

Implant-Retained Mandibular Overdentures with Immediate Loading: a 3- to 8-Year Prospective Study on 328 Implants

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ABSTRACT

Purpose: The purpose of this study is to evaluate prospectively survival and success rates of implants placed in the interforaminal area of edentulous mandibles and immediately loaded with an implant-supported overdenture.

Materials and Methods: Eighty-two patients, 33 males and 49 females, aged between 42 and 87 years (mean age 58.6 yr), presenting edentulous mandibles were rehabilitated with an implant-supported overdenture in the mandible. Three hundred twenty-eight screw-type osseointegrated implants (164 Ha-Ti®, Mathys Dental, Bettlach, Switzerland; 84 ITI Dental Implant System®, Straumann Institute, Waldenburg, Switzerland; 40 Brånemark Conical®, Nobel Biocare AB, Gothenburg, Sweden; 40 Frialoc, Friatec, AG Mannheim, Germany), were placed in the intraforaminal area of the mental symphysis (4 implants per patient). Immediately after implant placement, a U-shaped gold or titanium bar was fabricated and implants were rigidly connected with the bar and immediately loaded with an implant-retained overdenture. Success rate of implants was evaluated clinically and radiographically every year after the loading of the prostheses according to the following parameters: (1) absence of clinical mobility of implants tested individually after bar removal, (2) absence of periimplant radiolucency evaluated on panoramic radiographs, (3) absence of pain and radiologic or clinical signs of neural lesion, and (4) periimplant bone resorption mesial and distal to each implant less than 0.2 mm after the first year of prosthetic load.

Results: Of 328 implants placed, 296 were followed up from a minimum of 36 months to a maximum of 96 months, with a mean follow-up of 62 months. Seven implants in 6 different patients were removed owing to loss of osseointegration, whereas 18 implants, although still osseointegrated, did not fulfill success criteria due to bone resorption > 0.2 mm/year after the first year of loading. Despite implant losses, all patients maintained their bars supporting overdentures, although in 6 patients they were supported by 3 instead of 4 implants. The only patient who lost 2 implants received 2 new implants, which survived normally. Therefore, the absolute success and survival rates were 91.6% and 97.6%, respectively, whereas the cumulative survival and success rates of implants obtained with a life table analysis were 96.1% and 88.2%, respectively.

Conclusions: Results of this study seem to demonstrate that survival and success rates of immediately loaded implants placed in the intraforaminal area of the mandible and rigidly connected with a bar through an implant-supported overdenture are consistent with those reported in the international literature as far as delayed loading is concerned after 3 years of loading. After longer observation times, this study demonstrated that, while survival rates of implants and bar-supported overdentures are still consistent with results published in the international literature pertaining to delayed loading, a moderate decrease in success rates of implants was found. Nevertheless, it must be stressed that this decrease (88.8 and 90.4% after a 7- to 8-year observation period for Ha-Ti and ITI implants) is related only to two implant systems; no data are available for the other two implant systems because of the shorter follow-up period.

KEY WORDS: edentulous jaw, immediate loading, long-term effects, mandibular prosthesis, osseointegrated implants

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Since the first publications by Brånemark and colleagues¹ and Schroeder and colleagues,² one of the most important paradigms, both for submerged and nonsubmerged implants, for adequate osseointegration of dental implants has been absence of loading until osseointegration has occurred, with a waiting period varying approximately from 3 to 6 months. In the case of

patients with edentulous atrophic mandibles, this can create discomfort owing to the instability of the provisional denture, which frequently occurs because of reduction of sulci and superficial insertion of muscles such as the mentalis, genioglossal, and mylohyoid muscles. In recent years an increasing interest toward a shortening of times between implant placement and implant loading has developed.³⁻⁵ In particular, a number of articles have been published regarding immediate loading of implants supporting an overdenture for dental rehabilitation of edentulous mandibles, reporting survival rates of immediately loaded implants comparable with those of "delayed" loading.⁶⁻¹³

The aim of this study is to present a 3- to 8-year prospective analysis of survival and success rates of immediately loaded implants supporting an implant-retained overdenture using four different types of screw-shaped titanium implants.

MATERIALS AND METHODS

Patient Sample

In a 6-year period (1993–1999) 82 patients, 33 males and 49 females ranging in age from 42 to 87 years (mean 58.6 yr), with edentulous mandibles for at least 3 months prior were selected for implant treatment. The patients were required to be healthy and to have experienced functional difficulties with conventional dentures. Jawbone quantity and morphology and intermaxillary skeletal relationship were evaluated before surgery with profile and panoramic radiographs.

Inclusion criteria were as follows: adequate oral hygiene; absence of residual dentitions in the lower arch; absence of local inflammation; absence of oral mucosal disease; no history of local radiation therapy; residual bone height in the interforaminal area sufficient to harbor four screw-type titanium implants, 3.3 mm in diameter and at least 9 mm long; adequate bone quality (classes 1–3 according to Lekholm and Zarb¹⁴).

Exclusion criteria were the following: insufficient bone volume to harbor four implants, 3.3 mm in diameter and at least 9 mm long, in the interforaminal area of the mandible; severe intermaxillary skeletal discrepancy; strong gagging reflex; a severe clenching or bruxism habit; previous reception of implants in the interforaminal area; current drug or alcohol abuse; a moderate or heavy smoking habit (> 10 cigarettes/d); previous reception of radiotherapy in the head and neck area; previous treatment with antitumor chemotherapeutics;

chronic renal disease; chronic liver disease; uncontrolled diabetes; hemophilia, bleeding disorders or coumarin therapy; metabolic bone disorders; immunocompromised status, including infection with human immunodeficiency virus; current steroid treatment; pregnancy at time of evaluation; general contraindications for surgical procedures; and physical or psychiatric handicaps that could interfere with good oral hygiene and mucosal disease such as lichen planus.

Three hundred twenty-eight screw-type osseointegrated implants (164 Ha-Ti[®], Mathys Dental, Switzerland; 84 ITI Dental Implant System[®], Straumann Institute, Waldenburg, Switzerland; 40 Brånemark Conical[®], Nobel Biocare AB, Gothenburg, Sweden; 40 Frialoc, Friatec, AG Mannheim, Germany) were placed in the interforaminal area of the mental symphysis (4 implants per patient).

Surgical Protocol

Antimicrobial prophylaxis was obtained with the following regimen: mouthrinses with a 0.12% chlorhexidine digluconate solution, 3 times/d beginning 3 days prior to surgery; and oral antibiotics (2 g/d of clavulanic acid with amoxicillin). The prophylaxis was started 1 hour before surgery and continued until the third postoperative day. Implant placement was performed under local anesthesia after premedication with diazepam (0.2 mg/kg), given orally 30 minutes before surgery. The surgical procedure was begun with an intraoral crestal incision extending from the molar area of one side to the molar area of the opposite side, with buccal releasing incisions in the molar area, to identify both mental foramina. Subperiosteal dissection of the mucoperiosteum was performed both buccally and lingually to identify and visually control the symphysis area. When indicated, a flattening of the alveolar crest was performed with a bur assembled on a straight low-speed handpiece, under irrigation with sterile saline, to obtain an adequate extension of a flat bony base. Implant sites were prepared according to the standard procedures relative to each type of implant used. Four titanium implants, at least 9 mm in length and 3.3 mm in diameter, were placed anterior to the mental foramina following, whenever possible, indications obtained by prefabricated acrylic resin templates.

Prosthetic Rehabilitation

Four abutments were immediately screwed to the implants and the mucoperiosteal flaps were accurately

sutured around them. Using transfer copings an impression was made immediately (Impregum F®, ESPE Dental AG, Seefeld, Germany) using a previously prepared denture as an impression tray. The impression was sent directly to the dental laboratory. Once the master model, which incorporated implant analogs, was obtained, prefabricated gold or titanium copings were screwed to the standard abutments and a U-shaped Dolder bar was constructed, with copings soldered to the bar segments.

One day after surgery the bar was screwed to the abutments; the accuracy of the bar's fit was checked in the mouth. If passive fit was achieved (as evaluated by the Sheffield test), the bar was definitely screwed to the abutments and the patient bore the overdenture immediately. The retention system was formed by clips incorporated in the denture base, and the patients were permitted to resume normal masticatory function. A representative case is presented in Figures 1 to 7.

Follow-Up

Follow-up visits were scheduled for 6 and 12 months after the start of prosthetic loading and then annually. The following parameters were recorded: (1) implant stability, (2) radiographic assessment of marginal bone loss, (3) implant survival rates, and (4) implant success rates.

Implant Stability. Every implant was checked individually after removal of the bar and was tested using the handles of two dental mirrors.

Radiographic Assessment of Marginal Periimplant Bone Loss. Radiographic assessment of marginal periimplant bone loss was made using panoramic radiographs

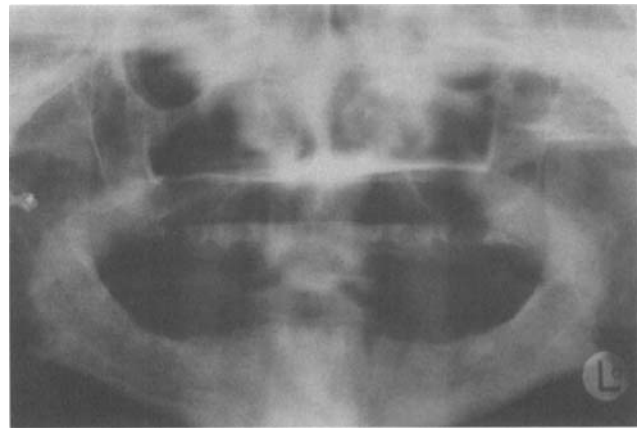


Figure 2 Preoperative panoramic radiograph.

obtained immediately following implant placement and then annually after the start of prosthetic loading. Crestal bone level was recorded where the marginal bone anchored directly to the implant. The measurement was taken mesial and distal to each implant by means of a transparent millimeter ruler, measuring the distance between the apex of the implant and the first visible contact with the implant surface. The measurements were made to the nearest half millimeter. It is known that panoramic radiographs can magnify actual dimensions of the maxillomandibular complex by up to 30%. To correct this and to obtain a more precise evaluation of periimplant bone resorption, the apparent dimensions of the implants were measured on the radiographs and compared with the actual size of the implants. The ratio between apparent implant dimension and actual implant dimension was used to modify the apparent measurement of periimplant bone resorption to obtain the actual values. The values obtained on radiographs taken at time of implant placement were



Figure 1 Preoperative intraoral view showing total edentulism of the mandible.



Figure 3 Intraoral situation immediately after placement of four implants, abutments, and transfer copings for immediate impression.

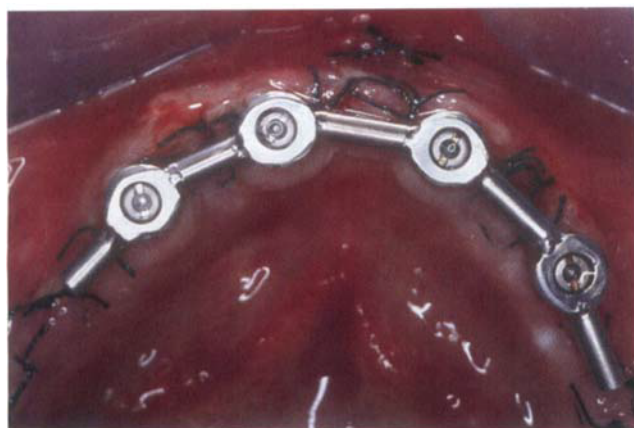


Figure 4 Intraoral situation after fixation of a U-shaped bar on the same day as the surgical procedure.

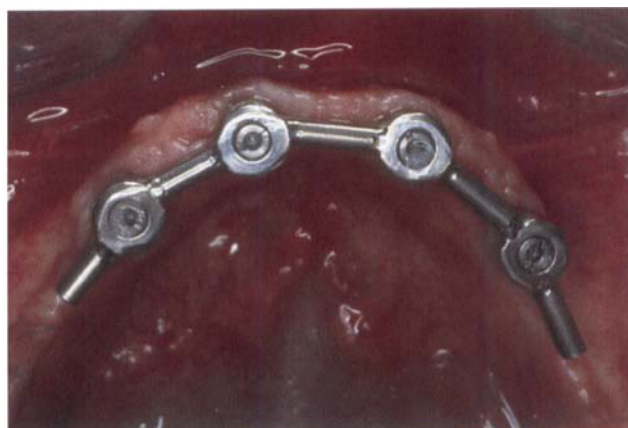


Figure 6 Intraoral situation 24 months after the start of prosthetic loading.

compared with those obtained on radiographs made each year after the start of loading.

Survival Criteria. Survival criteria applied in this study were as follows:

- That an individual implant was immobile when tested clinically using the handles of two dental mirrors
- That radiographs did not demonstrate any evidence of periimplant radiolucency
- That individual implant performance was characterized by absence of signs and symptoms such as pain, infection, neuropathies, paresthesia, or violation of the mandibular canal

Success Criteria. Success criteria applied in this study were as follows:

- That an individual implant was immobile when tested clinically using the handles of two dental mirrors

- That radiographs did not demonstrate any evidence of periimplant radiolucency
- That vertical bone loss was < 1 mm during the first year of prosthetic loading and < 0.2 mm annually in subsequent years
- That individual implant performance was characterized by absence of signs and symptoms such as pain, infection, neuropathies, paresthesia, or violation of the mandibular canal

RESULTS

The study group consisted of 82 patients. Fifty patients were completely edentulous in the maxilla (30 were treated with conventional dentures, 12 with removable implant-supported prostheses, and 8 with fixed implant-supported prostheses); 11 patients were partially edentulous in the maxilla and were treated with removable prostheses; and 9 patients were completely dentate in the maxilla or had undergone restoration with a fixed prosthesis. Three hundred twenty-eight



Figure 5 Immediate loading of implants with an implant-supported overdenture.

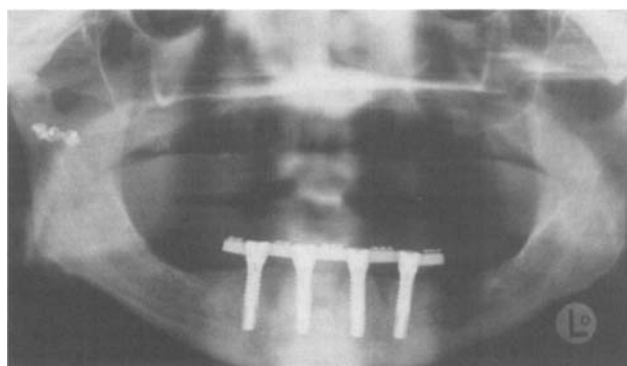


Figure 7 Radiographic control 24 months after the start of prosthetic loading.

screw-type osseointegrated implants (164 Ha-Ti, 84 ITI, 40 Brånemark Conical, 40 Frialoc) were placed in the intraforaminal area of the mental symphysis. Post-operative recovery was uneventful for all patients.

Of 328 implants placed, 296 were followed up from a minimum of 36 months to a maximum of 96 months, with a mean follow-up of 62 months. Eight patients (32 implants) did not adhere to the standard follow-up visits after final prosthetic rehabilitation. They refused to be controlled at the recall appointments because they felt they were symptom free and did not understand the need of such controls, despite the fact that the procedure had been well specified at the time of patient recruitment. As a result they dropped out of the study.

Seven implants in 6 different patients were removed due to loss of osseointegration, whereas 18 implants, although still osseointegrated, did not fulfill success criteria due to bone resorption > 0.2 mm/y after the first year of loading (Tables 1 and 2). Despite implant losses, the 5 patients who lost 1 implant each

maintained their bars supporting overdentures, although they needed a modification of the bar design. The patient who lost 2 implants after 3 years of service received 2 new implants placed 3 months after the original implants were removed and the bar was reconstructed. In this particular patient, all implants are still in service and do not present signs or symptoms of failure. No other adverse events occurred to the implants during the follow-up period.

The overall success and survival rates were 91.6% and 97.6%, respectively. The cumulative survival and success rates of implants obtained with a life table analysis were 96.1% and 88.2%, respectively (see Tables 1 and 2).

The cumulative survival rates concerning each implant type were 95.7% for Ha-Ti implants, 97.4% for ITI implants, 100% for Brånemark System implants, and 100% for Frialoc implants. The cumulative success rates were 88.8% for Ha-Ti implants, 90.4% for ITI implants, and 95% each for Brånemark and Frialoc

TABLE 1 Life Table Analysis Showing Cumulative Survival Rates of Implants*

Interval	No. of Implants Removed	No. of Implants Withdrawn	No. of Implants at Risk	Cumulative Survival Rate (%)
Loading-1 yr	0	0	328	100
1-2 yr	0	0	328	100
2-3 yr	1	56	328	99.7
3-4 yr	1	44	271	99.3
4-5 yr	2	28	226	98.3
5-6 yr	2	68	196	97.1
6-7 yr	1	56	126	96.1
7-8 yr	0	52	69	96.1

*Ha-Ti, ITI, Brånemark, and Frialoc.

TABLE 2 Life Table Analysis Showing Cumulative Success Rates of Implants*

Interval	No. of Implants Removed	No. of Failing Implants	No. of Implants Withdrawn	No. of Implants at Risk	Cumulative Success Rate (%)
Loading-1 yr	0	0	0	328	100
1-2 yr	0	7	0	328	97.9
2-3 yr	1	3	56	321	96.5
3-4 yr	1	2	44	261	95.3
4-5 yr	2	3	28	214	92.9
5-6 yr	2	2	68	181	90.4
6-7 yr	1	1	56	109	88.2
7-8 yr	0	0	52	25	88.2

*Ha-Ti, ITI, Brånemark, and Frialoc.

TABLE 3 Life Table Analysis Showing Cumulative Success Rates of Ha-Ti Implants

Interval	No. of Implants Removed	No. of Failing Implants	No. of Implants Withdrawn	No. of Implants at Risk	Cumulative Success Rate (%)
Loading-1 yr	0	0	0	164	100
1-2 yr	0	2	0	164	98.8
2-3 yr	0	1	8	162	98.1
3-4 yr	1	2	4	153	96.2
4-5 yr	1	2	24	146	94.0
5-6 yr	2	1	28	119	91.4
6-7 yr	1	1	32	88	88.8
7-8 yr	0	0	44	54	88.8

implants. Details concerning cumulative success rates are reported in Tables 3 to 6.

Although the different groups of implants are not comparable because of the different observation times and number of implants, a relevant difference in implant survival rates was found between the different implant types. Of seven implants removed, five were Ha-Ti implants and two were ITI implants; none of the Brånemark Conical and Frialoc implants were removed. It must be stressed, however, that the majority of implant losses occurred in the Ha-Ti group, which was the first group used in this study (from 1993 to 1996) and had the longest follow-up. The losses might be correlated to the initial learning curve and/or to the longer follow-up. Therefore, a longer observation period for Frialoc and Brånemark implants is needed to evaluate the long-term success rates of these implants and to compare the results with the other implant types.

DISCUSSION

Primary stability and absence of early loading of dental implants has been considered for years *sine qua non* to allow osseointegration of dental implants. However, the

idea not to load early was empirically based and not experimentally ascertained.^{1-3,15} It is therefore justifiable to question whether this healing period is an absolute prerequisite to obtaining osseointegration, or if, under certain circumstances, this period can be shortened without jeopardizing osseointegration and long-term results. In particular, it should be demonstrated whether or not any kind of movement transmitted to the implants during the early phases of integration can compromise the long-term results, or if there is a threshold below which micromovements may not compromise osseointegration.

Studies in the orthopedic literature¹⁶⁻¹⁹ have demonstrated the role of macromovements in tissue differentiation around endosseous implants placed in long bones such as tibia bones; macromovements induced fibrous tissue interposition between the implant surface and bone. Similar results have been found with regard to dental implants: Brunski and colleagues²⁰ identified early loading as a factor leading to fibrous tissue interposition at the bone-implant interface. In an experimental study in dogs, titanium-blade implants were immediately loaded on one side, whereas contralateral

TABLE 4 Life Table Analysis Showing Cumulative Success Rates of ITI Implants

Interval	No. of Implants Removed	No. of Failing Implants	No. of Implants Withdrawn	No. of Implants at Risk	Cumulative Success Rate (%)
Loading-1 yr	0	0	0	84	100
1-2 yr	0	2	0	84	97.6
2-3 yr	1	1	8	82	95.1
3-4 yr	0	0	0	72	95.1
4-5 yr	1	1	4	72	92.4
5- yr	0	1	40	66	90.4
6-7 yr	0	0	56	25	90.4
7-8 yr	0	0	0	13	90.4

TABLE 5 Life Table Analysis Showing Cumulative Success Rates of Brånemark Implants

Interval	No. of Implants Removed	No. of Failing Implants	No. of Implants Withdrawn	No. of Implants at Risk	Cumulative Success Rate (%)
Loading-1 yr	0	0	0	40	100
1-2 yr	0	1	0	40	97.5
2-3 yr	0	1	0	40	95

blades were left out of function. Immediately loaded implants presented fibrous tissue encapsulation, whereas the nonloaded implants osseointegrated normally. These observations were confirmed by other studies using titanium-screw implants.²¹

In contrast to the aforementioned studies, there are also reports in the experimental and clinical literature of implants exposed to early or immediate loading followed by successful osseointegration.^{7-14,22-26} In a pilot study on dogs,²⁵ three different groups of titanium alloy implants were compared: a nonsubmerged early loaded group, a nonsubmerged nonloaded group, and a submerged group as control. The latter two were loaded after osseointegration occurred. The early loaded group consisted of three implants splinted into one prosthetic restoration at 1 week post implantation. The authors found no statistical differences between the groups with regard to the quality of osseointegration, and in none of the groups was fibrous encapsulation of the implants found.

The current trend is not to consider implant movements per se as detrimental to osseointegration but rather to consider a threshold movement.^{27,28} This concept was introduced by Cameron and colleagues,¹⁸ and the hypothesis that micromovement at the bone-implant interface is tolerated below a certain threshold has been confirmed by other authors.²⁹ These studies seem to demonstrate that micromovements up to 150 μ should be considered excessive and therefore deleterious for osseointegration. On the contrary, movements < 50 μ seem to be tolerated. Thus, the critical

threshold, although dependent on the type of implant morphology and implant surface, seems to be between 50 and 150 μ .^{27,28,30}

Splinting implants together seems to be an effective way to reduce deleterious mechanical stress on early loaded implants.^{7-12,20,31} In an experimental study on monkeys,²⁴ a total of 48 implants was placed in 6 monkeys (24 in the posterior mandible and 24 in the posterior maxilla). Twelve implants in the mandible and 12 in the maxilla were immediately loaded with metal suprastructures (in the test group). All implants were splinted in a prosthesis. Block sections of the bone segments containing the implants were retrieved 9 months after surgical placement. In the test implants, a thick layer of lamellar bone with few marrow spaces in direct contact with the implant threads was found. This study showed that the percentage of direct bone-implant contact of immediately loaded implants was significantly greater than in the nonloaded ones.

Despite a lack of data to objectively quantify the micromovements to which implants are exposed in the immediate-loading situation, the method described in this study, which uses four implants rigidly connected by a curved U-shaped bar, allows good stabilization of immediately loaded implants. Thus, implants are not exposed to movements that could compromise osseointegration. Survival rates of implants in this study are consistent with those reported in the international literature for delayed loading.³²⁻³⁵

In a previous retrospective multicenter study by Chiapasco and colleagues,⁹ 226 patients and 904

TABLE 6 Life Table Analysis Showing Cumulative Success Rates of Frialoc Implants

Interval	No. of Implants Removed	No. of Failing Implants	No. of Implants Withdrawn	No. of Implants at Risk	Cumulative Success Rate (%)
Loading-1 yr	0	0	0	40	100
1-2 yr	0	2	0	40	95
2-3 yr	0	2	0	40	95

implants were placed in the intraforaminal area of the mandible to treat edentulous patients with an implant-supported overdenture following a similar surgical and prosthetic protocol. Seven hundred seventy-six implants (4 different implant systems) were followed up from a minimum of 2 years to a maximum of 13 years. The overall survival rate of implants was 96.1%, thus confirming the reliability of this method.

In a recent comparative study between immediate and delayed loading of implants supporting mandibular overdentures, no statistically significant differences were found between the two groups (97.5% survival rate of implants in both groups), demonstrating that immediate loading of splinted implants is a reliable method to shorten the rehabilitation times of edentulous patients.¹¹

However, the effective role of splinting implants together to prevent loss of osseointegration in cases of immediate loading might be reevaluated in the future. An increasing number of publications has recently appeared, demonstrating that unsplinted implants exposed to immediate loading may osseointegrate in an apparently "normal" way.^{5,12,36-39} Yet, it must be stressed that long-term comparative prospective studies are needed, and that a relevant difference must be underlined between immediate function and immediate loading of implants. *Immediate function* of implants means that implants are used immediately to support a prosthetic suprastructure, which is frequently out of occlusion and is therefore not immediately loaded. Therefore, an extensive application of real immediate loading of implants in situations different from the one described in this study should be considered with caution before sufficient data are collected.

Bone quality is another important factor to be evaluated intraoperatively when deciding whether to load implants immediately. Immediate loading has been applied only in the interforaminal area of the mandible and in cases of good bone quality (classes 1-3 according to Lekholm and Zarb's classification¹⁴). Whenever these conditions are not achieved, and in cases of any doubt concerning primary stability of the placed implants, the standard two-stage technique is recommended. Lekholm and Zarb's evaluation of bone quality is, however, quite subjective. To evaluate bone quality and primary stability of implants more objectively, new instruments such as resonance frequency analysis are recommended for future clinical investigations.^{40,41}

Although not objectively tested, it appears important that the whole surface of the implant be covered by bone. In cases of large periimplant bone fenestrations or dehiscences after implant placement, where the covering of the exposed implant by bone grafting or guided bone regeneration may be indicated, a two-stage standard procedure is indicated.

As far as the radiographic evaluation of crestal bone level around implants is concerned, the use of panoramic radiographs may be criticized because of its imprecision owing to dimensional distortion. It is known, in fact, that panoramic radiographs can magnify actual dimensions by up to 30%. This type of radiograph has been used routinely in this investigation because intraoral radiographs can be difficult to obtain in completely edentulous patients since the superficial insertion of the muscles of the mouth floor can interfere with the positioning of the radiographs. Nevertheless, dimensional modifications can be taken into account following criteria presented in the "Materials and Methods" section, above.

CONCLUSIONS

The purpose of this study was to evaluate the reliability of immediately loaded implants in the interforaminal area of edentulous mandibles with implant-supported overdentures. Results of this study seem to demonstrate that survival and success rates of immediately loaded implants are consistent with those reported in the international literature regarding delayed loading with a follow-up of 3 years of loading. The advantage here is a significant shortening of rehabilitation times and improved satisfaction of patients.

However, after longer observation times, although survival rates of implants and bar-supported overdentures in this study are still consistent with results published in the international literature concerning delayed loading, a moderate decrease in success rates of implants was found. Nevertheless, it must be stressed that this decrease (88.8% and 90.4% after a 7- to 8-year observation period) is related only to two implant systems; no data are available for the other two implant systems because of the shorter follow-up period.

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