

1 year Evaluation of Immediately Loaded INNO™ Implants in the Edentulous Mandible Using Fixed Bridges

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ABSTRACT

Background: The immediate loading concept has been extensively documented in the the edentulous mandible when primary stable implants are placed, splinted with a fixed prosthesis.

The aim of this study was to evaluate the follow-up success of immediately occlusal loaded INNO implants of platform switching in the edentulous mandible.

Materials and Methods: 128 implants placed in 13 patients and were connected with their abutments immediately after surgery. The implants were splinted using a fixed temporary restoration having occlusal contacts in the centric and anterior guidance in the lateral movements of the mandible (immediate occlusal loading). The patients were advised to use soft/liquid diet for the first 6 to 8 weeks of healing in order to reduce excessive loading in the bone-to-implant interface. Abutment level impressions were taken without removing the abutments in order to fabricate the final prostheses. The final restorations were delivered on 3 months after surgery. Clinical stability and radiological indices were evaluated at the start of loading, at 3-month interval after loading, and then annually.

Results: After a mean loading period of 13.2 months, no implant was lost (100% success rate). All clinical indices had values in normal levels. The crestal bone level was relatively stable and only minimal crestal bone loss was observed in some implants.

Conclusions: Short-term success and stability of the peri-implant tissues around immediately loaded mandibular implants are expected when implants with platform switching are restored with bridges without abutment removal.

KeyWords: immediate loading, implant, long-term success, mandible

INTRODUCTION

A load-free period of time around endosseous oral implants has been reported as a prerequisite in order to achieve osseointegration. In edentulous mandibles, it is possible to load implants immediately after surgery if some requirements are considered. Primary stability and rigid immobilization using a bar are important factors when loading with four implants using an overdenture takes place.^{1,2} Recent studies suggested the use of a different type of restoration in the lower jaw using prefabricated abutments or only the healing abutments.³⁻⁵

The general rule of this treatment concept is to load implants, without any excessive micromotions at the interface. Increasing the implant length, choosing an appropriate thread design, improving the surface roughness, reducing the loading forces, and

recommending

soft/liquid diet at the initial stages of healing are important factors in achieving bone-implant integration.⁶⁻⁹

Moreover, some authors increased the number of implants in order to compensate for loading forces, rigidly immobilized the implants with fixed restorations.^{7,8,10-15} Transitional (secondary) implants were preferred to load immediately for the temporary restoration and were splinted later with implants, which were already healed submerged (i.e., primary implants).^{8,16,17}

Looking critically at the present literature, there is no consensus between different authors for an exact definition of the term “immediate loading.” Some authors classified the type of loading according to the

Table 1. patient characteristics

Sex	Age	Disease	Smoker	Augmentations (site number)
Female	45	No	Yes	1
Female	58	High blood pressure	No	4
Female	61	No	Yes	4
Female	63	No	No	5
Female	71	No	No	0
Female	51	Deceased because of cancer	Yes	0
Male	69	Asthma, high blood pressure	No	0
Male	72	Angina pectoris, high blood pressure	No	0
Male	67	High blood pressure	No	1
Male	62	Diabetes type II, high blood pressure	Yes	4
Male	45	Deceased because of cancer	Yes	0
Male	61	No	No	0
Male	60	No	No	0

time of the prosthesis installation and the existence or not of occlusal contacts.^{13,18,19}

If loading starts in the first 3 days after implant placement, using a prosthetic restoration with occlusal contacts, the loading may be defined as an “immediate functional (occlusal) loading.” If the loading is performed after 3 days of healing, but within the first 3 weeks, it is an “early” but not “immediate” loading. If the loading of implants takes place in a later time, this loading is termed as a “delayed loading.” There is a lack of clarity in the literature with regard to terms. Many references to “immediately loaded implants” can be found for implants, which are in fact “early-loaded” implants and *vice versa*.

The present study was performed in order to evaluate, after ≥ 1 year, the follow-up success of immediately occlusal loaded INNO implants of platform switching in the edentulous mandible.

MATERIALS AND METHODS

Between January 2011 and August 2013, thirteen patients (seven male and six female) with an average age of 60.82 years were included in this study at Cowell USC implant clinic, Seoul, Korea. 128 implants (8~11 implants in each mandible) with sandblasted, acid etched surface (INNO® implant, Cowellmedi, Pusan, Korea) made from commercially pure titanium (grade IV), and were placed in the edentulous mandible using a surgical guide after clinical and radiological presurgical diagnostics. These implants had the diameters of 3.5, 4.0, 4.5, 5.0 and 6.0 mm. The lengths varied between 8 and 14 mm.

Patients were included in the study according to the

following criteria: (1) completely edentulous in the mandible or having hopeless remaining teeth requiring extraction; (2) rehabilitation with endosseous dental implants considered the ideal treatment of choice; (3) informed consent signed; and (4) physically and mentally able to tolerate conventional surgical and restorative procedures. The exclusion criteria were the following: (1) active infection in the sites selected for implant placement; (2) systemic diseases, such as diabetes without control; (3) pregnancy; and (4) severe bruxism (Table 1).

In the opposing upper arch dentitions, the patients had five different types of restorative arrangements existed.

The patients had in the maxilla implant supported restorations (seven patients), tooth-implant supported fixed bridge (one patient) or removable restoration (one patient), healthy teeth (two patients), or were edentulous wearing a full denture (two patients). Five patients were heavy smokers (smoking more than 10 cigarettes / day for a period of more than 10 years) (Table 1). The implants placed had the following diameters: 12 implants with a

Table 2 distribution of implants

Length (mm)	Diameter (mm)			Total
	3.5	4.0	5.0	
8	0	25	6	31
10	7	58	9	74
12	4	15	3	22
14	1	0	0	1
Total	12	98	18	128

diameter of 3.5 mm, 98 implants with 4.0 mm, and 18 implants with a diameter of 5.0 mm (Table 2). The implants had lengths as follows: 14 mm (1 implants), 12 mm (22 implants 10 mm (74 implants), and 8 mm (31 implants)(Table 2).

The implants were placed according to the prosthetic guidelines established from a diagnostic setup. This setup was then duplicated and a surgical guide was made using the Vac-u-form™ (Buffalo Dental Manufacturing Co., Inc., Syosset, NY, USA). In areas with inadequate autogenous bone quantity (19 implants at the mesial, buccal, and distal sites in each one of them), exposed threads were augmented simultaneously using synthetic bone with rhBMP-2. The augmented areas were not covered by barrier membrane. The implants were connected to abutments (straight or angulated standard abutments) immediately after their insertion (Figure 1) using the final torque (25 Ncm). The flap was sutured using silk-suture material and interrupted sutures.

All implants were splinted using a fixed temporary restoration immediately after surgery. The temporary bridges were made chairside with self curing resin around the abutments (Figure 2). The provisional bridges were cemented temporarily at the same day of the surgery using Temp Bond®-cement material (Kerr Co., Karlsruhe, Germany). The temporary restorations had occlusal contacts in the maximal intercuspitation (ICP) and

anterior guidance in the lateral movements of the mandible keeping the vertical dimension in the correct height (immediate occlusal functional loading).

The patients were advised to use soft/liquid diet for the first 6 to 8 weeks of healing in order to reduce excessive loading at the bone-to-implant interface. A postoperative antibiotic administration was given to all patients during the total treatment period.

Immediately after surgery, implant stability was evaluated using the Periotest device (Gulden, Bensheim, Germany) and 2 weeks after surgery all clinical periimplant indices (i.e., plaque index, sulcus bleeding index, and probing pocket depth at the mesial and buccal sites, and width of the keratinized mucosa) were evaluated (baseline). The bone loss was classified from the implant top to the marginal crest of bone at the baseline (Figure 3). One week to 10 days after surgery, the sutures were removed. The clinical indices were evaluated at the time of the delivery of the final prosthesis, as well as at 3-month follow-up visits. Radiological evaluations with panoramic radiographs recorded the peri-implant bone levels at the same time intervals according to Gomez-Roman and colleagues²⁰ using Panoramic X-rays with Easydent viewer version 4.5 software (Vatec, Anseong, Korea). Three to four weeks after surgery, the temporary restorations were removed in order to take impressions



Figure 1 Implant placement and abutment connection. A: preoperative mandibular edentulous ridge B:Teflon coverage sheet with abutment for prevention the contact of resin and cement with tissue C: Abutment connection with the placed implants



Figure 2 Temporary resin bridge placement. A: self curing resin adaptation for abutments under the prepared resin bridge B: adjustment of resin around abutments C: temporary resin bridge placed immediately after surgery.

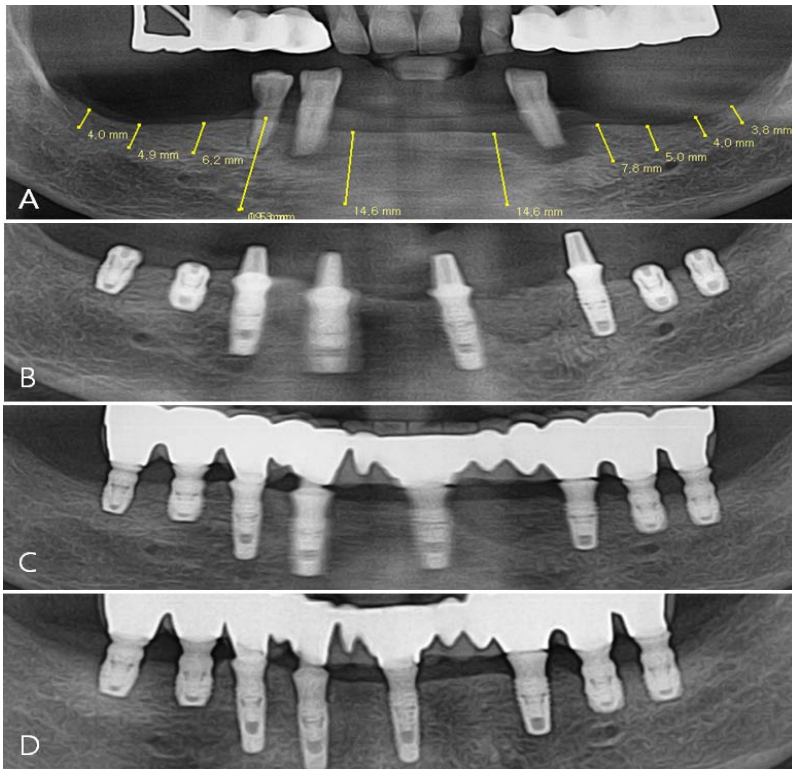


Figure 3 Radiological evaluation A: before implant surgery B: at the implant placement and immediate loading in anterior 4 implants C: final restoration after 3 month healing period D: at 1 year 9 months follow-up visit

for the final bridges. The abutments were in place and only impression caps were used for the final impressions. Occlusal registrations and determination of the vertical dimension were also performed. A custom-made framework was fabricated for a PFM fixed prosthesis. The final restorations were delivered 4 to 8 weeks after surgery and cemented temporarily in order to evaluate the peri-implant soft tissues at the different time intervals after removal of the restoration. The patients were checked for sufficient occlusal contacts. Excessive contacts in the lateral movements of the mandible were eliminated.

The criteria for success were the following: (1) no clinically detectable mobility; (2) no peri-implant radiolucency; (3) no complaint of pain at the implant site; (4) no recurrent or persistent peri-implant infection; (5) no neuropathy or paresthesia; and (6) no marginal bone loss more than 2 mm after 1 year of functional loading and less than 0.2 mm/year in the follow-up visits according to the criteria of success presented previously.²¹

The patients were examined annually clinically and radiographically and the crestal bone loss was determined.

RESULTS

After a mean loading period of average 13.2 months, no implant failure was observed (100% survival rate). The peri-implant clinical values were evaluated during the total loading period. The Periotest values presented a continuous reduction, which had a significant difference (t -test; $p < .05$) between the baseline (T0) and follow-up (T2) visit. All other clinical indices had values in normal levels, which explain the healthy peri-implant soft tissue condition. The bone loss represented by the radiographies showed vertical bone loss more than 2 mm (in only five sites) and horizontal bone loss more than 2 mm (in only one site). Specifically, a minimum of 2.11-mm and a maximum of 2.64-mm bone loss were observed. In 72 sites, a crestal bone loss (horizontal or vertical) less than 2 mm was found (Figure 6). No implant had a crestal bone loss more than 0.2 mm/year of loading.

Therefore, the success rate of this study was also 100%. Success of the immediately loaded implants was not related to bone quality, diameter, length, position of the implant, or simultaneous augmentation.

DISCUSSION

The present paper showed that only six implants with a high primary stability and a progressive thread design are adequate in order to restore edentulous mandibles using

fixed implant-supported restorations with the immediate occlusal loading protocol. The implants had a platform shifting and were loaded immediately after surgery using fixed (cement-retained) restorations with adequate occlusal contacts in the day of surgery (i.e., immediate functional/occlusal loading). An excellent splinting of the immediately loaded implants is necessary in order to avoid excessive movements at the bone to implant interface. The abutments were placed and torqued down at the day of surgery and had never been removed for the entire observation period.

Histological examination of the bone around immediately versus delayed loaded implants with the same implant thread design placed in the posterior part of the mandible in monkeys with poor bone quality showed that the bone-to-implant contact percentages had no significant differences between the two loading protocols^{22,23} and an excellent implant integration was found. Moreover, it has been shown that the mineralized bone (bone density) was significantly higher within the threads around immediately in comparison with delayed loaded implants in nonhuman primates.^{19,22} This density was higher around loaded (immediately or delayed) implants than around unloaded implants.^{19,23} The high success rate reported in this paper can be explained with the high stability of the implant system used. Because of the good primary stability of this implant system, six implants were necessary to restore edentulous mandibles with fixed implant-supported prostheses in comparison with other studies, showing that 10 to 12 implants are necessary using implants with different designs.^{7,13} There is no doubt that also other concepts, such as the “all-in-one-day” concept with the Brånemark TiUnite®-surfaced fixtures (Nobel Biocare, Gothenburg, Sweden), allow high survival rates in the long term, but this concept is recommended to be used specifically only by well-trained surgeons and prosthodontists.²⁸

However, there is no wide spectrum of experience from general practitioners using this concept in daily practice, but recent clinical findings seem to be very promising.²⁹

Van Steenberghe and colleagues³⁰ reported a cumulative survival rate of 92.7% after 1 year in 50 mandibles using the Brånemark Novum® (Nobel Biocare, Gothenburg, Sweden) concept (lower than the conventional loading protocol), where only three immediately loaded implants (with a wide diameter of 5.5 mm) were placed and connected together rigidly by a bar.

Becker and colleagues⁴ placed four Brånemark (Nobel Biocare, Gothenburg, Sweden) implants in the anterior part of the mandible and inserted a full denture, loading the implants 5 days after implant insertion. The implant restorations were replaced 6 months later and a bar-

reinforced fixed detachable denture was placed. The implants demonstrated a success rate of 96.3% after 2 years. The crestal bone level at 5 days was 2.1 mm maybe due to insufficient oral hygiene around the implants in the first stages of the healing (the denture flange did not allow optimal plaque control).

Malo and colleagues³¹ reported an immediate function concept with four Brånemark implants to restore edentulous mandibles with fixed prostheses. According to their data, a cumulative survival rate of 96.7% in the first 6 months of loading and a small amount of bone resorption have been reported. In contrast to that, immediately loaded Brånemark® implants with a simultaneous augmentation of the exposed threads covered by a membrane had a good prognosis in the long term when they were placed in areas with poor bone quality.³²

Misch and Degidi³³ presented data from 19 edentulous mandibles with a total number of 100 implants (5–10 implants per patient), which were loaded the day of surgery with a provisional bridge. The final restorations were fabricated and placed 7 months after surgery. In the follow-up observation of 1 to 5 years after loading, the survival rate was 100%.

In a multicentric study from four different centers, Testori and colleagues¹⁴ presented data from three hundred twenty-five 3i-Osseotite® (Biomet 3i, Palm Beach Gardens, FL, USA) implants placed in the edentulous mandibles of 62 patients and immediately loaded. No smokers or pregnant patients, no patients with systemic diseases such as diabetes, and no active infections in the sites of implant placement or areas with augmentations were included in this study. The provisional prosthesis was delivered in the first 48 hours after surgery and the final restoration placed 6 months after surgery. The cumulative success rate using this immediate loading protocol was 99.4% in a mean loading period of 29 months (range 12–60 months).

Previous studies performed with immediate loading in the mandible without addressing the topic of loading forces (opposing dentition and soft/liquid diet)^{14,34} compared with other authors, who suggest soft/liquid diet protocol.^{7,10}

Patients with known parafunctional habits (i.e., bruxism) were excluded from such treatment protocols and should be treated using conventional loading protocols.⁷

The rigid splinting (immobilization) of the immediately loaded implants using cross-arch splinting with fixed or bar restorations (screw-retained restorations) is mandatory immediately after surgery. Studies with cylindrical and symmetrical implant geometries (Brånemark® system) placed in poor bone qualities are

associated with lower survival rates.^{7,8,35}

Using this implant system, we were not able to find any failures (100% success) in a prospective, randomized split-mouth study after a 2-year period of loading in the posterior mandible in 12 patients,¹⁹ even in such anatomic regions the bending moments are relatively high.³⁶ Moreover, we were able to show histologically an excellent bone-to-implant integration in nonhuman primates.^{19,22,37}

In the present prospective clinical study, we demonstrated 100% success rate of immediately loaded implants in the mandible without evidence of periimplant marginal bone loss (crestal bone loss less than 0.5 mm), possibly due to the platform shifting and the issue that the abutments were placed at the day of the surgery and were never removed. This concept was initially documented in immediately loading concepts in the maxilla and mandible presenting successful short term results.³⁸

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