Early Functional Loading of Brånemark Dental Implants: 5-Year Clinical Follow-up Study

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ABSTRACT

Background: Short-term clinical studies have indicated the possibility of one-stage surgery and early loading of machined titanium implants. However, long-term data comparing the outcome to the conventional two-stage technique are missing.

Purpose: A clinical and radiographic study was performed to compare the outcome of oral rehabilitation of the edentulous mandible by fixed suprastructures connected to implants installed according to either (1) a one-stage surgical procedure and early loading (experimental group – EG) or (2) the original two-stage concept (reference group – RG). The EG and RG comprised 16 and 11 subjects, respectively.

Materials and Methods: The following specific inclusion criterion were adopted: (1) all patients had to consider themselves to be in good general health, (2) the amount of bone had to enable the installation of five to six, at least 10-mm long fixtures (Mk II fixtures; Nobel Biocare AB, Göteborg, Sweden) between the mental foramina, and (3) the patients had to be available for the follow-up and maintenance program. A total of 88 implants were placed in the EG compared to 30 in the RG. In the EG, fixed appliances were connected to the implants within 20 days following implant installation while the fixed appliances in the RG were connected about 4 months following fixture installation. At delivery of the suprastructures, all patients were radiographically examined, an examination that was repeated at the 18- and 60-month follow-ups.

Results: The analysis of the radiographs from the EG disclosed that during the observation period, between 18 and 60 months, the mean loss of bone support amounted to 0.2 mm (SD = 0.4). The corresponding value observed in the RG was 0.0 mm (SD = 0.5). During the 60-month observation period, no fixture was lost in any of the two groups examined. The implants under study as well as those in the reference material were at all observation intervals found to be clinically stable.

Conclusions: This clinical study demonstrated that it is, at least based on a 5-year observation period, possible to successfully load via a permanent fixed rigid cross-arch suprastructure titanium dental implants soon after installation. However, such a treatment approach has to be strictly limited to the interforamina area of the endentulous mandible. Furthermore, the bone resorption was found to be within the same range around such implants as around implants installed and loaded according to the original two-stage protocal.

KEY WORDS: clinical examination, early functional loading, mandible, one-stage procedure, radiographic examination, titanium dental implants

Over the years, the successful use of jawbone-anchored (osseointegrated) titanium dental implants for the rehabilitation of the edentulous[1–6] and the partially dentate patient[7–11] has been well documented in numerous publications. These studies are all based on the traditional two-stage surgical protocol using a two-piece implant. The reasons for such an approach have been to (1) minimize the risk of infection, (2) prevent apical downgrowth of mucosal epithelium along the fixture, and (3) minimize the risk for undue early loading.[12,13] Thus, a second surgery session is needed to connect mucosally piercing abutments to the fixtures before a suprastructure can be attached and functional loads applied. Similar successful treatment outcomes have been published by Åstrand et al[14] and Buser et al,[15] who reported on a number of one-piece implants (ITI) installed according to the one-stage surgical procedure.

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Recently, there have also been reports of successful treatments using two-piece implants placed according to the one-stage surgical protocol.[16–24]

In the above-mentioned clinical studies by Ericsson et al[16,17] and Åstrand et al,[14] a majority of the implants installed were serving as abutments for fixed cross-arch suprastructures. The complete dentures, worn during the initial 3-month healing period, were 10 to 12 days following implant installation adjusted and relined with a soft-tissue conditioner in order to avoid unfavorable loading of the implants. Nevertheless, it might be assumed that the individual mucosa-piercing implants during function were to some extent exposed to unpredictable loading via the denture. Furthermore, Henry and Rosenberg[18] stated that "controlled immediate loading of adequately installed, nonsubmerged implants, by reinsertion of a modified denture, does not appear to jeopardize the process of osseointegration in the anterior mandible." In addition, Glantz et al[25,26] have demonstrated that most favorable loading conditions are acquired via rigid fixed devices. Based on this knowledge, Randow et al[27] carried out a prospective study in 16 edentulous mandibles. The authors concluded from their 18-month follow-up study that "titanium fixtures ad modum Brånemark can be properly anchored in the inter-foramina mandibular area and successfully support a fixed cross-arch suprastructure even when immediately loaded following placement." Such a statement is supported by data from case reports.[28–32] Furthermore, Randow et al[27] stated that "the outcome of the study indicates that the bone resorption is within the same range around implants installed according to this one-stage surgical procedure and immediate loading as around implants installed and loaded according to the traditional two-stage protocol."

The aim of this 5-year follow-up study was to compare the outcome of oral rehabilitation of edentulous mandibles by fixed cross-arch bridges connected to implants installed according either to a one-stage surgical procedure and exposed to early functional loading (experimental group) or the original two-stage protocol (reference group), with the working hypothesis that there are no differences between the two methods concerning treatment outcome.

MATERIAL AND METHODS

The experimental group originally comprised 16 patients (9 females and 7 males, age range 53–77 years, mean age 66.3 years) who were edentulous in the mandible and described in detail in a previous study.[27] All of the patients were referred to the Brånemark Osseointegration Center, Malmö, Sweden, for treatment of their mandibular edentulism with implant-supported fixed cross-arch bridges. The patients' dentate status in the maxilla varied from a partially dentate jaw to an edentulous one supplied with a complete removable denture.

Surgical and Prosthetic Procedures

Experimental Group. Following a clinical and radiographic examination, the patients underwent implant surgery, and five to six Brånemark fixtures (Nobel Biocare AB, Göteborg, Sweden) were placed in the anterior mandible, between the mental foramina. Abutments were connected, the flaps adapted to the mucosally piercing implant pillars and tightly sutured. After about 10 days of soft-tissue healing, the sutures were removed, impressions taken, jaw relation registered, and the implant-retained dental appliance in porcelain fused to gold was fabricated. During the initial 10-day period after surgery, the patients wore no denture over the implants, but during the following 10 days (i.e., until the delivery of the final fixed appliance), they used the relined original dentures. Altogether, this means a total treatment period not exceeding 20 days from implant installation to delivery of the permanent fixed suprastructure designed with bilateral cantilevers not exceeding two premolar units length. For detailed information regarding the surgical and prosthetic procedures, see Randow et al.[27]

The reference group has been described in previous studies[16,17] of submerged versus nonsubmerged implants. A group of 11 patients with 30 implants installed according to the original two-stage surgical procedure served as reference group.

Radiographic Examination

Experimental Group. At the time of delivery of the prosthetic appliance, a radiographic examination was carried out, which was repeated at the 18-month follow-up. Reproducible projection geometry was ensured by constructing a device that was individually fabricated for each patient (for detailed information, see Randow et al[27]). The devices were unfortunately lost when moving the clinic. Therefore, at the 60-month follow-up examination, radiographs were taken with the aid of a film-holder[33] in the experimental and in the reference groups. Parallelling technique was used with rectangular collima-

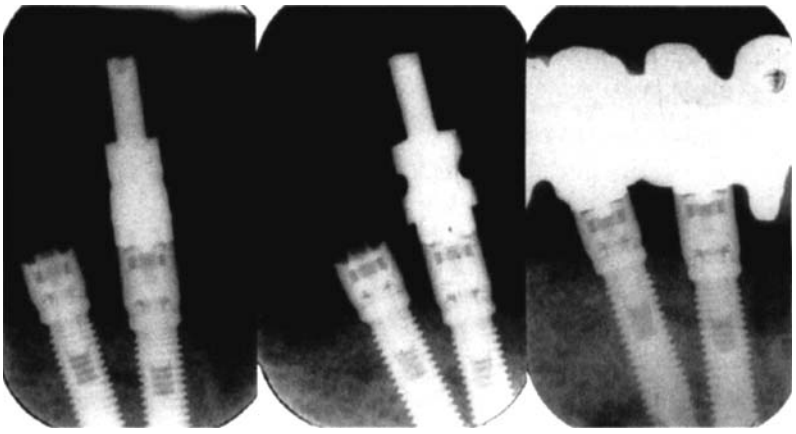

Figure 1. Representative radiographs from the initial (*left*), the 18-month follow-up (*middle*), and the 60-month examination (*right*), in the experimental group illustrating stable marginal bone level during the 5-year observation period.

tion (30 mm × 40 mm). Kodak Ektaspeed Plus film (Kodak Eastman Co., Rochester, NY, USA) was exposed at an average exposure time of 0.32 sec at 60 kVp and 7 mA using a Siemens Heliodent EC x-ray apparatus (Siemens, Bensheim, Germany). The films were developed immediately after exposure in an automatic developing machine (XR 24 Nova, Dürr dental GmbH, Bietigheim-Bissingen, Germany).

The radiographs were scanned in an HP ScanJet 6100 C/T scanner (resolution 600 dpi) into a personal computer. An image analysis program Image Tool for Windows, version 2.00 (The University of Texas Health Science Center, San Antonio, USA), was used to measure the distance between the fixture–abutment junction and the most coronal level of the bone judged to be in contact with the fixture surface. The radiographs from the initial and the 18-month follow-up examinations were re-evaluated together with the radiographs taken at the 60-month examination (Figure 1) in order to minimize any effect of the changed scanning and image analysis procedures.

Reference Group. Standardized radiographs were taken[33] immediately following connection of the bridges to the implants and at the 18- and 60-month follow-up examinations (Figure 2). Using an illuminated digitizer table (CalComp 91365, Digitizer Products Division, Scottsdale, Arizona, USA) and a cursor equipped with a magnifying lens (× 2.5), the radiographs were evaluated with regard to the mesial and distal alveolar bone levels (the distance between the fixture–abutment junction and the most coronal level of the bone judged to be in contact with the fixture surface). A computer program (Status XR, AEC, Göteborg, Sweden) was used to calculate bone contact levels (for detailed information, see Ericsson et al[16]).

For 30 randomly chosen fixtures, the measurements of the marginal bone height on the mesial and

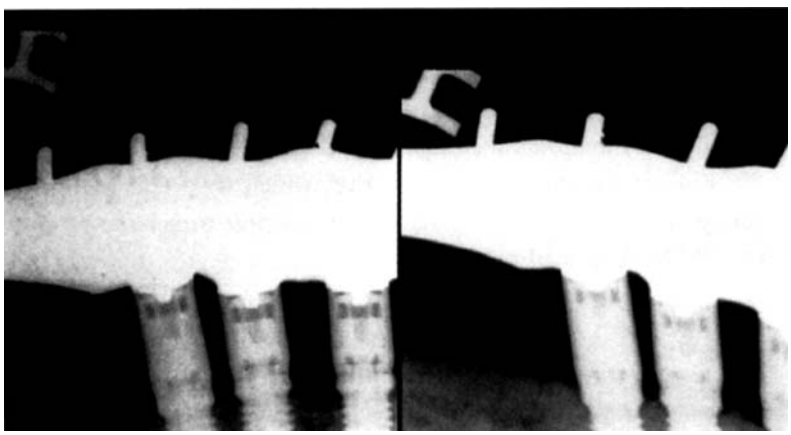

Figure 2. Representative radiographs from the 18-month (*left*) and 5-year (*right*) examination in the reference group illustrating stable marginal bone level.

distal surface were repeated with a time interval of not less than 1 week. The precision(s) of a single measurement was expressed as the standard deviation

$$s = \sqrt{\sum d^2/2n},$$

where d is the difference between two measurements and n is the number of double measurements.

The radiographs taken immediately after connection of the cross-arch bridges to the implants and those taken at the 18-month follow-up were used as reference images and compared with those obtained at the 5-year follow-up examination.

Maintenance

During the 60-month follow-up period, all of the patients were recalled every 4 to 6 months for check-up of the clinical conditions. Simultaneously, they were seen by a dental hygienist for professional cleaning, if necessary.

Clinical Examination

In the experimental group, the stability of each individual implant pillar was recorded (after removal of the suprastructure) using the Periotest system[34] (PV-1) (Periotest®, Siemens, Bensheim, Germany) at the time for delivery of the suprastructures and at the 18- and 60-month examinations (bridges removed). In the reference group, corresponding examination was performed only at the 18- and 60-month follow-up.

Dropouts

During the 60-month observation period, unfortunately, three female patients (together 16 implants) belonging to the experimental group died for reasons not related to the implant treatment. Two of these three patients died soon after the 18-month follow-up examination and the third one died 42 months after implant installation. This means that 13 patients (together 72 implants) participated in the final follow-up examination at 60 months.

RESULTS

Clinical Examination

In the experimental group, 88 fixtures were originally placed, of which 16 could not be evaluated during the entire observation period because of the decease of three patients, compared to 30 in the reference group (no dropout) (Table 1). So far, no fixtures have failed, and no complications have been reported or recorded. The clinical evaluation of the peri-implant soft tissues of the patients disclosed excellent conditions at all observation intervals (Figure 3). No differences were thus noted between the two groups examined.

The PV score values are reported in Table 2. All PV scores decreased between the 18- and 60-month follow-up examinations, indicating a more rigid anchorage in the bone. No difference was found between the two groups of patients.

Radiographic Examination

The measurement precision was found to be 0.15 mm for measurements of the marginal bone height. The average bone loss (Table 3) for the experimental group during the initial 18-month follow-up period was found to be 0.4 mm (SD = 0.5 mm) and during the following one up to 60 months another 0.2 mm (SD = 0.5 mm) (see Figure 1). The corresponding figures for the reference group were 0.8 mm (SD = 0.3 mm) and 0.0 mm (SD = 0.5 mm), respectively (see Figure 2).

DISCUSSION

This clinical trial clearly demonstrated that it is possible to successfully load Brånemark System® implants early following installation, at least via a rigid fixed cross-arch bridge. During the 5-year observation period, none of the implants in the experimental group failed. It is therefore tempting to recommend this approach for treatment of

TABLE 1. Lifetable Analysis Regarding Implant Successes Using All Implants Inserted in the Patients

Loading	18 Months		18–60 Months		60 Months	
	EG	RG	EG	RG	EG	RG
Number of successful implants	88	30	88	30	72	30
Number of failed implants	0	0	0	0	—	—
Number of withdrawn implants	0	0	16	0	—	—
Cumulative success rate	100%	100%	100%	100%	—	—

EG = experimental group, RG = reference group.

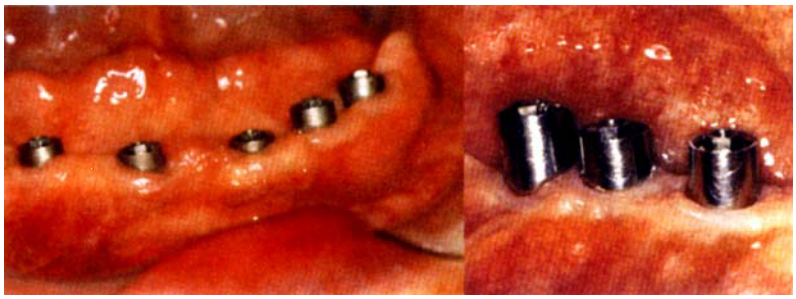

Figure 3. Clinical appearance at the 5-year examination in the experimental group (*left*) and, the reference group (*right*) with the suprastructure removed, illustrating excellent clinical soft-tissue conditions.

the edentulous mandible, but it has to be emphasized that it must be limited to the interforamina area.

Osseointegration is the result of biologic and biomechanical processes and functions.[12,13] It must be realized that each patient is unique and carries individual genetic codes and prerequisites, thus guiding the response to implant treatment. In other words, all implants planned for a particular indication and/or jaw type will not require identical healing periods. On the contrary, many implants can be loaded early or even immediately following installation, whereas others cannot. Important factors in this respect are, for example, the position of the implants in the jaw and their initial stability, the length of the implants, and whether the patient is judged to be a bruxer. The scientific evidence has today pointed out that Brånemark System® implants placed in the anterior mandible between the mental foramina, where optimal initial stability often can be obtained, in most situations can be early or even immediately loaded.[27,28,30,35] It has to be emphasized that the implants are not osseointegrated when exposed to early or immediate load but mechanically retained in the jaw bone. However, the splinting of the implants via the rigid suprastructure with time will predictably result in proper osseointegration of the fixtures.

Schnitman et al[28] reported on 61 Brånemark implants in 10 patients observed during a 10-year period. Twenty-eight of these 61 implants were exposed to immediate loading (within 24 hours) via an interim fixed denture. The success rate for these 28 implants was found to be about 85%, whereas none of the remaining 33 (submerged) implants was lost. This latter observation is identical to that in our reference group. Balshi and Wolfinger[30] have applied a similar treatment approach for edentulous mandibles as Schnitman et al.[28] The authors placed 40 Brånemark implants that were immediately loaded. Another 90 fixtures were submerged during the initial healing period. The authors reported that 8 of the immediately loaded and 2 of the submerged ones were lost (i.e., about a 20% and a 2% failure rate, respectively). Furthermore, Tarnow et al[29] have reported 1- to 5-year data regarding the treatment outcome of immediately loaded dental implants of four different brands (Brånemark, Astra, ITI, 3i) placed in six edentulous mandibles and in four edentulous maxillas. Sixty-seven of 69 implants, which were immediately loaded, integrated (success rate about 97%) and 37 of 38 submerged implants integrated (success rate about 97%). The authors concluded that "immediate loading of multiple implants, rigidly splinted around a completely

TABLE 2. Implant Stability (PV Score)* at Delivery of the Supraconstructions (Experimental Group) and at 18- and 60-Month Follow-up (Experimental and Reference Groups)

	Experimental Group at Suprastructure Connection (n = 16)	Experimental Group at 18-Month Follow-up (n = 11)	Reference Group at 18-Month Follow-up (n = 11)	Experimental Group at 60-Month Follow-up (n = 13)	Reference Group at 60-Month Follow-up (n = 11)
PV score (mean)	–2.6	–3.9	–1.8	–4.9	–3.5
SD	1.1	0.9	2.1	1.5	1.4
Min.–max.	–6...+5	–6...–1	–5...+1	–7...±0	–6...+6

*Schulte.[34]
n = number of patients.

TABLE 3. Marginal Radiographic Bone Changes at the Mesial and Distal Aspects of the Implants Up to 18 Months and between 18 Months and 5 Years Following Bridge Installation (Experimental and Reference Groups)

	Experimental Group 0- to 18-Month Follow-up (n = 16)	Reference Group 0- to 18-Month Follow-up (n = 11)	Experimental Group 18- to 60-Month Follow-up (n = 13)	Reference Group 18- to 60-Month Follow-up (n = 11)
Bone resorption (mm) (mean)	0.4	0.8	0.2	0.0
SD	0.6	0.3	0.5	0.5

n = number of patients.

edentulous arch, can be a viable treatment modality." Degidi et al[32] have reported on 138 implants (65 IMZ and 73 Frialit2) placed and "immediately" (1 to 7 days following placement) loaded in a series of different anatomic configurations in 24 patients. The observation period was at least 10 months. Six implants of the 138 placed were reported as failures (success rate about 95.5%). Some successful implants were retrieved, and around all of these a high percentage of bone–implant contact (60–70%) was observed, whereas in the removed failed implants, a dense fibrous connective tissue was consistently present between the implant and the surrounding bone. Recently, Cooper et al[36] reported on 116 Astra Tech implants placed in the canine regions of edentulous mandibles in 58 patients using a one-stage surgical approach. The patients were observed during a 2-year period. The unsplinted implant pillars were to a certain degree immediately loaded as the complete dentures were adjusted and relined with a soft-tissue conditioner and immediately placed following installation of the implants. Three months later, ball abutments were connected to the mucosally piercing implants and attachments were secured in the overdentures. Five implants were lost 2 to 4 months following insertion (i.e., a success rate of about 96% was reported). In the present clinical follow-up study, all implants were in service after 5 years. In other words, none of the implants has been lost due to early loading. Thus, our data are in agreement with the observations reported above based on case reports and prospective studies. However, it has to be noticed that in the present study, all implants were placed in the anterior mandible between the mental foramina, whereas in some of the studies cited, the implants were placed both in the anterior and in the posterior regions of the mandibles and of the maxilla.

Recently, Brånemark et al[35] reported on a new method for implant treatment of the edentulous mandible: "The new protocol involves prefabricated components and surgical guides, elimination of the prosthetic impression procedure and attachment of the permanent bridge on the day of implant placement." Fifty patients were followed 6 months to 3 years following completion of the rehabilitation. Three implants failed to integrate and three implants were lost during the observation period, resulting in an overall survival rate of 98% and a prosthetic survival rate also of 98%. The average bone loss was in agreement with figures reported for the original protocol and "did not exceed 0.2 mm per year when calculated from the 3-month examination." The data reported by Brånemark et al[35] are in line with those observed in the present study.

The recorded clinical implant stability value (PV score)[34] does, with all known limitations of the method, demonstrate negative mean values, indicating a good bone anchorage (osseointegration) of the fixtures, and correspond to values reported in previous studies.[16,17,37–40] The observation that the PV score values decreased progressively with time is in agreement with findings reported by van Steenberghe et al[39] and Ericsson et al.[17] These values are, however, not fully validated until more sophisticated methods for assessing implant stability are available for clinical work.[41]

Different film holders and x-ray apparatus were used at the radiographic examinations at the initial and 18-month follow-ups as compared to the 60-month follow-up of the experimental group because of lost equipment. However, all radiographs were taken with a parallelling technique, and the aim was to project the fixture threads as clearly as possible. The errors produced by changing the radiographic technique are presumably negligible when comparing the radiographs and could definitely not affect the observed level of the marginal bone at the 60-month observation interval.

Furthermore, the present clinical study indicates that titanium fixtures ad modum Brånemark can be properly anchored in the interforamina mandibular area and successfully support a fixed cross-arch suprastructure even when early loaded following placement. Such a statement is supported by data presented by Lazzara et al.[23] The authors reported on 429 Osseotite dental implants (3i) placed in different regions of both jaws in 155 patients. The implants were loaded about 2 months later and followed for another 10- to 12-month period. Seven failures were reported (about 2%). Six of the 7 nonintegrated implants were identified prior to provisionalization and loading.

In conclusion, the outcome of the present study indicates that the marginal bone level change is within the same range around implants installed according to this one-stage surgical procedure and early loaded as around implants installed and loaded according to the original two-stage protocol. Furthermore, this concept, with its overall favorable results, could initiate a paradigm shift regarding the treatment approach for the edentulous mandible.

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