

Comparative Analysis Study of 702 Dental Implants Subjected to Immediate Functional Loading and Immediate Nonfunctional Loading to Traditional Healing Periods with a Follow-up of up to 24 Months

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Purpose: The aim of this study was to clinically evaluate immediate functionally loaded (IFL) and immediate nonfunctionally loaded (INFL) implants for various indications compared to a control group with a conventional healing period. **Materials and Methods:** Two hundred fifty-three patients took part in the study. A total of 702 XiVE implants (Dentsply/Friadent, Mannheim, Germany) were placed: 253 IFL implants, 135 INFL implants, and 314 controls. **Results:** In each of the 3 groups, 2 implants failed. For all the other implants involved, from a clinical and radiographic point of view, osseointegration was successful. **Discussion:** As long as the prerequisites are fulfilled, immediate functional loading and immediate nonfunctional loading are predictable techniques, not only in completely edentulous patients but also in partially edentulous patients. **Conclusion:** Immediate functional loading and immediate nonfunctional loading appear to be techniques that can provide satisfactory implant success rates in selected cases. INT J ORAL MAXILLOFAC IMPLANTS 2005;20:99–107

Key words: immediate functional loading, immediate nonfunctional loading, primary stability

A healing period of approximately 4 to 6 months without loading has been a traditionally accepted protocol for obtaining mineralized bone at the dental implant interface.¹ These healing periods have never been determined experimentally. It was believed that premature loading of the implant could induce the formation of fibrous connective tissue instead of bone at the implant interface.² However, many studies have shown that, under the right conditions, satisfactory results can be achieved with a shorter loading period or immediate loading.

Immediate loading means delivering a prosthetic restoration (temporary or definitive) at the same time the implant is placed, or within 48 hours following surgery.³ Thus, fewer surgeries are necessary, and the risk of morbidity is lower. The patient is able to obtain an acceptable esthetic result during the entire treatment period, and functional rehabilitation is improved.^{4,5} The potential disadvantages are higher costs, with more chairtime and a larger number of components for provisional restorations, as well as the risk of overloading the bone-to-implant interface.

Immediate functional loading (IFL) refers to the use of a temporary or definitive prosthesis seated the same day as the surgery or shortly thereafter, supported by an adequate number of implants, in occlusal contact with the opposing arch.³

In cases where *immediate nonfunctional loading* (INFL) is used, a temporary or definitive prosthesis is delivered the same day as the surgery, supported by an adequate number of implants, but this prosthesis is *not* in occlusal contact with the opposing arch.³

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Fig 1 The characteristic design of the XiVE implant.

The INFL technique (temporary prostheses out of occlusion) combines the advantage of a single-stage procedure with those of immediate loading. In these cases the temporary restorations, not being in occlusion, serve primarily for esthetics and to guide the sculpting of the soft tissues.^{3,6} With respect to IFL, this technique has the advantage of reducing the risk of biomechanical overloading because of para-functional habits.³

In 1990, Schnitman and associates⁷ treated 10 patients with edentulous mandibles, comparing the immediate loading technique to that of the conventional one. Of the 63 Brånemark System implants (Nobel Biocare, Göteborg, Sweden) placed, 28 were used to support a temporary fixed prosthesis. The remaining 35 were left submerged. After 10 years of follow-up, no failures were recorded in any of the 35 submerged implants, while 4 of the immediately loaded implants had failed (survival rate of 85.7%). Balshi and Wolfinger⁸ reported on 10 patients with completely edentulous mandibles restored with 130 Brånemark System implants. Some were loaded immediately,⁴ while others were left submerged⁹ in such a way that the provisional fixed prosthesis was supported by only 4 implants. After a follow-up of 12 to 18 months, it was reported that with premature loading, only 80% of the implants were still clinically stable, while with the conventional technique, the survival rate was equal to 95.6%. They concluded that, on average, immediately loaded implants had a lower mean survival rate. In 1997 Tarnow and colleagues⁹ published a study on 107 implants in 10 patients using both the immediate loading and tra-

ditional techniques. Sixty-seven of the 69 implants that were immediately loaded appeared to be clinically osseointegrated, as were 37 of 38 submerged implants.

In cases where the implant was loaded earlier, highly mineralized bone tissue, not fibrous tissue, was found at the implant interface.¹⁰⁻¹⁵ High primary stability of the implants permits better bone regeneration and peri-implant tissue differentiation.¹⁶⁻²²

More recent human studies on immediately loaded implants have found that there was close contact between mineralized bone and the implant surface, with no fibrous tissue at the interface.²³⁻²⁸ The object of the present study was to clinically evaluate a new implant, the XiVE implant (Dentsply/Friadent, Mannheim, Germany) (Fig 1). Two groups of implants were loaded using the IFL and INFL techniques and compared to a group treated with traditional healing periods (the control group).

MATERIALS AND METHODS

In the period between July 2001 and July 2003, 253 patients (106 men, 147 women) between the ages of 20 and 78 (median 53) were consecutively enrolled in the study on the basis of the following criteria:

- Inclusion criteria: Controlled oral hygiene, the absence of any lesions in the oral cavity, sufficient residual bone volume to receive implants at least 3.5 mm in diameter and 9.5 mm in length, and implant placement torque > 25 Ncm, willingness to participate in a postoperative control program
- Exclusion criteria: Insufficient bone volume, type 4 bone,²⁹ a high degree of bruxism, smoking more than 20 cigarettes/day, excessive consumption of alcohol, localized radiation therapy of the oral cavity, chemotherapy, liver pathologies, blood diseases, kidney diseases, immunosuppression, taking corticosteroids, pregnancy, inflammatory and autoimmune diseases of the oral cavity, poor oral hygiene, implant placement torque ≤ 25 Ncm.

In 253 patients, a total of 702 implants were distributed in the following manner: 253 implants in 34 patients were placed using IFL, 135 implants in 63 patients were placed using INFL, and 314 control implants in 156 patients were placed using the traditional technique (1- or 2-stage procedures). Implant distribution according to length and diameter is reported in Figs 2 and 3.

In the IFL group 14 edentulous mandibles with 92 implants and 20 edentulous maxillae with 161 implants were treated. The INFL group consisted of

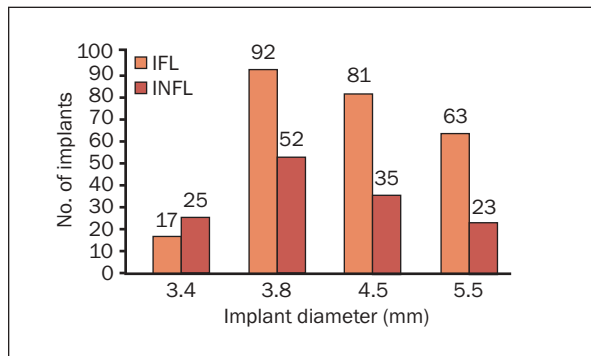


Fig 2 Implant distribution according to diameter.

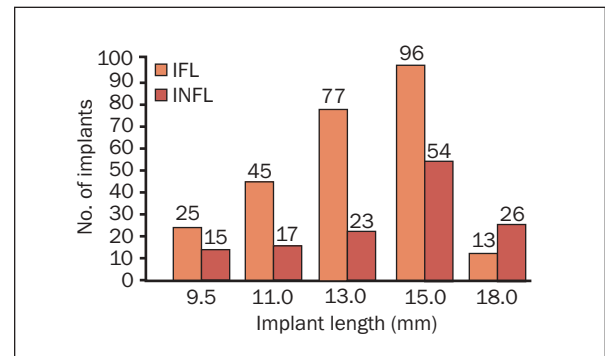


Fig 3 Implant distribution according to length.

10 anterior mandibles (25 implants), 16 posterior mandibles (50 implants), 6 anterior maxillae (14 implants), and 9 posterior maxillae (24 implants). An additional 22 single implants were placed and immediately restored out of occlusion. In the control group, 5 anterior mandibles (13 implants), 47 posterior mandibles (131 implants), 3 edentulous mandibles (12 implants), 1 edentulous maxilla (7 implants), 6 anterior maxillae (19 implants), and 22 posterior maxillae (60 implants) were treated, in addition to 72 single implants. The IFL group consisted of completely edentulous cases, while the INFL group was composed of partially edentulous patients.

XiVE Implants

The XiVE implant has a shallower thread in the coronal section. When it is threaded into place, it exerts a “condensing effect” that significantly increases the primary stability of the implant. The collar has a lateral microextension (slight flaring) that causes a friction effect, resulting in an increase of the mechanical retention.³⁰ Three different zones of surface roughness (Ra) can be distinguished: (1) the 1.1-mm collar or “epithelial area,” which is machined to a high finish (Ra = 0.5); (2) the underlying zone or “subepithelial area,” which is 0.9 mm in height and has an etched surface (Ra = 0.9); and (3) the remainder of the implant or “endosseous area,” which is grit-blasted and acid-etched (Ra = 2.23) (Fig 1).³⁰

Surgical Technique

Because of its macrodesign, this implant should provide an increased level of primary stability in all types of bone. By adjusting the cutting depth of the crestal drill, it is possible to derive an advantage from the condensing and friction effect of the implant, resulting in an increase in primary stability.³⁰ In type 1 bone, use of the aforementioned drill to its entire depth (6 mm) is recommended. In type 4 bone, the

drill is not used at all. The 2-stage placement procedure is recommended in poor-quality bone.

The surgical technique consists of reflecting a full-thickness flap in healed sites or utilizing the extraction socket in immediate postextraction cases. In the latter case, if the buccal plate is questionable, elevation of a mucoperiosteal flap is recommended. Once the implant site is prepared with the system-specific drills, the crestal drill is used to the depth recommended by the quality of the bone present. The implant is threaded into place at a low speed (15 rpm) using a contra-angle handpiece and a surgical unit. The placement torque can be monitored in some of the surgical units that are commercially available, such as the FRIOS Unit E (Dentsply/Friadent) drill used in this study. The data are expressed in Ncm and recorded on a memory card. The data can be transferred to a computer, and a printout can be kept in the patient’s chart. Based on the authors’ experience, the torque value for implant placement should be > 25 Ncm when proceeding directly to an immediate restoration. At this point, resonance frequency analysis (RFA) is performed by means of a special transducer (Fig 4). Only the implants with an implant stability quotient (ISQ) > 60 should be immediately restored.³¹

Prosthetic Technique

The XiVE implant is supplied with a premounted titanium abutment (TempBase) that can serve as an implant mount, a temporary abutment, or an impression post for “indexing” (transfer of the position of the implant position to the master cast during the first surgical step) (Fig 5a). A small resin cap (Temp-Base Cap) perfectly adapts onto this temporary abutment to facilitate fabrication of an accurate immediate provisional restoration (Fig 5b). The cap also has a flange that can hold a reinforcing ribbon or metal wire when several caps are being connected in the



Fig 4 Measuring the RFA with the transducer attached to the implant.



Fig 5a An edentulous mandible with 7 implants. The multifunctional TempBase abutments are visible.



Fig 5b An acrylic resin cap (TempBase Cap) is seated on the TempBase to facilitate temporary fabrication.



Fig 5c To render the temporary prosthesis more rigid, one can insert a metal wire using the tab of the small cap as a guide.

temporary prosthesis (Fig 5c). The cap is incorporated into and acts as a base for the temporary prosthesis. The temporary prosthesis is then finished, polished, and cemented or screw-retained.

The provisional or temporary restoration in partially edentulous patients is never in occlusal contact with the opposing arch; in completely edentulous patients, the contacts are distributed evenly on the implants.

The completely edentulous mandibular cases were restored with 4 implants, a bar, and an immediate overdenture. This technique does not differ from that described in an earlier publication by the authors.³ Normally, 4 hours are required from the time the impression is made for fabrication of the bar. Therefore, the patient has to wait in the clinician's office, and the bar is delivered later with the relined overdenture.

Criteria for Success

The following were considered conditions for implant success: the absence of clinical mobility, the absence of any peri-implant radiopacity/radiolucency 1 year after loading, less than 1.5 mm bone loss in the first year, and the absence of pain, infection, and paresthesia. Failure was defined as the presence of these characteristics.

Regardless of the implant technique used, the patients were monitored by means of panoramic and intraoral radiographs (Fig 6). Peri-implant probing depths and bleeding upon probing were also

noted at 1, 3, 6, 12, and 18 months after the implants were loaded. The stability of each implant was evaluated clinically after the prosthetic superstructure was removed at each of the aforementioned follow-ups.

The bone levels were obtained by analyzing the periapical radiographs obtained at the time of the surgery and 6, 12, and 18 months postoperatively. A conventional Rinn cone (technique with the long cone) (Densply/Rinn, Elgin, IL) was used following a standardized technique. The distance from the margin of the implant crown to the most coronal point where the bone appeared to be in contact with the implant was measured (Fig 7). The mesial and distal measurements were taken with the help of a 7-fold magnifying lens. The accuracy of the measurement was definitely very close to 0.2 mm. All the measurements were made by the same person (MD). The implant failures were evaluated using a life table analysis (Table 1) based upon the total number of implants placed.

RESULTS

IFL

During the 24 months of follow-up, 2 of the 253 implants placed with this technique failed. Both were maxillary implants. The implant success rate was 99.2% (100% for the mandible and 98.7% for the maxilla) (Table 2). The prosthetic success rate was 100%.



Fig 6 (Above) Postoperative radiograph.

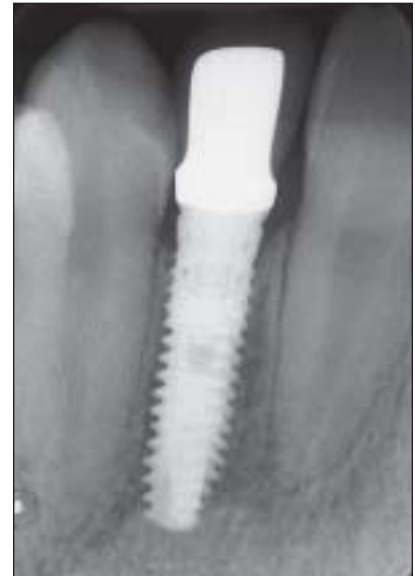


Fig 7 (Right) Measurement of the bone loss. CBL = crestal bone level; ICM = implant crown margin.

Table 1 Life Table Analysis

Implants	Months																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
IFL + INFL	388	388	388	370	350	322	300	274	251	230	221	221	191	169	152	136	126	109	74	65	37	34	21	21
IFL	253	253	253	244	232	224	210	193	179	162	162	162	135	117	106	93	88	78	53	53	26	26	18	18
INFL	135	135	135	126	118	98	90	81	72	68	59	59	56	52	46	43	38	31	21	12	11	8	3	3
Control	314	314	314	276	237	217	189	182	152	105	79	79	57	49	35	24	22	5	4	1	1	0	0	0
Failures	—	—	1	—	1	1	1	—	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—

Table 2 Results for the IFL Group

Anatomic configuration	No. of patients	No. of implants	No. of failed implants	% implant success	% prosthetic success
Edentulous mandible	14	92	0	100.0	100
Edentulous maxilla	20	161	2	98.7	100
Total	34	253	2	99.2	100

INFL

Only 1 of the 135 implants placed with this technique failed. The implant success rate was 99.2% (100% for fixed prostheses and 95.4% for single teeth) (Table 3). The prosthetic success rate was 97.2% (100% for all fixed prostheses and 94.1% for single teeth).

Controls

Of the 314 implants placed with this technique, 2 maxillary implants failed. The implant success rate was 99.4% (100% for the mandible and 99.1% for the maxilla) (Table 4). The prosthetic success rate was 100%.

Analysis of the Failures

Five of the 702 implants failed: 22 in the IFL group, 1 in the INFL group, and 2 in the control group (Table 5). The failures occurred in a time frame that varied from 3 to 11 months after immediate prosthetic loading. In 2 cases, the patient was a smoker. In 2 cases, the bone was classified as DII quality, while in the other 3 cases the bone was classified as DIII quality.³² The implants that failed were all placed in the maxilla: 2 in the central incisor position, 1 in the canine position, and 2 in the maxillary molar region. All 5 of the implants had been placed in postextraction sites. During preparation of the surgical site in 4 of the 5 cases, it appeared that during the opening of the floor of the sinus and/or nasal cavity that there was a rupture of the membrane.

Table 3 Results for the INFL Group

Anatomic configuration	No. of patients	No. of implants	No. of failed implants	% implant success	% prosthetic success
Anterior mandible	10	25	0	100.0	100.0
Posterior mandible	16	50	0	100.0	100.0
Anterior maxilla	6	14	0	100.0	100.0
Posterior maxilla	9	24	0	100.0	100.0
Single	22	22	1	95.4	95.4
Total	63	135	1	99.2	98.4

Table 4 Results for the Control Group

Anatomic configuration	No. of patients	No. of implants	No. of failed implants	% implant success	% prosthetic success
Anterior mandible	5	13	0	100.0	100.0
Posterior mandible	47	131	0	100.0	100.0
Anterior maxilla	6	19	1	94.7	100.0
Posterior maxilla	22	60	1	98.3	100.0
Single	72	72	0	100.0	100.0
Edentulous mandible	3	12	0	100.0	100.0
Edentulous maxilla	1	7	0	100.0	100.0
Total	156	314	2	99.4	100.0

Table 5 Failures

Site of failure	Implant size (diameter/length) (mm)	Sinus			Patient				Type of loading
		Ncm	RFA	nasal floor penetration	Mo. in function	Gender	Age (y)	Smoker	
11 (23)	5.5/13	45	63	Yes	11	M	67	No	IFL
2 (17)	5.5/11	20	61	Yes	7	M	56	Yes	IFL
9 (21)	4.5/15	30	66	No	5	F	40	No	INFL
8 (11)	4.5/15	30	60	Yes	6	F	42	Yes	Control
1 (18)	5.5/13	30	64	Yes	3	M	51	No	Control

Bone quality was adequate in all cases.
 Universal (FDI) tooth numbers used.

Bone Loss

Bone loss was measured for 18 months in all the groups (to date, 12 months have been analyzed), and no statistically significant differences in values were found ($P > .05$). The mean \pm SD marginal bone loss (average between the mesial and distal values) during the first 12 months was 0.7 ± 0.2 mm in the IFL and INFL groups and 0.6 ± 0.2 mm in the control group.

DISCUSSION

Some factors were considered to be extremely important in the planning and execution of the immediate

loading technique. The search for primary stability is fundamental, especially for single-tooth restorations and fixed prostheses. Cross-arch splinting in totally edentulous cases provides primary stability even in cases where it is partially or totally lacking because of the quality of bone. Useful objective guides for assessment of primary stability were provided by the insertion torque and RFA measurements.

As reported in previous studies, the authors maintain that an ISQ greater than 60 and a torque placement value greater than 25 Ncm are useful objective reference parameters that should be adhered to.³¹ RFA measurements at implant delivery are reported in Fig 8. Placement torque measurements at implant delivery are reported in Fig 9.

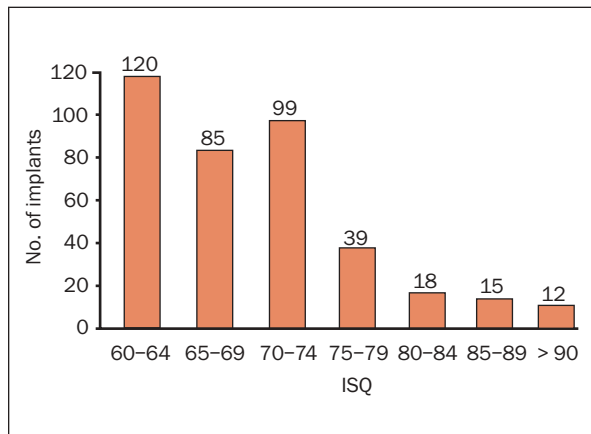


Fig 8 RFA values.

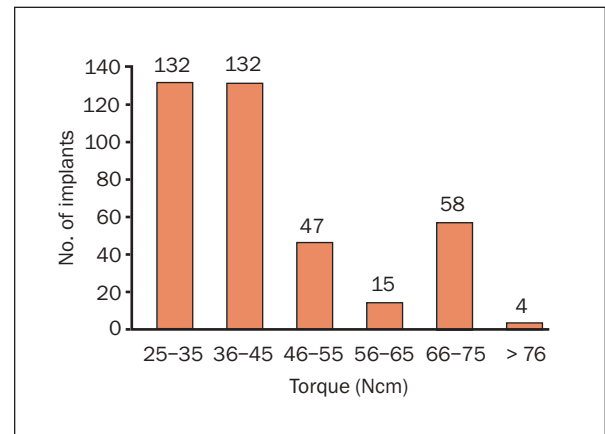


Fig 9 Torque values.

As can be seen in Table 5, none of the implants that failed were the smaller-diameter implants. There were no reported failures of the 3.4-mm-diameter implants. Therefore, the 3.4-mm implants may be successfully used for IFL and INFL. Thus far, they have shown values comparable to implants of greater diameter.

The analysis of peri-implant bone levels in a group of 220 implants for 12 months indicated that they were comparable to levels involving implants placed following traditional protocols.

Concerning the implant, certainly some designs such as the one utilized in this study provide increased primary stability compared to others. For the immediate loading technique, the surface of the implant can play an important part in improving the stability of the coagulum, increasing the formation of bone, and facilitating osseointegration.³³⁻³⁵

Regarding the timing of the seating of an immediate prosthetic restoration, immediate loading (whether IFL or INFL) means "same-day teeth." While a delay of 1 or 2 days will probably not change matters significantly, aside from the discomfort to the patient, delivering the temporary or the definitive prosthetic restoration a few weeks postoperatively might endanger the repair process and expose the patient to a greater risk of failure. In fact, immediate loading is far from being immediate osseointegration. It is nothing more than an immediate osseofixation that permits the implant to integrate according to the biologic time necessary for healing.

The radiographic data obtained in the present study suggest that peri-implant bone loss in the cases of IFL and INFL is comparable to peri-implant bone loss in cases where 1- or 2-stage traditional techniques were used and the implants were subjected to an equal period of loading.³⁶⁻⁴⁷

Intraoperative Complications and Deviations from the Protocol

In 4 cases, during implant site preparation there was most likely a rupture of the sinus and/or nasal cavity membrane lining. It is the authors' 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 probably led to implant failure. Whenever this complication arises, the implant should not be immediately loaded, given the high risk of failure.

The immediate loading of implants in postextraction sites increases the risk for failure because of the risk of residual infection.⁴¹ It is likely that bacterial contamination of the implant site related to the presence of a periodontal pocket could be the principal reason for the failures that were encountered in these cases.^{45,46,48} De Bruyn and Collaert⁴¹ observed in their statistics from 184 implants in 36 patients that of the 153 implants that were placed in mature bone, there was only 1 failure (0.7%), while 12 of the 31 implants placed in postextraction sites failed (39%). This finding is certainly significant, considering that all 5 of the implants that failed in the present population were immediately placed in extraction sockets.

CONCLUSIONS

The success rates of the IFL, INFL, and control groups were similar in the present study. Crestal bone loss was also similar in the 3 groups. All of the failures occurred in postextraction sites. Immediate loading of dental implants appears to be a technique that can provide satisfactory implant success rates in selected cases.

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