

Early Functional Loading at 5 Days for Brånemark Implants Placed into Edentulous Mandibles: A Prospective, Open-Ended, Longitudinal Study

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Background: Traditionally, implants placed in the mandible heal for 3 to 4 months before they are loaded. In maxillae, healing time usually takes 5 to 6 months. The purpose of this study was to evaluate placement of 4 to 6 implants in edentulous mandibles. The implants were placed between mental foramina for support of non-metal, reinforced, fixed, implant-supported provisional prostheses. A unique method was used to convert existing dentures into fixed, implant-supported appliances. The implants were functionally loaded early (5 days).

Methods: Twenty patients with edentulous mandibles or with 2 to 3 remaining mandibular teeth were enrolled in this open-ended, prospective study. Existing dentures without porcelain teeth were modified for use as a surgical guide. These dentures were used as temporary fixed prostheses. Patients were to have metal-reinforced appliances fabricated by the referring dentists after 3 to 4 months of healing. After implant installation, prosthetic abutments were fixed to the implants and tightened to 20 Ncm without counter torque. Bone quality and quantity as well as implant size and position were entered into a computer database. Impression copings were attached to the abutments, and the modified denture was used for a pick-up impression. After the impression was made, implant replicas were fitted to the impression copings and casts were poured. Gold cylinders were processed into the tissue side of the denture. Laboratory screws were used to attach the denture with gold cylinders to abutment replicas. The dentures were processed, polished, and inserted 5 days after implant surgery. Radiographs were taken to verify proper fit of the gold cylinders to the prosthetic abutments (baseline). Radiographs were taken at each follow-up visit and were used to measure changes in crestal bone levels.

Results: Twenty patients received 92 machined-surface commercially pure titanium implants in fully edentulous mandibles. Of the total number of implants placed, two were lost between 0 to 1 year and one between 1 to 2 years. Twenty patients with a total of 90 implants were followed between 0 to 1 year. Fourteen patients have been followed between 1 to 2 years, 7 between 2 to 3 years, and 2 between 3 to 4 years. One patient died after 9 months of loading (4 implants loaded, 2 sleeper implants); another died between 1 to 2 years. A total of 6 implants remained buried (sleepers). At 2 years, the cumulative success rate is 96.3%. Survival of the implant bridges is 100.00%. The mean crestal bone level at 5 days for 11 patients was 2.1 mm (SD 0.526, SE mean 0.159) (measurements were not available for the deceased patient), while the mean level at an average of 15 months was 1.96 mm (SD 0.585, SE mean 0.176). Differences between the measurements taken at 5 days with those taken at an average of 15 months were not significant ($P < 0.683$).

Conclusions: Results of this study indicate that 4 to 5 implants can be placed and loaded within 5 days of implant insertion with high success (96.3%). Success rates for the interim and final prosthesis are 100%. A simple, possibly cost-effective method of using non-metal reinforced dentures as interim fixed, provisional dentures has been described. Impressions and registrations for making the prosthesis can be made at the time of implant installation, and this method is accurate enough to make provisional restorations. The modified denture can function as an interim fixed, implant-supported prosthesis for up to 30 months. Results of x-ray measurements indicate stable crestal bone levels for up to an average of 15 months. *J Periodontol* 2003;74:695-702.

KEY WORDS

Dental implants, immediate loading; denture, provisional; titanium.

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The original work of Brånemark and colleagues defined protocols for predictable implant placement.¹ These protocols required submerging implants for 3 to 4 months in the mandible and 5 to 6 months in maxillae. Submerging implants prevented premature implant loading and bacterial contamination. Over the past 20 years, the original protocols have been significantly modified. There are numerous reports of loading mandibular implants immediately after implant placement. Babbush et al.² placed 4 implants in fully edentulous mandibles and splinted these together with Dolder bars within a few days after implant placement. The retrospective success rate was 88% for 1,739 titanium plasma-sprayed screw implants. Schnitman et al. reported immediately loading of 63 Brånemark implants (3.75 mm) in mandibles of 10 patients.^{3,4} Twenty-eight implants were immediately loaded, while the remaining 35 were submerged according to the second-stage protocol. These implants were to be used if the immediately loaded implants were lost. They reported a 10-year follow-up for these patients. Of the 28 implants that were immediately loaded, 4 failed. Of the 35 implants placed in function, all osseointegrated, and at 10 years, remained in function. The 10-year survival rate for the 28 immediately loaded implants was 84.7% and 100% for the submerged implants. An immediate loading protocol was tested in 10 patients receiving a total of 130 implants.⁵ Forty implants were immediately loaded. The remaining implants were loaded using a standard 2-stage protocol. The survival rate for the immediately loaded implants was 80%, and 96% for those loaded with the standard protocol. Salama et al.⁶ treated 2 patients with extra implants for loading within a week of placement. At 3 years, all implants integrated and were restored with fixed restorations.⁷ Others placed immediately loaded implants in 10 consecutive patients and followed these patients from 1 to 5 years.⁸ A minimum of 10 implants were placed in each treated arch, with 5 being submerged as backups if the loaded implants were lost. A total of 107 implants were placed. Patients received implants manufactured by various implant companies (6 patients, Nobel Biocare; 1 patient, ITI Bone Fit; 2 patients, Astra Tech TiOblast; and 1 patient, 3i implants). Six mandibles and 4 maxillae were treated. Of the 107 implants placed, 104 osseointegrated. Jaffin et al.⁹ treated 27 patients (23 mandibles, 4 maxillae) with 149 implants that were immediately loaded. Twenty-seven were machined titanium screws (MTS), while 122 were either TPS (titanium plasma sprayed) or SLA titanium screws. Seven MTS (ma-

chined titanium screws) failed to integrate, while 1 TPS/SLA implant failed, corresponding to a 95% survival rate. Henry and Rosenberg¹⁰ reported an open-ended pilot study of 5 patients treated with immediately loaded implants in the mandible, who were followed for 5 years. At 5 years there was no implant loss. Another group compared implants loaded within 20 days (16 patients) of insertion to those loaded after a 3-month healing interval (2-stage protocol).¹¹ Over the 18-month follow-up, there was no further loss of fixtures, and crestal bone loss was minimal. Excellent clinical results have been reported for different types of implants that were immediately loaded.¹² These authors reported a 99% survival rate for the immediately loaded implants. Szmukler-Moncler et al.¹³ extensively reviewed the literature relating to early and immediate loading protocols and suggested that protocols clearly document and access the predictability of these procedures.

One of the major concerns of immediate implant loading is micromovement with subsequent fibrous implant encapsulation. Micromotion greater than 100 µm should be avoided,¹⁴⁻¹⁶ and may result in implant fibrous encapsulation. Studies on the placement of Brånemark implants in one stage have reported favorable results.¹⁴⁻¹⁶ These unsplinted implants likely received micromovement forces as a result of tongue pressure and food flow, yet the 1-stage procedures have high survival rates.¹⁷⁻¹⁹ Micromovement on these implants was apparently insufficient to cause implant fibrous encapsulation. Brånemark et al.²⁰ presented clinical results from a study that loaded 5 mm wide implants the same day as implant insertion. The method is precise, utilizing prefabricated parts to splint the implants with titanium bars. The metal bars are processed to patients' existing dentures. The survival rate was 98%.

The purpose of this prospective, open-ended study was to evaluate success rates for 4 to 6 Brånemark implants placed into fully edentulous mandibles, and functionally loaded 5 days after implant insertion. This study used converted existing complete mandibular dentures with non-metal, reinforced, transitional fixed restorations. Bone levels were measured from non-standardized, parallel cone periapical x-rays taken at implant loading and up to 1 year postloading.

MATERIALS AND METHODS

A total of 20 patients ranging in age from 54 to 86 years (mean 69.9 years) were treated between January 2000 and January 2002. Thirteen males (age range, 60 to 86) and 7 females (age range, 54 to

84) participated in the study. Presurgical evaluations consisted of medical and dental histories, maxillary and mandibular study casts, photographs, panoramic radiographs, occlusal and periapical radiographs, and assessment of maxillary teeth (fully or partially edentulous) (Fig. 1). Seven patients had complete maxillary dentures, and 5 patients were dentate in the maxillary arch.

Exclusion criteria included smoking more than 20 cigarettes per day; poorly controlled diabetes; or a history of coronary heart attack or cerebral vascular incidents within the previous 6 months.

Inclusion criteria were: 1) agreement to have existing dentures remade prior to surgery if worn longer than 5 years or if they were made with porcelain teeth; 2) placement of implants 10 mm or longer between mental foramina; and 3) radiographic evidence of good bone quality (Type 1-3) and quantity (jaw shapes A-C).²¹

Success criteria were verification of implant stability after prosthesis removal, stable bone crests as evaluated by periapical radiographs, and absence

of pain or implant mobility.^{22,23} Functional loading was defined as the teeth contacting in centric occlusion.

Patients were given detailed explanations of the study purpose, and all patients signed consent forms. All treatment was performed in accordance with the Helsinki accords. The day before surgery, the location of implant placement was marked on the dentures. The dentures were removed and delivered to the dental laboratory. The laboratory technician removed a minimum of one molar bilaterally and opened a window in the lingual aspect of the denture between the mandibular second bicusps (Fig. 2A). The relieved denture was used as a surgical guide and as a pickup for the final impression.

One hour prior to surgery, patients took 1 g of amoxicillin orally. Intravenous conscious sedation and

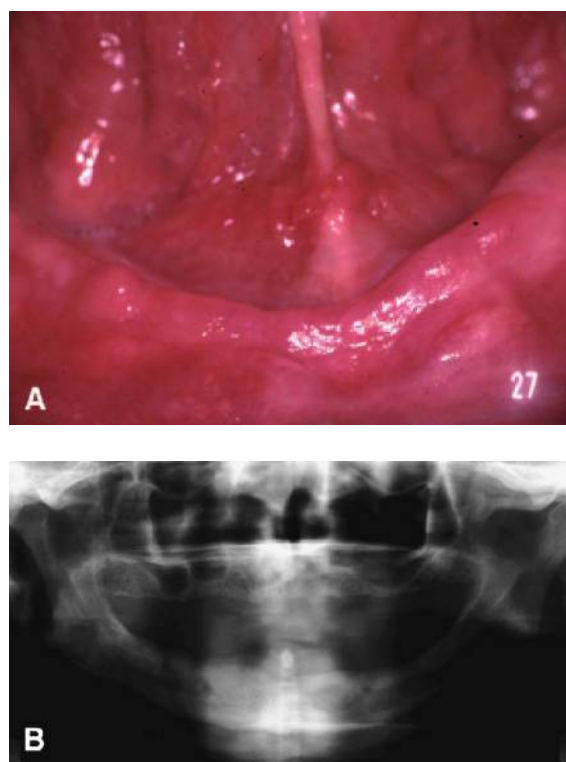


Figure 1.
A. Preoperative clinical view of edentulous mandible. **B.** Panoramic view of fully edentulous mandible demonstrating good bone volume between mental foramina.



Figure 2.
A. Mandibular denture has been modified to serve as a drilling guide and for a pick-up impression. **B.** Denture was used as a drilling guide. Implants were placed within confines of denture guide. Prosthetic abutments were placed onto the implants, and transfer copings were placed onto the prosthetic abutments.

Case Series

appropriate local anesthesia were administered. Three patients had 2 to 3 remaining mandibular teeth with advanced periodontal disease. These were removed at the time of implant placement. Full-thickness, lingual-to-crest incisions were made from the mandibular second bicuspid, bilaterally. When the alveolar crest was thin, it was reduced to a width of 4 to 5 mm with bone burs under a constant stream of saline. The relieved denture was inserted and used as a drilling guide (Fig. 2B). Implant placement was performed according to the method described by Adell and coworkers,¹ except that surgical sites were not tapped. All implants were placed anterior to the mental foramina. When teeth were present and removed, implant sites were prepared adjacent to the extraction sockets. The sockets were debrided, but not grafted. All sites received countersinking. Four to 6 implants were placed between mental foramina. Self-tapping, 3.75 mm implants[§] were inserted with a torque between 30 and 40 Ncm. Bone quality, quantity, implant length, and width were recorded and entered into a computer database. All implants were stable after insertion. Once inserted, the implants were hand tightened. Multiunit abutments (3 mm)^{||} were connected to the implants and machined tightened to 20 Ncm with a torque controller without using a countertorque device. Impression copings were attached to the implants and hand tightened (Fig. 2B) and never extended beyond the occlusal aspect of the dentures. Flap margins were adjusted to adapt to the prosthetic abutments and sutured with interrupted, resorbable sutures (Fig. 3A). The tissue surface of the denture was painted with adhesive, and polyvinyl siloxane impression material was placed into the tissue side of the dentures. An impression syringe with material was used to deliver impression material around the impression copings. The denture was placed into the mouth, and impression material was added to the occlusal surfaces, providing an interocclusal recording. Once the material set, the denture was removed from the mouth, and impression copings were removed and seated into the impression. Flaps were carefully inspected for retained impression material; healing abutments were placed onto the prosthetic abutments; and the patients were given appropriated analgesics and dismissed. The authors made all impressions and recordings described above.

Implant analogs were attached to the impression copings, and the denture was delivered to the dental laboratory. The laboratory technician poured the master model and mounted the casts on an articulator,

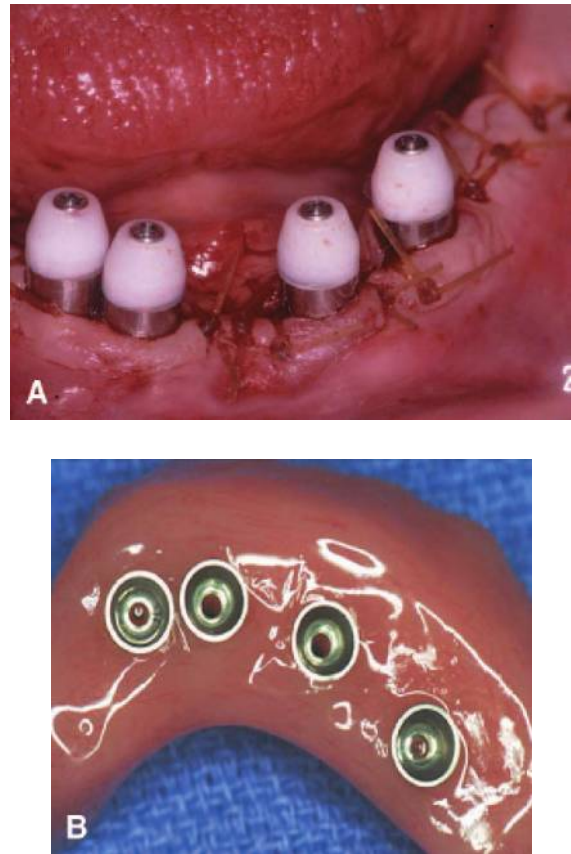


Figure 3.

A. Flap margins were sutured prior to taking the impression. Healing abutments were placed on the abutments. **B.** Gold cylinders were processed into the tissue side of the denture.

using the interocclusal record. Multiunit gold cylinders^{||} were placed onto the abutment replicas, and vinyl sleeves were trimmed to accommodate the slotted laboratory screws (Fig. 3B). In 19 patients, 2 bicuspids were extended distal to the terminal implants (cantilevers), while one patient had 2 bicuspids and one molar distal to the terminal implant. The dentures were flaked, and heat-cured acrylic was used to process the gold cylinders into the lingual cut-out area of the denture. The dentures were trimmed and polished in the usual manner.

The ability of the laboratory to complete processing of the dentures in less than 5 days was the determining factor in choosing 5 days for prostheses delivery. Five days after implant placement, the healing abutments and sutures were removed. The processed dentures were inserted and connected to the pros-

[§] MK III, Nobel Biocare, Yorba Linda, CA.

^{||} Nobel Biocare.

thetic abutments with laboratory screws (Fig. 4A). At denture insertion at 5 days, non-standardized periapical radiographs were taken to evaluate proper fit of the gold cylinders to the prosthetic abutments (Fig. 4B). These radiographs were considered baseline. Laboratory screws were hand tightened, and the occlusal openings were closed with temporary material. The occlusion was adjusted to provide uniform occlusal contacts in centric occlusion. Occlusion was evaluated with articulating paper and adjusted according to the occlusal markings. Patients were instructed in proper oral hygiene and asked to maintain a relatively soft diet for 4 to 6 weeks. All patients were seen weekly for 4 weeks. Success criteria were evaluated at 4 months, 6 months, 12 months, and annually thereafter. At these appointments, the dentures were removed and the implants were evaluated for mobility with 2 mirror handles. Follow-up radiographs were taken at 4 months, after final prosthesis insertion, and annually. At 4 to 6 months, patients were requested to return to their restorative dentists for construction of metal bar-retained fixed dentures (Fig. 5A).

Periapical radiographs were taken at 5 days and at 1 year (Fig. 5B). The x-rays were scanned into a

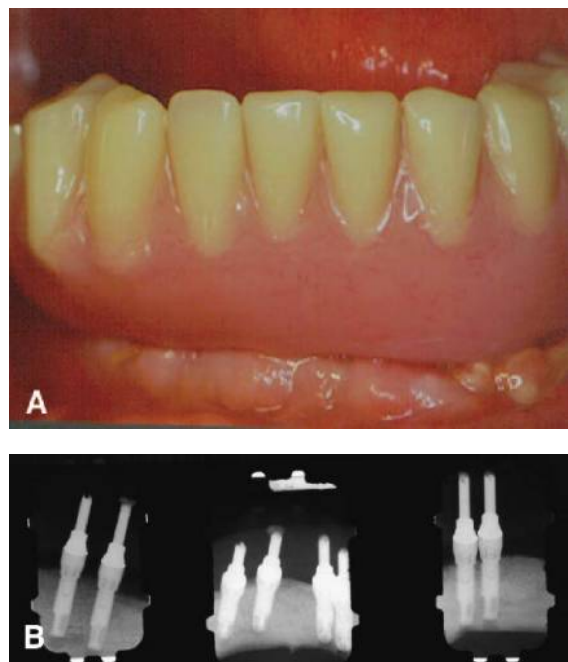


Figure 4.

A. The fixed-detachable interim denture was attached with laboratory screws 5 days after implant placement. **B.** Radiographs were taken at the time of prosthesis insertion. Note precise fit of gold cylinders to prosthetic abutments.

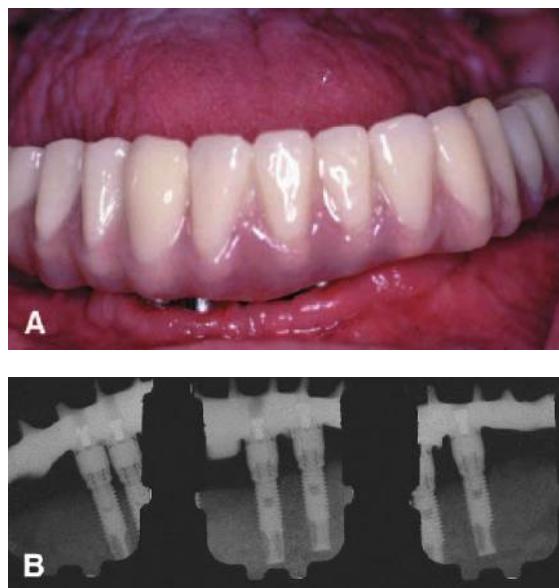


Figure 5.

A. Six months after implant placement, the metal bar, reinforced, fixed-detachable denture was delivered to the patient. **B.** Radiographs were taken at the 12-month follow-up visit. Marginal bone levels were stable.

computer at 300 dpi (dots per inch) and compared for changes in crestal bone. Radiographs were available for 11 patients. A computer program was used to measure crestal bone levels from the scanned images.[¶] Mesial and distal measurements were made in millimeters (1.3 mm from the top of the implant platform to the first thread), measuring from the top of the implant platform to the first point of bone-to-implant contact. Mesial and distal measurements for each implant were averaged as were the measurements for each measured implant, thus providing a patient mean for each examination time. The data were copied to a statistical computer program for analysis.[#]

Statistical Analysis

Life-table analysis was used to determine implant success rates.²⁴ The paired *t* tests for related samples were used to compare differences between x-ray measurements.

RESULTS

Twenty patients received 92 machined-surface commercially pure titanium implants in fully edentulous mandibles. In maxillae, 9 patients were restored with

[¶] NIH Image, Scion Corp., Bethesda, MD.

[#] Mini Tab 10Xtra Inc., State College, PA.

Case Series

complete maxillary dentures, and 11 were partially edentulous. Of the total number of implants placed, two were lost between 0 to 1 year and one between 1 to 2 years (Table 1). Twenty patients with a total of 90 continuously functioning loaded implants (average 4.0 implants per patient) were followed from 0 to 1 year. Two patients died during this period. Fourteen patients were followed from 1 to 2 years, 7 patients from 2 to 3 years, and 2 patients from 3 to 4 years. A total of 6 implants remain buried. At 2 years, the cumulative success rate is 96.3%. At 4 postoperative months, 16 patients had their dentures remade with metal reinforcement, and the remaining 4 continue to wear the acrylic modified dentures. Table 2 describes the number of implants placed according to bone quality and quantity. Eighty implants were placed into Type 2 bone quality (good density).²² Fifty implants were placed into Type A jaw shape (minimal bone resorption). Table 3 shows the number of implants placed according to implant size. Eighty-nine implants were 3.75 mm wide, while three were 4.0 mm in diameter. Fifty implants were 13 mm in length, 33 were 15 mm long, and one was 11.5 mm long. Three implants were lost. Two were 13 mm long, and the other was 10 mm long. Twenty dentures were attached to the prosthetic abutments at 5 days. One of the gold cylinders did not precisely fit to the implant abutment. The denture was repaired and attached to the prosthetic abutments within 3 hours. Success rates for interim and final prostheses are 100%.

For 11 patients, radiographs taken at 5 days and an average of 15 months follow-up were available for crestal bone measurements. Radiographic measurements revealed stable crestal bone levels for up

Table 1.

Life-Table Analysis for Implants

Time Period (years)	Patients	Implants	Lost	SR*	CSR†
0	20	92	0	100	100
0-1	20	90	2	97.8	97.8
1-2	14	64	1	98.4	96.3
2-3	7	32	0	100	96.3
3-4	2	10	0	100	96.3

* Success rate.

† Cumulative success rate.

Table 2.

Bone Quality and Quantity for Implants²¹

Quality	Quantity				Total
	A	B	C	D	
1	0	4	0	0	4
2	44	33	3	0	80
3	6	2	0	0	8
4	0	0	0	0	0
Total	50	39	3	0	92

Table 3.

Implant Size, Number Placed, and Number Lost

Implant Size	Number Placed	Number Lost
3.75 × 10	8	1
3.75 × 11.5	1	0
3.75 × 13	50	2
3.75 × 15	30	0
4.00 × 15	3	0

to an average of 15 months. The mean crestal bone level at 5 days for 11 patients was 2.1 mm (SD 0.526, SE mean 0.159) (measurements were not available for the deceased patients), while the mean level at 1 year was 1.96 mm (SD 0.585, SE mean 0.176). Differences between the measurements taken at 5 days with those at 1 year were not significant ($P < 0.683$).

DISCUSSION

Results of this study provide evidence that implants placed in mandibular edentulous patients and receiving early functional loading (5 days) after insertion are predictable (success rate 96.3%). The results further indicate that an average of 4 loaded implants is sufficient to support a fixed, functionally loaded provisional hybrid denture. "Functionally loaded" implies that the teeth contacted in centric occlusion. Extra implants were placed during the early phase of this study to protect patients from undergoing additional surgery in the event of implant loss. Placement of numerous extra implants adds extra cost for the

patient and may be unnecessary. One patient lost an implant at 3 months, but continued to function on 3 implants until his death after 9 months. Others have constructed implant-supported bridges on 3 dental implants; however, 9.5% of the functionally loaded implants and 15% of the prostheses failed within a year.²⁵ All provisional prostheses had a minimum of 2 bicuspid cantilevered distal to the terminal implants. A technique was described wherein the periodontist places the implants, and can take the impressions and occlusal registrations at the time of surgery. This method is accurate for fabrication of provisional, fixed, implant-supported dentures without metal reinforcement and is similar to that reported by Balshi.²⁶ Fifteen patients returned to their dentists for fabrication of metal bar retained fixed prostheses (one died prior to fabrication of the bar retained prosthesis). It is interesting to note that in our study, 4 patients, for various reasons, have not returned to their restorative dentists for fabrication of metal framed, fixed implant-supported restorations. These provisional restorations have been worn symptom free for almost 3 years. The results of this study confirm the findings of others, in that 4 implants placed between mental foramina are sufficient to support fixed hybrid dentures.²⁷ For 11 patients, radiographic evaluations were made at the provisional installation and at an average of 15 months follow-up. In the present study, there was a statistically and clinically insignificant loss of bone at exam 1 and 2, 0.8 mm and 0.7 mm, respectively. The loss noted immediately after implant placement may have been a result of countersinking. This change also may have occurred as a result of measurement error or may have been related to not standardizing the x-rays. These measurements are similar to those of others,^{11,28} who reported a loss of 0.6 mm and 0.4 mm, respectively. These measurements indicate that crestal bone levels remain stable after implant placement and immediate loading of splinted implants.

The advantage of early functional loading of implants after insertion is that patients can begin functioning without waiting the traditional 4 months for healing. The method provides patients who have been unable to wear conventional dentures the ability to speak and eat without the embarrassment of having to remove their dentures while eating. The intent of the study was to have patients restored with final, metal framework restorations 4 months after implant insertion. It is interesting to note that 4 patients continue to function on the all acrylic fixed dentures without breakage. The major differences between this

study and other immediate loading or early loading studies are the number of implants placed and loaded (average 4), the use of one implant system, and insertion of non-metal reinforced acrylic dentures as fixed interim prostheses.

The early study by Schnitman and coworkers⁴ placed extra implants to be used if there was extensive loss of the immediately loaded implants. One study placed 107 implants of various designs in 10 patients.⁸ Half of the implants were buried as a "safety precaution" in case the immediately loaded implants failed.⁸ The present study followed a standard surgical protocol, using one implant design. The results of this study confirm those of others and validate the concept of early loading of Brånemark implants. The important factor in the successful outcome of early functionally loading implants during the first few weeks of insertion is apparently the prevention of implant micromovement. Functional loading of implants during the first few weeks of healing requires implant immobilization. It appears that acrylic dentures without metal reinforcement are sufficient to stabilize early functionally loaded implants for a period between 4 and 30 months.²⁹

CONCLUSIONS

Results of this study indicate, in the edentulous mandible, that implants can be placed and loaded within 5 days of insertion with high success (96.3%). Success rates for the interim and final prosthesis are 100%. A simple, possibly cost-effective method of using non-metal reinforced dentures is described. Impressions and registrations for making the prosthesis can be made at the time of implant installation. This method is accurate enough to make fixed, implant-supported provisional restorations. The modified denture can function as an interim, fixed, implant-supported prosthesis for up to 15 months. Results of x-ray measurements indicate stable crestal bone levels for up to an average of 15 months.

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