Immediate Fixed INNO™ Implant Rehabilitation of the Edentulous Maxilla: A 12-Month Study

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ABSTRACT

Purposes: The aims of this study were to evaluate a surgical/prosthetic protocol for the immediate rehabilitation of the anterior maxilla, and to compare the outcomes of conventional loaded implants placed in posterior maxillary site (test group) versus immediate loaded anterior maxillary (control group) sites in the same patients.

Materials and Methods: Twenty patients were included in the study. 155 implants (90 test and 65 control) were placed. Implants placed in anterior maxilla (control group) were splinted using a fixed temporary restoration having occlusal contacts in the centric and anterior guidance in the lateral movements of the mandible. Implants placed in posterior maxilla (test group) were splinted with implants of test group after 6 months healing period using a fixed PFM restoration. All patients were followed for 1 year. Radiographic evaluation of the marginal bone resorption were performed. Clinical stability and radiological indices were evaluated at the start of loading, at 3-month interval after loading, and then annually.

Results: Two control implants failed in one patients, giving a cumulative 1-year success rate of 98.7%; the prostheses success rate was 100%. The mean marginal bone resorption around control and test implants at the 1-year evaluation were similar (0.47 ± 0.25 mm and 0.43 ± 0.21 mm, respectively).

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

Key Words: dental implants, edentulous atrophic maxilla, immediate loading, marginal bone resorption, maxillary sinus augmentation, resonance frequency analysis

INTRODUCTION

Full-arch fixed implant-supported rehabilitation of the atrophic edentulous maxilla is often complicated by poor bone quality and limited bone quantity in the premolar–molar region.[1] Different therapeutic options have been proposed over the years to overcome this anatomical limitation. The use of tilted implants and distal cantilevers may avoid the placement of implants in the posterior regions, but this technique requires an adequate bone volume in the anterior maxilla for the placement of at least four implants; long cantilevers(15 mm) are reportedly associated with reduced implant and prosthesis survival rates.[2–4] Short implants may represent an alternative, but their predictability in an atrophic posterior maxilla with an unfavorable inter maxillary relationship is controversial; regardless,
a minimum vertical bone height of 7–8 mm should exist.[5,6] The placement of implants in specific anatomical areas, such as the pterygomaxillary and tuberosity regions,7,8 or the zygoma,[9,10] may represent an alternative, but they require demanding surgical and prosthetic
procedures because of the variable anatomy and different

degrees of alveolar atrophy of the maxillofacial region. They are also associated with an increased risk of morbidity and soft-tissue complications, such as gingivitis and local infections at the implant sites.

Bilateral sinus floor augmentation using autogenous bone or synthetic bone with rhBMP-2 is a reliable method to enable implant placement in severely atrophic posterior areas.[11,12] The predictability of such anaugmentative technique is documented by a growing body of literature even in the long-term follow-up.13 However, the multistep process of maxillary implant supported rehabilitation and the long healing periods for bone graft consolidation (4–8 months) and implant osseointegration (4–9 months) may include patient discomfortand inconvenience.[11–14] Another disadvantage is that patients undergoing such therapy need to wear are movable provisional prosthesis over the surgical site for several months, which may be unstable and have traumatizing effects on peri-implant bone, jeopardizing treatment outcome.[15] Therefore, increasing interest among clinicians has been expressed in reducing the treatment time and the number of clinical steps necessary to complete maxillary rehabilitations after bonegrafting procedures.[16]

An emerging protocol is the immediate loading of implants, which can be defined as prosthetic restoration attachment to the implants no later than 1 week after surgery and achievement of occlusion with the teeth of the opposite jaw.[17–19] Changes in macroscopic implant morphology, surface treatments, and rigid cross-arch stabilization have been shown to successfully allow the immediate loading of titanium implants, even in an augmented maxilla where the probability of a successful outcome is lower compared with native bone.[20–22]

Therefore, The aims of this study were to evaluate a surgical/prosthetic protocol for the immediate rehabilitation of the anterior maxilla, and to compare the outcomes of conventional loaded implants placed in posterior maxillary site (test group) versus immediate loaded anterior maxillary (control group) sites in the same patients.

MATERIALS AND METHODS

Between January 2011 and August 2013, 20 patients (9 men and 11 women; mean age 54.6; range, 47–69 years) were included in this study at Cowell USC implant center, Seoul, Korea. 128 implants (8~11 implants in each mandible) with sandblasted, acid etched surface (INNO®, Cowellmedi, Pusan, Korea) made from commercially pure titanium (grade IV), and were placed in the edentulous maxilla 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.

The inclusion criteria consisted of the following:

physical as well as psychological ability to tolerate conventional surgical and restorative procedures (ASA Class I and II),[24] totally edentulous maxilla or having hopeless remaining teeth requiring extraction, adequate bone volume in the anterior maxilla for the placement of two or three implants with a minimum diameter of 3.5 mm and a minimum length of 8 mm, bilateral severe atrophy in the posterior areas with a residual alveolar ridge height 23 mm, a request for fixed implant-supported prosthesis, and willingness to comply with all study requirements.

Patients were included in the study according to the following criteria: (1) completely edentulous in the mandible; (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.[28]

Prior to treatment, each patient was accurately evaluated through (a) clinical analysis of oral status, residual dentition of the opposite arch, and inter-arch relationship;(b) panoramic X-rays with Easydent viewer version 4.5 software (Vatec, Anseong, Korea) to evaluate the sinus anatomy and pathology and the volume of residual alveolar bone (Figure 1); and (c) dental study casts and diagnostic setup of teeth in wax. Factors considered in the diagnostic setup included aesthetics (support for lips and cheeks), position of the anterior teeth, vertical occlusal dimension, and the space available for the prosthetic rehabilitation.

The opposing dentition was natural teeth or full arch fixed prostheses on natural teeth in six patients, natural teeth and removable prostheses in two patients, natural teeth and implant-supported fixed partial prostheses in five patients, and full-arch fixed implant supported prostheses in seven patients.

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 bone quantity (19 implants at the mesial, buccal, and distal sites in each one of them), exposed threads and 8 sites of

shallow infra-sinus ridge were augmented simultaneously using synthetic bone with rhBMP-2. The augmented areas were not covered by barrier membrane. The implants of anterior maxilla were connected to abutments (straight or angulated standard abutments) immediately after their insertion (control group) (Figure 1) using the final torque (25 Ncm) and implants of posterior maxilla was submerged (test group). 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. 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 intercuspidation (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.

Implants placed in posterior maxilla (test group) were splinted with implants of test group after 6 months healing period using a fixed PFM bridge (Fig. 2).

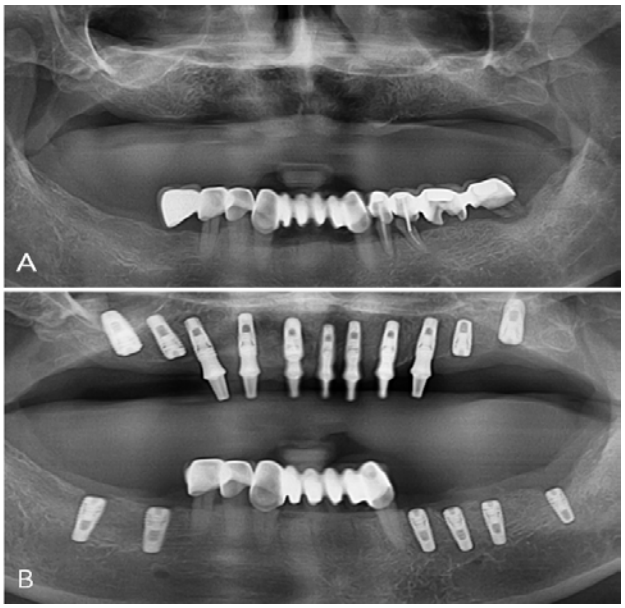

Figure 1 A**:** Preoperative panoramic radiograph B: Post-operavtive panoramic radiograph.

Figure 2 A**:** Implants placed in posterior maxilla (test group) splinted with implants of anterior maxilla (control group) after 6 months healing period B:single fixed PFM bridge

Clinical and Radiographic Examinations

The health and stability of the soft tissues around the implants were evaluated using the modified plaque index (mPI) and the modified bleeding index (mBI) recorded at the mesial, distal, buccal, and palatal aspects of each implant.[33] At the same time and sites, the periimplant probing depth (PD) was also registered using a calibrated manual periodontal probe (UNC 15; Hu-Friedy) and rounded off to the nearest mm. For each implant, one MPI, MBI, and PD value was calculated based on the mean of the four obtained values. In addition,

the width of keratinized mucosa (KM) was assessed on the midfacial aspect. These parameters were assessed at 3 and 12 months after removing the prostheses.

Radiological evaluations with panoramic radiographs recorded the peri-implant bone levels at the same time intervals using Panoramic X-rays with Easydent viewer version 4.5 software (Vatec, Anseong, Korea).

Success and Failure Criteria

The success criteria for the implants were chosen according to Albrektsson and colleagues[35] and included the following: the absence of persistent subjective complaints such as pain, a foreign body sensation, and/or dysesthesia; absence of peri-implant infection with suppuration; absence of mobility; absence of a continuous radiolucency around the implant; and MBR less than 1.5 mm in the 1 year of function. Implants that did not fulfill the success criteria were considered

failures.

A prosthesis was considered successful if it was functional, had no fractures, and provided patients with adequate masticatory, aesthetic, and phonetic function, even if one or more implants were lost. The prosthesis was considered a failure if the number of implant failures

was large enough to require the removal of the entire prosthesis, therefore leading to the lack of function of the prosthesis.[36]

Patient Satisfaction

At the 1-month follow-up visit after prosthesis placement, patients completed a self-administered questionnaire for assessment of satisfaction with function, chewing comfort, aesthetics, ability to speak, and ease of cleaning. Each item was rated on a verbal scale as excellent, good, sufficient, or poor. The same questionnaire was completed at the 12-month evaluation.[38]

Statistical Analysis

All data were analyzed with Statistical Package for the Social Sciences (SPSS) version 15.0 statistical package (SPSS Inc., Chicago, IL, USA), utilizing the implant as the unit of measure. Clinical and radiographic data are presented as the mean value 1 standard deviation (SD). Differences between groups with respect to clinical and radiographic parameters at the different time periods were tested using the unpaired *t*-test for normally distributed values. When normal distribution and homogeneity of variance were not verified by the Levene test,

the nonparametric Mann–Whitney *U*-test was used. For comparison of changes in all clinical and radiographic parameters over time within each group, the one-way repeated measures analysis of variance was applied. Differences between the two groups in the proportion of failures at 12 months were compared by means of Fisher's exact test. The paired *t*-test was used to compare the pain and swelling scores reported by the patients between reconstructive and implant surgeries. All tests were two-tailed and conducted at the 5% significance level.

RESULTS

Of 155 implants, 65 (41.9%) were positioned in the control sites and 90 (58.1%) in the test sites. Eighty three implants (53.5%) were placed in soft bone, 42 (27.1%) were placed in normal bone, and 30 (19.4%) were placed in dense bone. The lengths and diameters of the placed implants are presented in Table 1.

During the observation period, two implant failures in one patients were recorded in the control group, giving a cumulative success rate of 97.7% (2/90); however, no implants were lost in the test group, giving a cumulative success rate of 100% (0/65). The difference in cumulative success rates between the control and test groups was not significant (p = .2989). All failed implants were placed in the canine and first premolar position within 6 months after immediate loading. The patients felt some pain when the temporary immediate prostheses were removed for splinting with implants of posterior maxilla at 6 months after surgery. The implants were found to be mobile and were immediately removed. At the 12-month follow-up, the overall implant success rate was 98.7%. The cumulative success rate for the prostheses was 100%.

Four biologic complications occurred in four patients. One patient reported intermittent soft-tissue soreness around an implant in the left canine region. The implant was stable and displayed no signs of soft-tissue inflammation. It was left in situ, untreated.

Table 1 Implant size distribution

Implant Length (mm)	Implant Diameter(mm)			Total (%)
	3, 5	4	4, 5	
9	2	3		5 (1)
11	8	12	8	28 (18)
13	31	16	19	66 (42.6)
15	29	16	11	56 (38.4)
Total (%)	70 (45.2)	47 (30.3)	38 (24.5)	155

Table 2 Distribution of implants according to surgical site and peak of insertion torque

Surgical site	Peak of insertion torque (Ncm)				
	15	25	35	45	55
Posterior	8	52	22	8	
Anteior		16	24	17	8
Total (%)	8 (4.9)	68 (44.1)	46 (29.7)	25 (16.1)	8 (5.2)

Table 3 Gingival Parameters of the Control and Test Implants Evaluated at 3 and 12 Months (Mean 1 Standard Deviation)

Parameter	Group	3 Months	12 Months	*p*
mPI	Control	0.79 ± 0.54	0.48 ± 0.68	.0033
	Test	0.6 ± 0.53	0.4 ± 0.42	.0131
mBI	Control	0.58 ± 0.53	0.33 ± 0.39	.0016
	Test	0.88 ± 0.57	0.38 ± 0.43	<.0001
PD (mm)	Control	3.42 ± 0.82	3.17 ± 0.64	.0385
	Test	3.66 ± 0.81	3.38 ± 0.87	.0361
KM (mm)	Control	2.8 ± 0.63	2.92 ± 0.67	.093
	Test	2.62 ± 0.74	2.76 ± 0.78	.0601

KM = width of keratinized mucosa at the facial aspect; mBI = modified bleeding index; mPI = modified plaque index; PD = probing depth.

Analysis of variance; $p < .05$.

After about 6 months, the soreness disappeared. Three patients had one implant each affected by peri-implant mucositis 5–6 months after implant placement. After repeated professionally delivered oral hygiene and diode laser treatments, use of local antibiotics, and remotivation in oral hygiene maintenance, the situation improved.

During the follow-up period, some minor prosthetic complications occurred. The most commonly occurring problems were composite teeth fractures (n = 3), followed by abutment screw loosening (n = 2), and the need for prostheses modification because of excessive pressure on the patient's mucosa (n = 2). All prosthetic complications were easily solved on the same day the patients came to the practice, and the prostheses served well after revision. Note that all teeth fracture and loose abutment screw complications were recorded on the same two patients, in whom the presence of occlusal wear facets was seen during the follow-up controls at 3–6 months. In both cases, the repeat of such complications was prevented by the fabrication of an occlusal night guard as protection against parafunctional habits.

Implant Stability Evaluation

The mean peak IT for control implants was 37.88 ± 8.72Ncm. For test implants, the mean IT was 29.18 ± 6.4 Ncm. A significant difference was observed for IT between control and test implants ($p < .0001$). IT distribution according to the surgical site is detailed in Table 2.

Clinical Parameters

Clinical parameter values at different time points are

presented in Table 3. The mean mPI and mBI values indicated significant differences when comparing control and test implants at the 3-month evaluation (p = .0369 and p = .0007, respectively), but not at the 12-month evaluation (p = .3653 and p = .4762, respectively). For both groups, a significant decrease was observed when comparing the mean mPI and mBI values at the 3-month evaluation with that after 12 months of loading ($p \leq .05$) (Table 3).

The mean PD in the control group was 3.42 ± 0.82 mm and 3.17 ± 0.64 mm after 3 and 12 months, respectively; in the test group, the mean values were 3.66 ± 0.81 mm and 3.38 ± 0.87 mm, respectively. A significant decrease occurred in the PD values over time in both groups (Table 3), but no significant difference was found between control and test values at both the 3- and 12-month evaluations (p = .0725 and p = .0912, respectively).

The mean KM in the control group was 2.8 ± 0.63 mm and 2.92 ± 0.67 mm after 3 and 12 months, respectively (Table 3). The corresponding values in the test group were 2.62 1 0.74 mm and 2.76 ± 0.78 mm, respectively. No significant differences ($p \geq .05$) were found within or between groups.

At the 12-month evaluation, about 70% of all implants had PD 23mm and KM 33 mm, indicating the maintenance and health of the peri-implant soft tissues through the entire duration of the study.

Radiographic Evaluation

The mean marginal bone resorption values in the control group were 0.07 ± 0.1 mm at prosthesis placement, 0.3 ± 0.17 mm after 6 months, and 0.47 ± 0.25 mm after 12 months of function. The corresponding values for the test group were 0.08 ± 0.11 mm, 0.27 ± 0.18 mm, and 0.43 ± 0.21 mm, respectively. A significant increase in MBR was observed within the groups with time ($p \leq .0001$), but no significant differences were detected at any time period between the two groups ($p \geq .05$). One hundred twelve implants (73.2%) had marginal bone resorption ≤0.5 mm after 12 months of functional loading. In 36 cases (23.5%), the marginal bone resorption ranged between 0.5 and 1 mm; in five cases (3.3%), it was ≥1 mm. These findings confirmed the good maintenance of marginal bone levels over time.

Patient Satisfaction

All patients completed questionnaires for satisfaction evaluation at the 1- and 12-month recall visits (Table 4). At the final evaluation, aesthetics (teeth and smile) were judged as excellent or good by 90% of patients. Only 1 of the 20 patients was not satisfied with the aesthetics of the fixed restoration, rating its appearance as poor and requesting the remaking of the restoration after 6 months. Masticatory function was considered excellent by 75% of patients and good by 25%. Ability to speak was judged excellent in 35% of cases and good in 65%. In particular, two patients with an imperfect pronunciation of the dental phonemes at the first follow-up examination reported that these problems disappeared after 6–7 months of loading, with a great increase in the speech score. Ease of cleaning was considered good in 55% of cases and sufficient in 45%.

DISCUSSION

In the preliminary clinical and radiographic data obtained from this study, the application of an the immediately loaded anterior maxillary implants and the late loaded posterior maxillary implants drastically reduced the total conventional healing time of 12–14 months (surgical and prosthetic healing times combined) before any type of restorations were placed onto the implants.[14,]

These results suggest that the immediate loading protocol can be compared with the high implant success rates that had been previously reported in the dental literature for the augmented maxilla with the delayed loading approach.[11–14,] A recent study in which a rhBMP-2 bone graft was used for sinus augmentation in the same proportion as in this study reported a 100 % implant success rate after 12 months of function.[12]

The clinical and radiographic outcomes in the present study did not appear to be influenced by the nature of the implant sites (anterior vs posterior maxilla).

Two control implants failed in one patients because the resin immediate prosthesis was broken.

Calandriello and Tomatis34 on immediate/early function in the atrophic maxilla reported that both implant failures occurred in the same patient as a result of crack propagation and fracture of the provisional acrylic full-arch prosthesis. Other authors [4,22] who have used all acrylic resin immediate prostheses without metal frameworks have reported high survival rates, stating that once multiple implants are splinted together with a rigid and passive connection, the individual implant will become part of an integrated system that supersedes the value of individual implant stability in contrasting micromotions at the early critical phase of the

Table 4 Results of the Patient Satisfaction Questionnaires at 1- and 12-Month Follow-Up Evaluations

	1 month (%)	12 month (%)
Aesthetics Excellent Good Sufficient Poor	4 (20) 13 (65) 2 (10) 1 (5) 	5 (25) 14 (70) 1 (5) 0
Function Excellent Good Sufficient Poor	3 (15) 14 (70) 3 (15) 0 	5 (25) 15 (75) 0 0
Ability to speak Excellent Good Sufficient Poor	5 (25) 13 (65) 2 (10) 0 	7 (35) 13 (65) 0 0
Ease of cleaning Excellent Good Sufficient Poor	0 6 (30) 11 (55) 3 (15) 	0 11 (55) 9 (45) 0

osseointegration process. Consequently, primary stability of the individual implant is important, but not as critical as in a single implant situation. On a related side note, a study has suggested that immediate occlusal loading of implants in the augmented maxilla might provide a positive stimulatory effect on bone/graft maturation and enhance osseointegration outcomes.[46] The significant increase in ISQ values with time in the test sites seems to corroborate this hypothesis and probably reflected the enhanced bone apposition at the implant interface.

From the patients' self-administered questionnaires, a progressive increase in satisfaction with aesthetics, function, and speech ability was noted passing from the 1-month to the 1-year evaluations (Table 4). Patients reported a final high level of satisfaction with their full arch fixed prostheses.

Less satisfaction with cleaning comfort was reported by half of the patients at 1 year. This is a well-known side effect of a fixed implant-supported prosthesis, particularly in atrophic maxillae,

CONCLUSIONS

Short-term success and stability of the peri-implant tissues around immediately loaded anterior maxillary implants and late loaded posterior maxillary implants are expected when implants with platform switching are restored with bridges without abutment removal.

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