants.

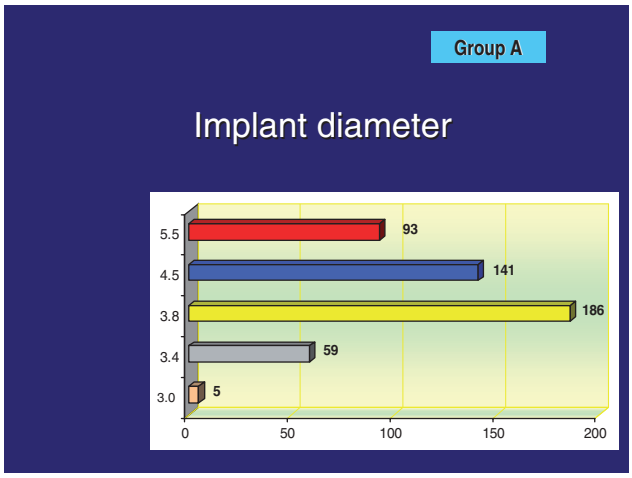

Figure 3 Implant diameter in immediately loaded implants.

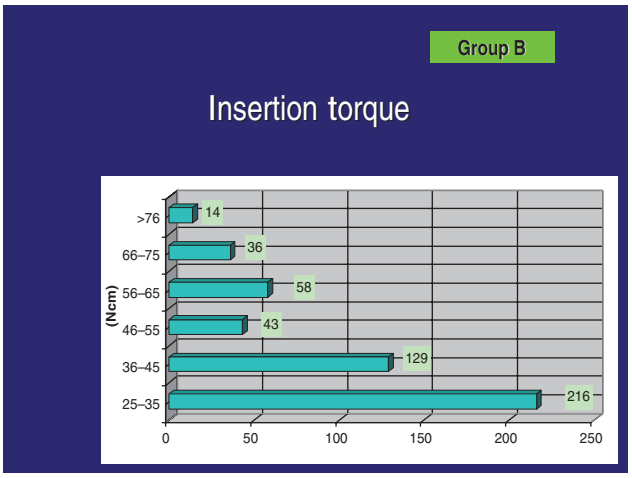

Figure 6 Insertion torque in control implants.

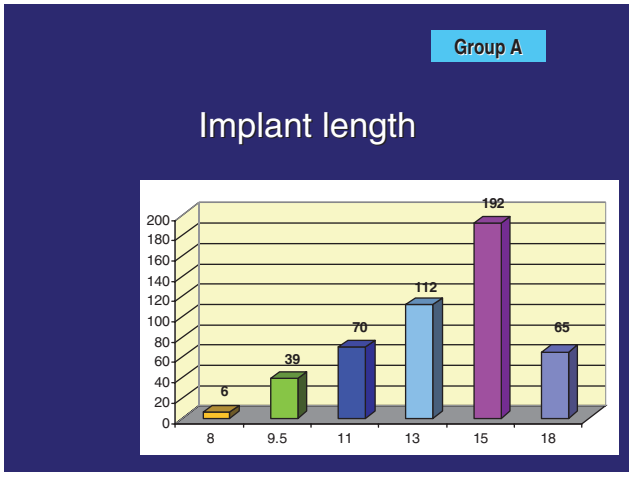

Figure 4 Implant length in immediately loaded implants.

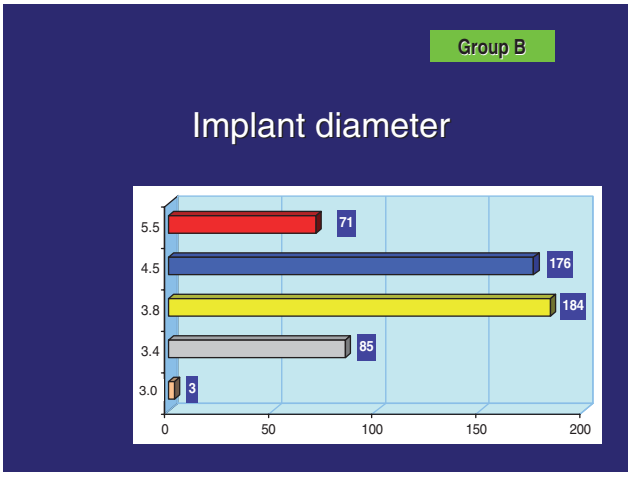

Figure 7 Implant diameter in control implants.

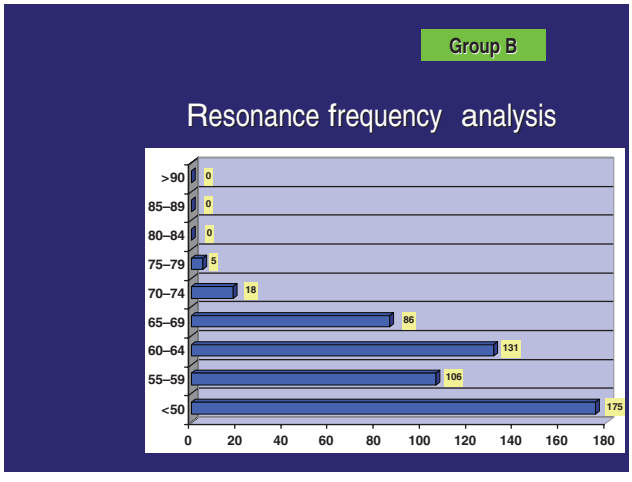

Figure 5 Resonance frequency analysis in control implants.

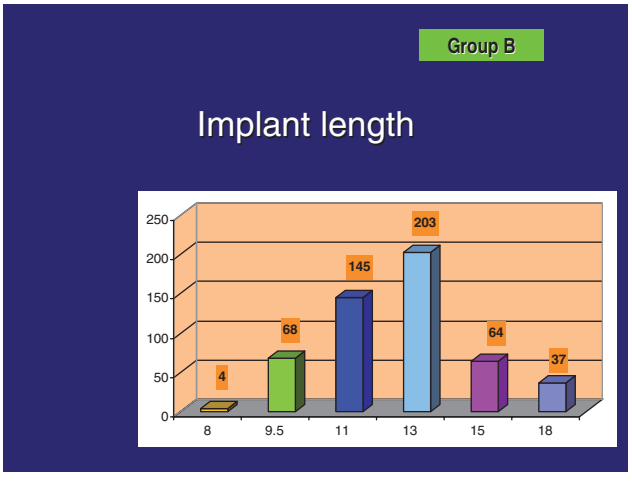

Figure 8 Implant length in control implants.

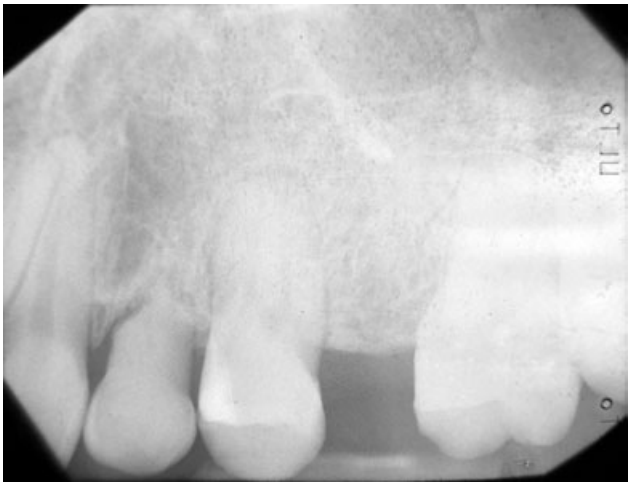

Figure 9 Preoperative periapical x-ray.

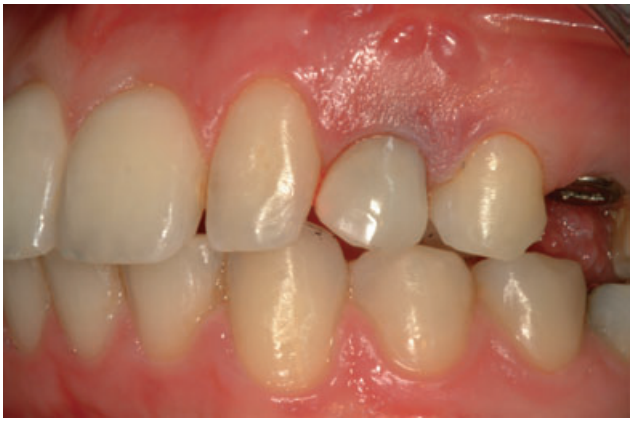

Figure 12 Immediate temporary restoration (cuspid test) and one-stage healing (premolar – control).

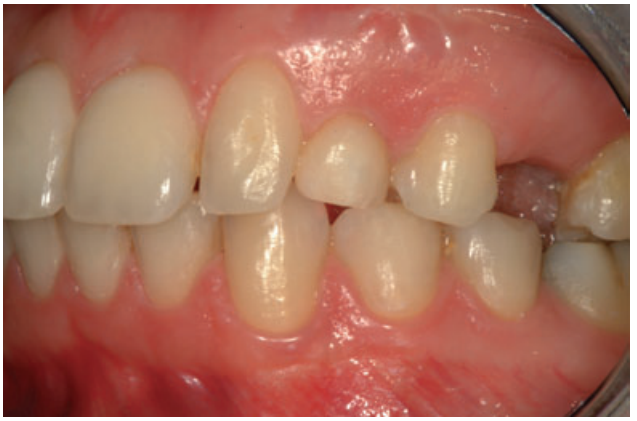

Figure 10 A deciduous mobile upper cuspid and missing second premolar.

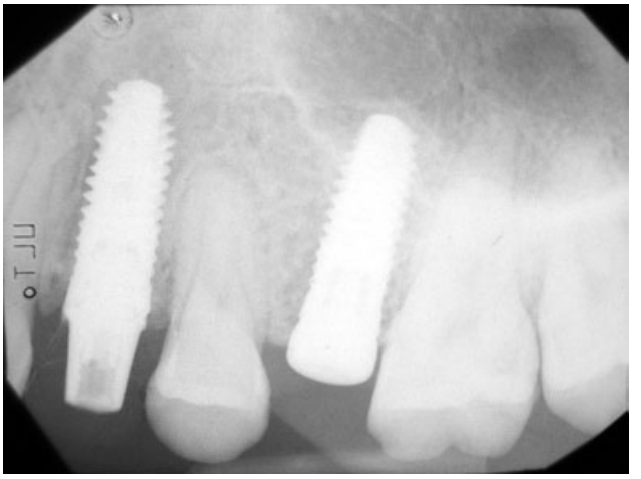

Figure 13 Postoperative periapical x-ray.

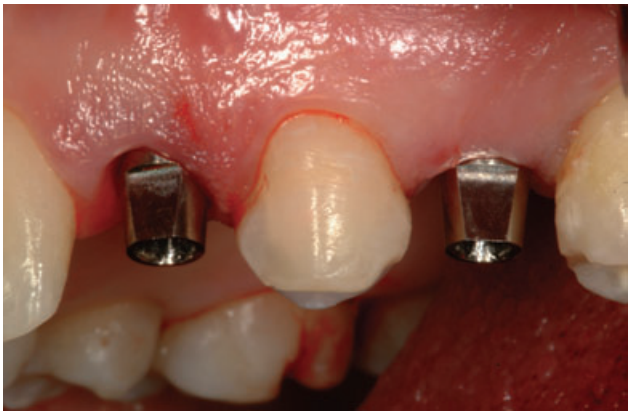

Figure 11 Implants in place.

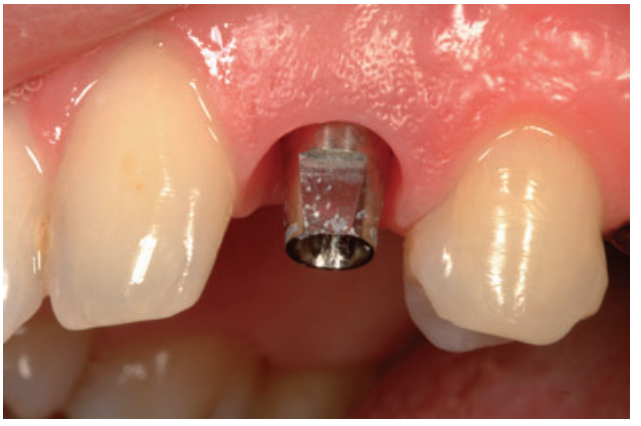

Figure 14 Soft tissues 6 months later.

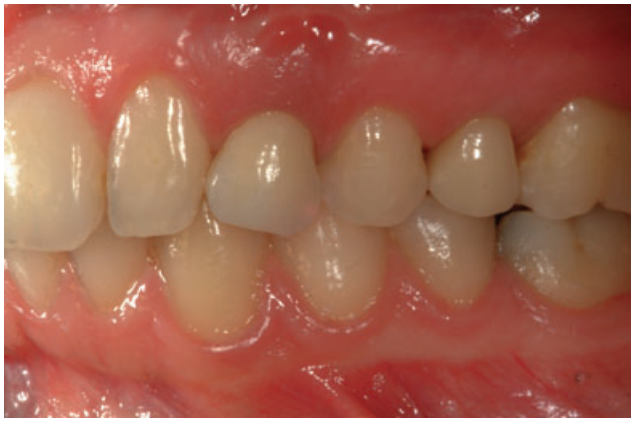

Figure 15 Final restoration.

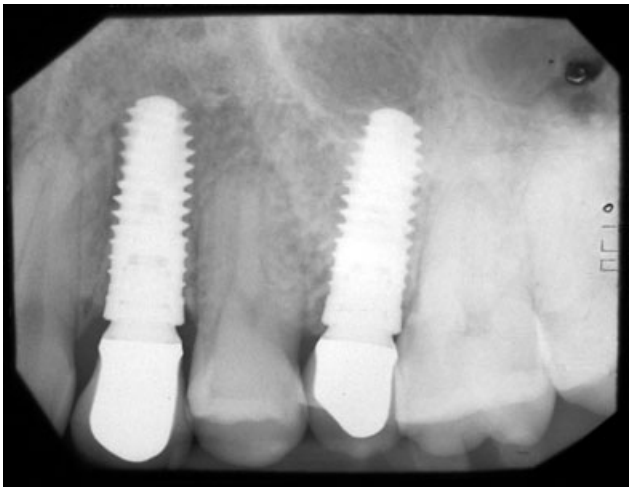

Figure 17 Periapical x-ray 2 years after loading.

restoration was relined with acrylic, trimmed, polished, and cemented or screw-retained 1–2 hours later (Figures 11 and 12). Occlusal contact was avoided in centric and lateral excursions. After the provisional crown placement, a periapical radiograph was impressed by means of a customized Rinn® (Elgin, IL, USA) holder device (Figure 13). This device was necessary to maintain the x-ray cone perpendicular to a film placed parallel to the long axis of the implant. Sutures were removed 14 days after surgery. After 24 weeks from implant insertion, the provisional crown was removed (Figure 14) and a final impression of the abutment was recorded by using a polyvinylsiloxane impression material. The final restoration was always cemented and was delivered approximately 32 weeks after implant insertion (Figures 15–17). All patients were included in a strict hygiene recall.

Statistical Analysis

Univariate Analysis. The survival curves of the implants were calculated according to the product-limit method (Kaplan-Meier algorithm).[22] *Time zero* was defined as the date of the initial placement of the implants. Implants that were properly placed (survived) were included in the total number of at risk of failure only up to the time of their last follow up. Therefore, the success rate changed only when a failure occurred. The calculated survival curve was the 'most likely' estimate ('maximum likelihood' estimate) of the true success curve. Log rank test was used to explore the differences among the survival curves stratified for the variable of interest. The success rate of the implants was evaluated by life table analysis, by using fixed cut-off points of 1 year each from 0 to 2 years.

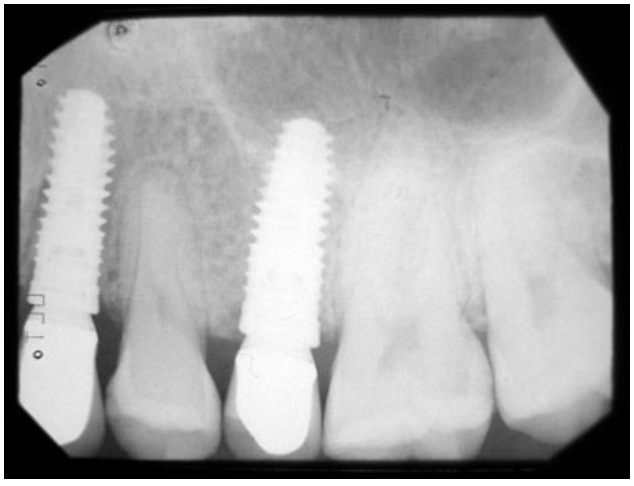

Figure 16 Periapical x-ray 1 year after loading.

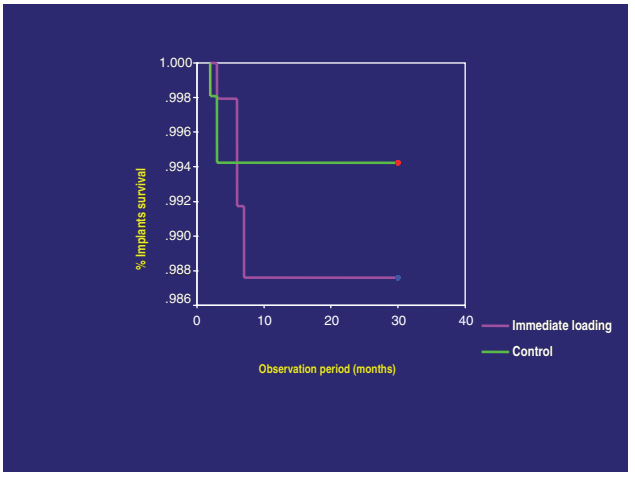

Figure 18 Univariate analysis of the differences between the two groups.

TABLE 3 Statistical Analysis: Implant Survival Curve According to Kaplan-Meier Algorithm

	Total	Number of Events	Number of Censored	Censored (%)
Control	521	3	518	99.42
Immediate loading	484	6	478	98.76
Overall	1005	9	996	99.10
$p = .2670$, log rank test				

TABLE 4 Failures in Immediately Loaded and Control Implants

Group A

	Load	Bone Quality	Bone Quantity	Ø Implant	Implant Length	Location	Primary Stability	Abutment
PT 1	INFL	D4	A	4.5	15	23	No	Acrylic
PT 2	INFL	D3	A	4.5	13	35	Yes	Titanium
PT 3	IFL	D2	A	3.8	13	24	Yes	Titanium
PT 3	IFL	D3	A	3.8	13	26	Yes	Titanium
PT 4	IFL	D4	A	5.5	15	23	Yes	Titanium
PT 5	IFL	D3	A	4.5	11	37	Yes	Titanium

Nasal-Sinus Perforation	Type of Restoration	Age	Sex	Parafunction Habits	Extraction Site	Months Since Loading	Last Drill	Torque	Smoker
Yes	FTB Cemented	31	F	No	Yes	3	3.8	10	No
Yes	FTB Cemented	52	F	No	Yes	7	4.5	63	No
Yes	FTB Cemented	77	F	No	No	6	3.8	30	No
Yes	FTB Cemented	77	F	No	No	6	3.8	30	No
Yes	FTB Cemented	68	M	No	Yes	6	5.5	45	No
No	FTB Cemented	65	M	No	No	7	4.5	45	No

Group B

	Load	Bone Quality	Bone Quantity	Ø Implant	Implant Length	Location	Primary Stability
PT 1	Control	D2	A	4.5	13	11	Yes
PT 2	Control	D4	A	5.5	13	18	Yes
PT 3	Control	D2	A	3.8	11	22	Yes

Abutment	Nasal-Sinus Perforation	Age	Sex	Extraction Site	Months Since Loading	Torque	Smoker
Titanium	Yes	38	F	Yes	6	35	Yes
Titanium	Yes	50	M	No	6	18	No
Titanium	Yes	49	F	No	6	21	No

FTB = fixed temporary bridge; IFL = immediate functional loading; INFL = immediate nonfunctional loading.

RESULTS

The implant survival was 98.7 and 99.4% in the immediately loaded and control groups, respectively (see Tables 1 and 2).

Univariate analysis showed no statistically significant difference between the two groups (Table 3 and Figure 18).

Table 4 shows the failed implants of the immediately loaded and control groups.

The implant success rate (corresponding to the absence of persisting peri-implant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm/year during the following years[21] was 99.7 and 99.1% in immediately loaded and control groups, respectively (see Tables 1 and 2). No statistically significant difference between the two groups was present. The mean marginal bone loss was 0.7 and 0.6 mm at 12 months, and 0.9 and 1.0 mm at 24 months in immediately loaded and control groups, respectively.

DISCUSSION

Patients are increasingly concerned with aesthetic considerations, and thus increasingly ask for immediately loaded implants. A strict observance of established guidelines is fundamental to achieving the desired results.

Immediate loading has been successfully used in totally edentulous patients to avoid removable prostheses in the healing phase.[23–24] Later, excellent results have been reported for immediately loaded implants in cases of partial edentulism.[25] Immediate implant restoration seems to be a reliable treatment.[26,27]

Our results demonstrated no significant statistical difference between immediately loaded and control group survival, and the mean value was above 99%. This high success may be predicted in the control group as it is comparable to the current literature regarding the one- or two-stage procedure. The comparable survival rate of immediately loaded XiVE implant may be attributed to several factors such as fulfillment of the inclusion criteria and implant design that provide an increased primary stability compared to others.

As for the failures, in the immediately loaded implants, in five out of six cases during the implant site preparation, there was most likely a rupture of the sinus and/or nasal cavity membrane lining. It is our opinion that this complication in itself represents a serious deviation from the implant protocol for immediate loading and as such, should be considered a contraindication for this procedure. This aspect was not considered and consequently led to implant failure.

The immediate loading of implants in post-extraction sites increases the risk for failure most likely due to residual infection.[27] It is likely that bacterial contamination of the implant site, due to the presence of the periodontal pocket, could be the principal reason for the failures that were encountered in these cases.[28] De Bruyn and Collaert[28] observed in their statistics of 184 implants in 36 patients that of the 153 implants that were inserted in mature bone, there was only one failure (0.7%), while 12 of the 31 implants placed in post-extraction sites failed (39%). This finding is certainly significant considering that, in our series, all three implants that had failed had been immediately placed into extraction sockets. Furthermore, in two cases, there was a poor bone quality that is a protocol deviation.

In the implants of the control group, the main reason of the failures was a nasal sinus floor perforation.

The implant success rate (corresponding to the absence of persisting peri-implant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm/year during the following years[21]) was 99.7 and 99.1% in the immediately loaded and control groups, respectively (see Tables 1 and 2), and no statistically significant difference between the two groups was detected. The mean marginal bone loss was 0.7 and 0.6 mm at 12 months, and 0.9 and 1.0 mm at 24 months in the immediately loaded and control groups, respectively.

CONCLUSION

In a previous report,[17] we have shown that immediate loading offered a predictable and reliable procedure also for the XiVE implants, at least in the short period. In this study, we confirmed the results of the previous study and added information regarding the survival rate and marginal bone level stability with a 2-year follow up.

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