Implant-retained Mandibular Overdentures with Brånemark System MKII Implants: A Prospective Comparative Study Between Delayed and Immediate Loading

Matteo Chiapasco[1]/Silvio Abati[2]/Eugenio Romeo[3]/Giorgio Vogel[4]

This study was designed to compare the results of immediate and delayed loading of implants with implant-retained mandibular overdentures. Ten patients (test group) received 40 Brånemark System MKII implants (4 per patient) placed in the interforaminal area of the mandible. Standard abutments were immediately screwed to the implants, rigidly connected with a bar, and immediately loaded with an overdenture. Ten patients (control group) received the same type and number of implants in the same area, but the implants were left to heal submerged. Four to 8 months later, standard abutments were screwed to the implants and the same prosthetic procedure was applied. Each implant was evaluated at the time of prosthetic loading and at 6, 12, and 24 months after the initial prosthetic load with the following parameters: modified Plaque Index (MPI), modified Bleeding Index (MBI), probing depth (PD), and Periotest. Peri-implant bone resorption was evaluated on panoramic radiographs taken 12 and 24 months after initial prosthetic loading. No significant differences were found between the 2 groups regarding MPI, MBI, Periotest, peri-implant bone resorption, and PD at 6 and 24 months ($P > .05$). The only difference was found regarding PD values on the mesial and lingual sites at 12 months ($P < .05$). The cumulative success rate of implants was 97.5% in both groups. Results from this study showed that immediate loading of endosseous implants rigidly connected with a U-shaped bar does not seem to have any detrimental effect on osseointegration. Conversely, this method significantly shortens the duration of treatment with relevant satisfaction for the patients. (Int J Oral Maxillofac Implants 2001;16:537–546)

Key words: *endosseous dental implants, immediate loading, implant overdenture*

Although dental rehabilitation with conventional removable prostheses in patients with completely edentulous mandibles may represent a satisfactory solution to restore function and esthetics for many patients, in others, complete dentures may create functional and psychologic problems. When a fixed prosthesis anchored to osseointegrated implants is not indicated because of anatomic, functional, or economic reasons, implant-retained overdentures may be considered as possible alternative treatment.[1–10] As with implant-supported fixed prostheses, a waiting period of 3 to 6 months is usually indicated to obtain osseointegration, both for submerged and non-submerged implants. It is possible that this healing period may prove inconvenient to the patient, thereby discouraging pursuit of such treatment.

As demonstrated by Ledermann[11,12] and Graber and Besimo,[13] rigid connection of 3 or 4 interforaminal implants with a U-shaped bar can reduce macromovements, as in the situation of immediate loading with an overdenture. However, long-term results involving this method are very scarce[8,14] and

[1]Chairman, Department of Oral Surgery, Dental Clinic, School of Dentistry, University of Milan, Milan, Italy.
[2]Associate Professor, Department of Medicine, Surgery, and Dentistry, Dental Clinic, School of Dentistry, University of Milan, Milan, Italy.
[3]Chairman, Department of Prosthodontics, Dental Clinic, School of Dentistry, University of Milan, Milan, Italy.
[4]Head, Dental Clinic, School of Dentistry, University of Milan, Milan, Italy.

Reprint requests: Dr Matteo Chiapasco, Clinica Odontostomatologica, Via Beldiletto 1/3, 20142 Milano, Italy. Fax: +390-2-8130200. E-mail: matteo.chiapasco@unimi.it

there is a lack of comparative studies on the effects of immediately loaded implants in the support and retention of overdentures.

The purpose of this study was to evaluate the effect of immediate loading on osseointegration of Brånemark System MKII implants (Nobel Biocare, Göteborg, Sweden) using implant-retained overdentures and to compare these results with those for delayed loading.

METHODS AND MATERIALS

Patients

From 1996 to 1997, 20 patients (5 males and 15 females), ages 44 to 73 years (mean age 58.4 years), with edentulous mandibles dating at least 3 months were selected for implant treatment. The patients were required to be healthy and to have experienced functional difficulties with conventional dentures. Jaw bone quantity and morphology and maxillomandibular skeletal relationships were evaluated before surgery with profile and panoramic radiographs.

Inclusion criteria were as follows:

1. Adequate oral hygiene
2. Absence of residual mandibular dentition
3. Absence of local inflammation
4. Absence of oral mucosal disease
5. No history of local radiation therapy
6. Residual bone height in the interforaminal area sufficient to harbor 4 screw-type titanium implants, 3.75 mm in diameter and at least 13 mm long
7. Class I, II, or III bone quality according to the Lekholm and Zarb classification[15]

Exclusion criteria included:

1. Severe maxillomandibular skeletal discrepancy
2. Gagging reflex
3. Severe clenching or bruxism
4. Implants already placed in the interforaminal area
5. Drug or alcohol abuse
6. Smoking habit (more than 10 cigarettes per day)
7. History of radiation therapy in the head and neck region because of malignancies of the head and neck
8. Current treatment with antiblastic chemotherapy
9. Severe chronic renal disease
10. Severe chronic liver disease
11. Uncontrolled diabetes
12. Hemophilia, bleeding disorders, or coumarin therapy
13. Metabolic bone disorders
14. Immunocompromised status, including infection with human immunodeficiency virus
15. Current treatment with steroids
16. Pregnancy at time of evaluation
17. General contraindications for surgical procedures
18. Physical or psychiatric handicaps that could interfere with good oral hygiene
19. Presence of mucosal lesions such as lichen planus

Patients were randomly assigned to 1 of 2 treatment groups: immediate loading (test group, n = 10) or delayed loading (control group, n = 10). Patients assigned to the test group received a U-shaped connecting bar and overdenture within 3 days of implant placement, while the control group patients were restored in the same manner 4 to 8 months after implant placement (Figs 1a to 1e).

Presurgical assessment included the analysis of articulator-mounted diagnostic casts. These casts were used to evaluate the maxillomandibular jaw relationship and intermaxillary space. An acrylic resin template was prepared to establish the ideal position for implant placement. Patients were thoroughly informed about this study, and signed informed consent was obtained from each.

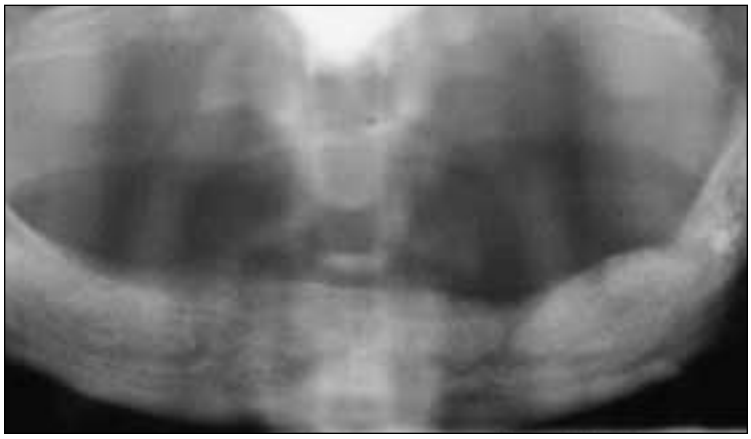
Surgical and Prosthetic Protocol

The surgical protocol for implant placement was the same for both groups. The same surgeon performed the surgical procedure for all patients. Antimicrobial prophylaxis was obtained with the following regimen: *(1)* mouthrinses with a 0.12% chlorhexidinedigluconate solution, 3 times a day starting 3 days before surgery; and *(2)* oral antibiotics (2 g per day of clavulanic acid and amoxycillin). 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 for implant placement followed the standard procedures relative to the Brånemark System. Four titanium implants, 3.75 mm in diameter and at least 13 mm long, were placed anterior to the mental foramina following, whenever possible, indications obtained by prefabricated acrylic resin templates. Implant length was selected to possibly enable engagement of the cortex of the inferior border of the mandible.

Prosthetic treatment followed the random assignment for the test and control groups. In the test group, 4 standard abutments were immediately screwed to the implants, and the mucoperiosteal

Fig 1a Preoperative panoramic radiograph (patient #5, test group) demonstrating complete edentulism of the mandible with enough bone height to place 4 implants 15 mm long.



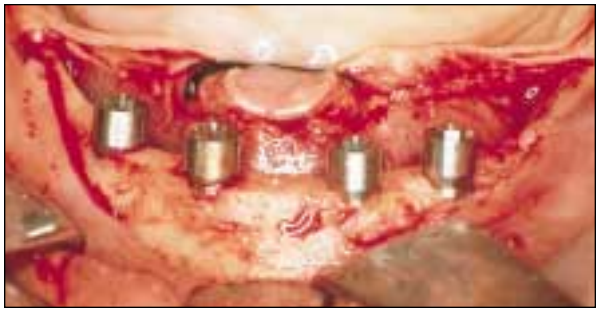


Fig 1b Intraoperative view at the completion of implant placement with immediate abutment connection.

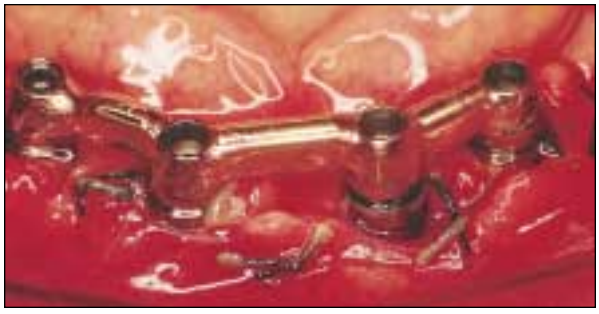


Fig 1c Connection of the bar 3 days after implant placement to support an implant-retained overdenture (sutures are still present).

Fig 1d Radiographic examination at time of prosthetic loading (3 days after surgery).

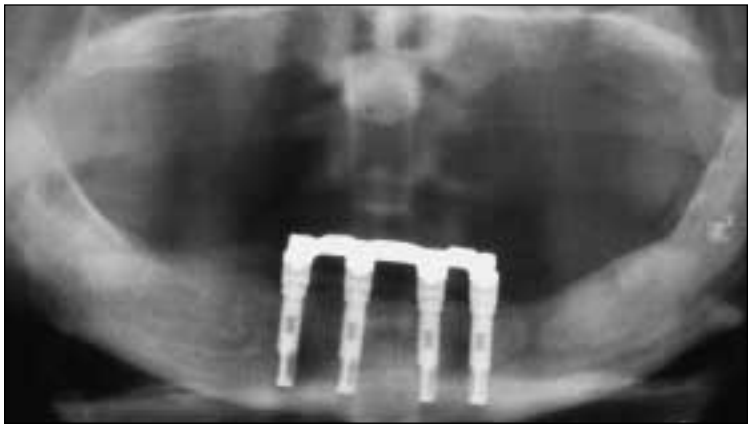
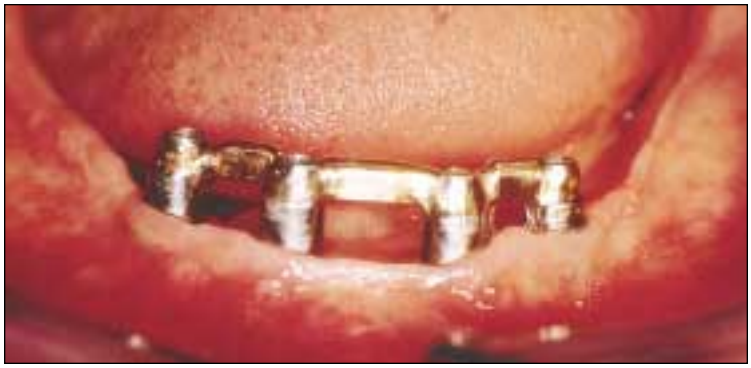


Fig 1e Clinical intraoral examination 2 years after initial prosthetic loading.



flaps were accurately sutured around them. Using transfer copings, an impression was immediately made (Impregum F, ESPE Dental AG, Seefeld, Germany) using a previously prepared denture as an impression tray. On the master cast obtained, which incorporated implant analogs, the same transfer copings used for the first impression were joined with autopolymerizing resin (Duralay, Reliance Dental, Worth, IL). After 12 hours, the copings were separated with a sectioning disc, repositioned on the standard abutments in the patients, and reassembled with small quantities of Duralay; after polymerization, a second impression was made. On this master cast, the prefabricated Brånemark gold copings were screwed to the standard abutments and a U-shaped Dolder bar fabricated, soldering the gold copings with bar segments. Two to 3 days after implant placement, the Dolder bar was connected to the implant abutments. Accuracy of fit of the bar was evaluated using the Sheffield test. Once accurate fit of the bar was ensured, it was connected definitively using gold retaining screws tightened to 32 Ncm. Retention clips were placed in the denture base, and the patient was permitted to resume normal masticatory function.

In the control group, standard titanium cover screws were used and the flaps were approximated using 4-0 silk sutures. Transitional mucosa-supported prostheses were withheld for 2 postoperative weeks. Then these prostheses were relined with a soft denture liner (Hydro-cast, Dental Products, Kay-See Dental, Kansas City, MO). Four to 8 months following implant placement, the implants were uncovered and standard abutments were placed. The mandibular prosthesis was fabricated using the same techniques that were used in the test group.

Follow-up Protocol

Follow-up visits were scheduled in both groups for 6, 12, and 24 months after the beginning of prosthetic loading. Implant stability was checked individually after removal of the bar. The following parameters were recorded: radiographic assessment of marginal bone loss; peri-implant soft tissue parameters (modified Plaque Index [MPI], modified Bleeding Index [MBI], probing depth [PD]); and Periotest (Siemens AG, Bensheim, Germany). Radiographic assessment was made using panoramic radiographs obtained immediately after implant placement. The radiographic bone level mesial and distal to each implant was measured to the nearest half millimeter using a millimeter ruler. To correct for dimensional distortion, the apparent dimensions of the implants were measured on the radiographs and compared to the actual size of the implants. These values were compared to bone levels on panoramic radiographs made at 12 and 24 months following implant placement. Mean PI and BI scores were recorded at 4 sites for every implant (mesial, buccal, distal, lingual) according to the modifications described for implants by Mombelli and coworkers.[16] Probing depth measurements were made at 4 sites (mesial, buccal, distal, lingual) to the nearest millimeter using a calibrated probe. Implant mobility was tested with the Periotest (Siemens AG, Bensheim, Germany). Periotest measurements were made for each implant at the time of abutment connection and at 6, 12, and 24 months after initial prosthetic loading. Every implant was tested independently, after removal of the connecting bar.

Implant success was evaluated according to the success criteria proposed by Albrektsson and associates.[17]

Statistical Analysis

Descriptive analysis of the raw data was performed with commercial statistical software (StatView 5.0, SAS Institute, Cary, NC). With the same software package the pertinent comparisons between the relevant variables in the 2 groups were calculated. The Mann-Whitney *U* test was used to compare MPI, PD, MBI, and Periotest values between the 2 groups. The Student *t* test was used to compare peri-implant bone resorption between the 2 groups. In connection with statistical evaluations, a *P* value of .05 was considered statistically relevant. Since multiple implants in the same subject are not statistically independent, the subject medians and ranges were used for analysis, thus obtaining an effective sample size of 10 per group.

RESULTS

The study group consisted of 20 patients (5 males and 15 females), ages 44 to 73 years (mean age 58.4 years). Eleven patients were completely edentulous in the maxilla (of whom 6 were treated with conventional dentures, 3 with removable implant-supported prostheses, and 2 with fixed implant-supported prostheses). Five patients were partially edentulous in the maxilla and treated with removable prostheses, and 4 patients were completely dentate in the maxilla or had undergone restoration with fixed prostheses. Demographic data and clinical features are reported in Table 1. Postoperative recovery was uneventful for all patients in both groups. No patients dropped out of the study in the follow-up period.

Of the 40 implants placed in the test group, 1 was removed 3 months after initial functional loading

Table 1 Analytic Description of Test and Control Groups

Group/patient	Sex	Age (y)	Maxillary dentition	Implant length (mm)	Implant placement	Implant loading	Follow-up (months)	Complications
Test group								
#1	M	66	CD	18	15.4.96	17.4.96	42	One implant lost
#2	F	55	RPD	13	3.7.96	6.7.96	40	None
#3	F	59	RPD	18	21.11.96	24.11.96	36	None
#4	F	61	CD	13	29.1.97	31.1.97	34	None
#5	F	61	CD	15	29.1.97	31.1.97	34	None
#6	F	73	CD	15	7.4.97	9.4.97	30	None
#7	M	50	RPD	13	13.6.97	15.6.97	28	None
#8	F	51	RPD	15	26.6.97	29.6.97	28	None
#9	F	60	FP	15	1.10.97	3.10.97	24	None
#10	F	57	FP	15	5.10.97	7.10.97	24	None
Control group								
#1	M	58	ISR	18	2.2.96	4.6.96	40	None
#2	F	60	ISO	13	13.3.96	15.9.96	38	None
#3	F	66	FP	13	15.4.96	25.11.96	36	None
#4	M	65	FP	15	11.6.96	10.1.97	34	None
#5	F	58	CD	15	15.7.96	10.1.97	34	None
#6	M	51	ISO	18	15.1.97	30.8.97	26	None
#7	F	65	ISO	13	3.3.97	6.9.97	26	One implant lost
#8	F	57	RPD	15	17.3.97	8.10.97	24	None
#9	F	52	CD	13	3.4.97	9.10.97	24	None
#10	F	44	ISR	15	17.7.97	20.11.97	24	None

ISR = implant-supported restoration; ISO = implant-supported overdenture; FP = fixed prosthesis; CD = complete denture; RPD = removable partial denture.

Table 2 Bone Resorption Test and Control Groups

	Bone resorption (mm)		
Group	12 months (median and range)	24 months (median and range)	No. of implants followed
Test group (immediate loading)	0.7 (0.1–1.3)	1.5 (0.4–2.5)	39
Control group (delayed loading)	0.8 (0.1–1.9)	1.2 (0.4–2.5)	39

Student *t* test (level of significance: $P < .05$); non-significant at 12 and 24 months.

because of peri-implant infection that was not responsive to local treatment (patient #1). Two months later, the removed implant was replaced and immediately loaded after modification of the bar. During the healing period following implant removal, the bar was screwed to the remaining 3 implants and the functional load was continued. No other adverse events occurred in the test group during the follow-up (Table 1).

Of the 40 implants placed in the control group, 1 implant lost osseointegration 4 weeks after initial prosthetic loading and was removed (patient #7). The patient refused substitution of the lost implant with a new one; therefore, the bar was modified and screwed to the remaining 3 implants. Two years after the start of functional loading, no other adverse events occurred during the follow-up (Table 1).

Although some patients presented a 3-year follow-up (3 patients in each group), only the data obtained 24 months after the prosthetic load are reported in detail in the present study. The medians and ranges of peri-implant bone resorption in the test and control groups, 12 and 24 months after the initial prosthetic loading, are reported in Table 2. No statistically significant differences were found between the 2 groups ($P > .05$) (Table 2). Bone resorption in both groups was within the normal limits proposed by Albrektsson and associates[17] (ie, ≤ 1.5 mm in the first year of functional loading and ≤ 0.2 mm per year in the following years).

Table 3 Modified Plaque Index in Test and Control Groups

	Modified Plaque Index (median and range)		
Group/site	6 months	12 months	24 months
Test group			
Mesial	0.8 (0–2)	0.3 (0–2)	0.5 (0–2)
Buccal	0.5 (0–2)	0 (0–2)	0 (0–3)
Distal	0 (0–2)	0 (0–2)	0 (0–3)
Lingual	0 (0–2)	0 (0–3)	0.8 (0–2)
Control group			
Mesial	0 (0–2)	0 (0–1)	0 (0–2)
Buccal	0.5 (0–2)	0 (0–1)	0.5 (0–2)
Distal	0 (0–2)	0 (0–0)	0 (0–2)
Lingual	0.3 (0–2)	0 (0–1)	1 (0–1)

Mann-Whitney *U* test (level of significance: $P < .05$); non-significant at 6, 12, and 24 months.

Table 4 Modified Bleeding Index in Test and Control Groups

	Modified Bleeding Index (median and range)		
Group/site	6 months	12 months	24 months
Test group			
Mesial	0 (0–1)	0 (0–2)	0 (0–1)
Buccal	0 (0–0)	0 (0–2)	0 (0–0)
Distal	0 (0–2)	0 (0–1)	0 (0–1)
Lingual	0 (0–1)	0 (0–1)	0 (0–1)
Control group			
Mesial	0 (0–2)	0 (0–1)	0 (0–1)
Buccal	0 (0–1)	0 (0–1)	0 (0–1)
Distal	0 (0–1)	0 (0–1)	0 (0–1)
Lingual	0 (0–1)	0 (0–1)	0 (0–1)

Mann-Whitney *U* test (level of significance: $P < .05$); non-significant at 6, 12, and 24 months.

Table 5 Probing Depths in Test and Control Groups

	Probing depths (median and range)		
Group/site	6 months	12 months	24 months
Test group			
Mesial	2 (1–3)	2.5 (1–4)	2 (1–4)
Buccal	2 (1–3)	2.5 (1–4)	2.5 (1–3)
Distal	2 (1–5)	2.8 (1–5)	2.3 (2–3)
Lingual	2.3 (1–3)	2 (1–3)	2 (1–3)
Control group			
Mesial	2.3 (2–5)	3 (2–5)	2.5 (2–4)
Buccal	2 (2–4)	2 (2–5)	2 (1–3)
Distal	2 (2–7)	3 (2–4)	2 (1–6)
Lingual	2.3 (1–6)	2.5 (2–4)	2.5 (1–4)

Mann-Whitney *U* test (level of significance: $P < .05$); non-significant at 6, 12, and 24 months.

The medians and ranges of MPI values recorded at 6, 12, and 24 months after prosthetic loading in the test and control groups are reported in Table 3. No significant differences were found between the groups ($P > .05$). The medians and ranges of MBI values recorded at 6, 12, and 24 months after prosthetic loading in the test and control groups are reported in Table 4. No significant differences were found between the 2 groups ($P > .05$). The medians and ranges of PD values recorded at 6, 12, and 24 months after prosthetic loading in the test and control groups are reported in Table 5. No significant differences were found between the 2 groups at 6, 12, and 24 months after initial prosthetic loading ($P > .05$). The medians and ranges of Periotest values in the test and control groups measured at the time of prosthetic loading, 6, 12, and 24 months after prosthetic loading are reported in Table 6. No statistically significant differences were found between the 2 groups at any time ($P > .05$).

The cumulative success rate of the implants, according to the criteria proposed by Albrektsson et al,[17] was 97.5% in both groups after 2 years of functional loading (Table 7).

DISCUSSION

Primary stability and absence of micromovement are considered fundamental prerequisites for the osseointegration of endosseous implants. For this reason, a waiting period between 3 and 6 months before loading is usually recommended. However, the necessity for not loading was empirically based and not experimentally ascertained.[18,19] 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 literature[20,21] have demonstrated the role of macromovements in tissue differentiation around endosseous implants placed in metaphyseal bone; macromovements induced fibrous tissue interposition between the implant

Table 6 Periotest Values in Test and Control Groups

Group	Periotest values (median and range)			
	Prosthetic loading	6 months	12 months	24 months
Test group	–4 (–6 to 2)	–4 (–6 to –1)	–4 (–7 to 1)	–4.3 (–7 to –1)
Control group	–3 (–4 to –1)	–4 (–5 to –2)	–5 (–6 to –2)	–4.5 (–5 to –2)

Mann-Whitney *U* test (level of significance: $P < .05$); non-significant at time of prosthetic load, and at 6, 12, and 24 months after prosthetic loading.

Table 7 Life Table Analysis Showing Cumulative Survival Rates of Test and Control Groups

Group/time	No. of implants followed	No. of implants failed	No. withdrawn	CSR (%)
Test group				
Placement to loading	40	0	0	100
Loading to 1 year	40	1	0	97.5
1 to 2 years	39	0	0	97.5
2 to 3 years	39	0	15	97.5
3 to 4 years	24	—	—	—
Control group				
Placement to loading	40	0	0	100
Loading to 1 year	40	1	0	97.5
1 to 2 years	39	0	0	97.5
2 to 3 years	39	0	19	97.5
3 to 4 years	20	—	—	—

CSR = cumulative survival rate.

surface and bone. Similar results were found with regard to dental implants.[22,23] Brunski and coworkers[24] 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 blades were left out of function. Immediately loaded implants presented fibrous tissue encapsulation, while the nonloaded implants osseointegrated normally. These observations were confirmed by other studies with titanium screw-type implants.[25]

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.[11–14,26–30] In a pilot study in dogs,[29] 3 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 2 were loaded after osseointegration occurred. The early loaded group consisted of splinting 3 implants into 1 prosthetic restoration at 1 week post-implantation. The authors found no statistical differences between the groups with respect to the quality of osseointegration, and in none of the groups was fibrous encapsulation of implants found.

The current trend is not to consider implant movement per se as detrimental to osseointegration, but rather to consider a threshold movement beyond which osseointegration is threatened.[31,32] This concept was introduced by Cameron and associates,[22] and the hypothesis that micromovement at the bone-implant interface was tolerated below a certain threshold has been confirmed by other authors.[33] These studies seem to demonstrate that micromovements up to 150 µm should be considered excessive and therefore deleterious for osseointegration.[32] On the contrary, movements less than 50 µm seem to be tolerated. Thus, the critical threshold, although dependent on the type of implant morphology and implant surface, seems to be comprehended at between 50 and 150 µm.[31,34]

Splinting implants together seems to be an effective way to reduce deleterious mechanical stress on early loaded implants.[11–13,24,35] In an experimental

study in monkeys,[28] a total of 48 implants were 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 (test group). All implants were splinted with a prosthesis. Block sections of the bone segments containing the implants were retrieved 9 months after surgical placement. In test implants, a thick layer of lamellar bone with few marrow spaces in direct contact with the implant threads was found. The study showed that the percentage of direct bone-implant contact of immediately loaded implants was significantly greater than that of 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 the present study, which utilizes 4 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. Different connecting systems have been used and compared for overdentures supported by implants placed in a 2-stage procedure. Results showed that success rates were not correlated to the connection system used.[36,37] Moreover, in a 2-stage procedure, the common belief that, if a load is distributed to an increasing number of implants, the magnitude of stresses in the bone around each implant will decrease[35,38] has not been confirmed by other authors.[2,39] However, the number of implants placed, their distribution, and the type of rigid connection used appear to be critical in the immediate loading situation. The choice of 4 implants and a U-shaped bar to rigidly connect them is based on the assumption that this number can guarantee stability and avoid movements that may compromise osseointegration.[11–13] However, there is to date a lack of long-term data regarding the possibility of obtaining successful osseointegration using a lesser number of implants rigidly connected with a bar and immediately loaded.

The choice of a U-shaped gold bar is based on the notion that with this kind of bar, it is possible to minimize rotational movements and to transfer loads to the implants mostly in a vertical direction.[11–13] This may reduce the risk of macromovements, with a subsequent lower risk of compromising osseointegration. Other designs, such as Akermann bars with a round profile or Dolder bars with an oval profile in a straight (not U-shaped) arrangement, may not prevent rotation of the denture and extra-axial loads to the implants as well as the design used in the present study.[11–13] Therefore, the risk of nonosseointegration could be higher. It is very important to stress the fact that this technique has been applied only in the interforaminal area of the mandible and in cases of good bone quality (class I, II, or III according to Lekholm and Zarb[15]). Whenever these conditions are not achieved, and where there is any doubt concerning primary stability of the placed implants, the standard 2-stage technique is recommended. Although not objectively tested, it seems important that the whole surface of the implant be covered by bone. In case of large peri-implant bone fenestrations or dehiscences appearing after implant placement, when covering of the exposed implant by bone grafting or guided bone regeneration may be required, a 2-stage standard procedure is indicated.

Success rates of this study (97.5% in both groups) fulfill success criteria proposed by Albrektsson and coworkers[17] and are consistent with those reported in the literature for implant-retained overdentures with delayed loading.[2–4,36,37,40–42] Marginal bone loss values around implants reported here for both groups are consistent with those reported by other authors in cases of delayed loading.[8,36,43–45] Radiographic evaluation of crestal bone level around implants by means of a panoramic radiograph may be criticized, because this type of radiograph can be rather imprecise. This type of radiograph was used routinely in this investigation because intraoral radiographs can be very difficult to obtain in completely edentulous patients, as a result of the very superficial insertion of the muscles of the floor of the mouth and because patients frequently report related discomfort.

Peri-implant soft tissue parameters (MPI, MBI, and PD) did not present significant differences between the test and control groups after 2 years of functional loading and are also consistent with those reported in the literature.[37,40,41,46,47] The Periotest values obtained in this study did not present significant differences between the 2 groups and are also consistent with those reported in the literature for delayed loading situations.[40,42]

No statistically or clinically relevant differences could be detected between the test and control groups. The small sample size limited the power of the tests; therefore, the lack of statistical significance taken alone is not strong evidence of similarity between the groups. On the other hand, other facts suggest that there is truly no difference: The biologic knowledge is consistent with this conclusion, previous studies yielded similar results, and nonsignificant differences were found even when the power of the tests was enhanced by using (incorrectly) the individual implants as units of analysis (n = 39 per group). The reported evidence

is sufficient to conclude at least that a broader field study could be safely initiated on the basis of this pilot randomized prospective study.

CONCLUSION

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 and to compare the results of osseointegration and survival of implants with implants that underwent delayed loading. Preliminary results from this study seem to indicate that immediately loaded implants, when rigidly splinted and used to support an overdenture prosthesis, performed no differently than implants placed and restored using the standard healing period. Clinical and radiographic success criteria demonstrated no statistically significant differences.

ACKNOWLEDGMENTS

The authors would like to thank Dr Andrea Lazza and Dr Dario Maj for their contribution in collecting data during the follow-up period and for the prosthetic rehabilitation of the patients. They would also like to thank Dr Carlo Clauser for the statistical analysis of data.

REFERENCES

1. Naert I, De Clerq M, Theuniers G, Schepers E. Overdentures supported by osseointegrated fixtures for the edentulous mandible: A 2.5-year report. Int J Oral Maxillofac Implants 1988;3:191–196.
2. Mericske-Stern R. Clinical evaluation of overdenture restorations supported by osseointegrated titanium implants: A retrospective study. Int J Oral Maxillofac Implants 1990; 5:375–383.
3. Quirynen M, Naert I, van Steenberghe D, Teerlinck J, Dekeyser C, Theuniers G. Periodontal aspects of osseointegrated fixtures supporting an overdenture. A 4-year retrospective study. J Clin Periodontol 1991;18:719–728.
4. Johns RB, Jemt T, Heath MR, et al. A multicenter study of overdentures supported by Brånemark implants. Int J Oral Maxillofac Implants 1992;7:513–522.
5. Zarb GA. Overdentures: An alternative implant methodology for edentulous patients. Int J Prosthodont 1993;6: 203–208.
6. Adell R, Lekholm U, Rockler B. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. J Oral Surg 1981;10:387–416.
7. Branemark P-I, Hansson BO, Adell R, et al. Osseointegrated implants in the treatment of the edentulous jaw: Experience from a 10-year period. Scand J Plast Reconstr Surg 1977;11: 1–132.
8. Spiekermann H, Jansen VK, Richter EJ. A 10-year follow-up study of IMZ and TPS implants in the edentulous mandible using bar-retained overdentures. Int J Oral Maxillofac Implants 1995;10:231–243.
9. Jemt T, Chai J, Harnett J, et al. A 5-year prospective multicenter follow-up report on overdentures supported by osseointegrated implants. Int J Oral Maxillofac Implants 1996;11:291–298.
10. Boerrigter EM, Van Oort RP, Raghoebar GM, Stegenga B, Schoen PJ, Boering G. A controlled clinical trial of implant-retained mandibular overdentures. J Oral Rehabil 1997;24: 182–190.
11. Ledermann PD. Stegprothetische Versorgung des zahnlosen Unterkiefers mit Hilfe von plasmabeschichteten Titanschraubenimplantaten. Dtsch Zahnärztl Z 1979;34:907–911.
12. Ledermann PD. Sechsjaehrige klinische Erfahrung mit dem titanplasmabeschichteten ITI-Schraubenimplantat in der Regio Interforaminalis des Unterkiefers. Schweiz Monatsschr Zahnmed 1983;93:1080–1089.
13. Graber G, Besimo C. Hybridprothetische Suprastrukturen mit Konuskronen oder Hulsen-stift-systemen auf Ha-Ti implantaten. Fortsch Zahnärztl Implantol 1991;7:125–130.
14. Chiapasco M, Gatti C, Rossi E, Haefliger W, Markwalder T. Implant-retained mandibular overdentures with immediate loading: Results on 226 consecutive cases. Clin Oral Implants Res 1997;8:48–57.
15. Lekholm U, Zarb G. Patient selection and preparation. In: Brånemark P-I, Zarb G, Albrektsson T (eds). Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago: Quintessence, 1985:199–209.
16. Mombelli A, Van Osten MAC, Schürch E, Lang NP. The microbia associated with successful or failing osseointegrated titanium implants. Oral Microbiol Immunol 1987;2:145–151.
17. Albrektsson T, Zarb G, Worthington P, Eriksson RA. The long-term efficacy of currently used dental implants: A review and proposed criteria of success. Int J Oral Maxillofac Implants 1986;1:11–25.
18. Brånemark P-I, Breine U, Adell R, Hanson BO, Lindström J, Ohlsson A. Intraosseous anchorage of dental prostheses. I. Experimental studies. Scand J Plast Reconstr Surg 1969;3: 81–100.
19. Brånemark P-I. Osseointegration and its experimental background. J Prosthet Dent 1983;50:399–410.
20. Unthoff HK, Germain LP. The reversal of tissue differentiation around screws. Clin Orthop 1975;123:248–252.
21. Søballe K, Hansen ES, Brockstedt-Rasmussen H, Bünger C. Tissue ingrowth into titanium and hydroxyapatite coated implants during stable and unstable mechanical conditions. J Orthop Res 1992;10:285–299.
22. Cameron H, Pilliar RM, Macnab I. The effect of movement on the bonding of porous metal to bone. J Biomed Mater Res 1973;7:301–311.
23. Schatzer J, Horne JG, Summer-Smith G. The effect of movement on the holding power of screws in bone. Clin Orthop Rel Res 1975;3:257–262.
24. Brunski JB, Moccia AF, Pollock SR, Korostoff E, Tratchenberg DI. The influence of functional use of endosseous dental implants on the tissue implant interface: I. Histological aspects. J Dent Res 1979;58:1953–1969.
25. Akagawa Y, Hashimoto M, Kondo N, Satomi K, Tsuru H. Initial bone-implant interfaces of submergible and supramergible endosseous single-crystal sapphire implants. J Prosthet Dent 1986;55:96–101.

26. Deporter DA, Watson PA, Pilliar RM, Howley TP, Winslow J. A histological evaluation of a functional endosseous, porous-surfaced titanium alloy dental implant system in the dog. J Dent Res 1988;67:1190–1195.
27. Hashimoto M, Akagawa Y, Hashimoto M, Nikai H, Tsuru H. Single crystal sapphire endosseous implant loaded with functional stress: Clinical and histological evaluation of peri-implant tissues. J Oral Rehabil 1988;15:65–76.
28. Piattelli A, Ruggieri A, Franchi M, Romasco N, Trisi P. A histologic and histomorphometric study of bone reactions to unloaded and loaded non-submerged single implants in monkeys: A pilot study. J Oral Implantol 1993;19:314–320.
29. Sagara M, Akagawa Y, Nikai H, Tsuru H. The effects of early occlusal loading on one-stage titanium implants in beagle dogs: A pilot study. J Prosthet Dent 1993;69:281–288.
30. Randow K, Ericsson I, Nilner K, Petersson A, Glantz P-O. Immediate functional loading of Brånemark dental implants: An 18-month clinical follow-up study. Clin Oral Implants Res 1999;10:8–15.
31. Szmukler-Moncler S, Salama H, Reingewirtz Y, Dubruille JH. Timing of loading and effect of micromotion on bone-dental implant interface: Review of experimental literature. J Biomed Mater Res 1998;43:192–203.
32. Pilliar RM, Lee GM, Maniatopoulos C. Observations on the effect of movement on bone ingrowth into porous surfaced implants. Clin Orthop Rel Res 1986 Jul;(208):108–113.
33. Maniatopoulos C, Pilliar RM, Smith D. Threaded versus porous-surfaced designs for implant stabilization in bone-endodontic implant model. J Biomed Mater Res 1986;20: 1309–1333.
34. Pilliar RM, Deporter D, Watson PA. Tissue-implant interface: Micromovement effects. In: Vincenzini P (ed). Advances in Science and Technology. Vol 12: Materials in clinical applications: Proceedings of the 8th CIMTEC-World Ceramics Congress and Forum on New Materials, Florence, Italy, June 28 to July 4, 1994. Faenza, Italy: Techna, 1995:569–579.
35. Skalak R. Biomechanical considerations in osseointegrated prostheses. J Prosthet Dent 1983;49:843–848.
36. Bergendal T, Engquist B. Implant-supported overdentures: A longitudinal prospective study. Int J Oral Maxillofac Implants 1998;13:253–262.
37. Naert I, Quirynen M, Hooghe M, van Steenberghe D. A comparative prospective study of splinted and unsplinted Brånemark implants in mandibular overdenture therapy: A preliminary report. J Prosthet Dent 1994;71:486–492.
38. Jennings KJ, Lilly P. Bar-retained overdentures for implants: Technical aspects. J Prosthet Dent 1992;68:380–384.
39. Meijer HJA, Starmans FJM, Steen WHA, Bosman F. A three-dimensional finite element study on two versus four implants in an edentulous mandible. Int J Prosthodont 1994; 7:271–279.
40. Nishimura K, Itoh T, Takaki K, Hosokawa R, Naito T, Yokota M. Periodontal parameters of osseointegrated dental implants. A 4-year controlled follow-up study. Clin Oral Implants Res 1997;8:272–278.
41. Mericske-Stern R, Steinlin-Schaffner T, Marti P, Geering AH. Peri-implant mucosal aspects of ITI implants supporting overdentures: A five-year longitudinal study. Clin Oral Implants Res 1994;5:9–18.
42. Mericske-Stern R, Milani D, Mericske E, Olah A. Periotest measurements and osseointegration of mandibular ITI implants supporting overdentures: A one-year longitudinal study. Clin Oral Implants Res 1995;6:73–82.
43. Albrektsson T, Bergman B, Folmer T, et al. A multicenter study of osseointegrated oral implants. J Prosthet Dent 1988;60:75–84.
44. Adell R, Eriksson B, Lekholm U, Brånemark P-I, Jemt T. A long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws. Int J Oral Maxillofac Implants 1990;5:347–359.
45. Chaytor DV, Zarb GA, Schmitt A, Lewis DW. The longitudinal effectiveness of osseointegrated dental implants. The Toronto study: Bone level changes. Int J Periodontics Restorative Dent 1991;11:1134–1145.
46. Levy D, Deporter DA, Watson PA, Pilliar RM. Periodontal parameters around porous-coated dental implants after 3 to 4 years supporting overdentures. J Clin Periodontol 1996; 23:517–522.
47. Boerrigter EM, Van Oort RP, Raghoebar GM, Stegenga B, Schoen PJ, Boering G. A controlled clinical trial of implant-retained mandibular overdentures. J Oral Rehabil 1997;24: 182–190.