Effect of loading time on the survival rate of anodic oxidized implants: prospective multicenter study

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PURPOSE. The purpose of this prospective study was to evaluate the effect of early loading on survival rate or clinical parameter of anodic oxidized implants during the 12- month postloading period. **MATERIALS AND METHODS.** Total 69 implants were placed in 42 patients. Anodic oxidized implants (GS II, Osstem Cor., Busan, Korea) placed on the posterior mandibles were divided into two groups, according to their prosthetic loading times: test group (2 to 6 weeks), and control group (3 to 4 months). The implant survival rates were determined during one-year postloading period and analyzed by Kaplan-Meier method. The radiographic peri-implant bone loss and periodontal parameters were also evaluated and statistically analyzed by unpaired t-test. **RESULTS.** Total 69 implants were placed in 42 patients. The cumulative postloading implant survival rates were 88.89% in test group, compared to 100% in control group ($P<.05$). Periimplant marginal bone loss (T: 0.27±0.54 mm, C: 0.40±0.55 mm) and periodontal parameters showed no significant difference between the groups ($P>.05$). **CONCLUSION.** Within the limitation of the present study, implant survival was affected by early loading on the anodic oxidized implants placed on posterior mandibles during one-year follow-up. Early implant loading did not influence peri-implant marginal bone loss, and periodontal parameters. **[J Adv Prosthodont 2012;4:18-23]**

KEY WORDS: Anodic oxidized; Loading time; Survival

INTRODUCTION

Based on the conventional Brånemark protocol, it has been recommended that any loading on dental implants should be avoided for a certain healing period. Early loading might cause formation of connective tissue between the implant and its surrounding bone. It has been reported that radiographic horizontal and vertical marginal bone loss were observed due to the overloading on dental implants.[1]

Dental implants with machined surface, traditionally, require six months of healing time in maxilla, and three months in mandible for successful osseointegration.[2] Albrektsson suggested that the first one month after implant placement was a critical period wherein overloading might lead to failure of the osseointegration due to imbalance between the bone formation and resorption.[3] Recent implants with improved surface characteristics shorten the healing time with the increased contact between bone and implant.

Some randomized controlled trials supported immediate or early loading concept in the full-arch restorations for the success of implant osseointegration.[4-6] In a meta-analysis study of 13 prospective trials by Ioannidou *et al*., early implant loading, whether in partial or full arch, was not found to be associated with worse outcomes compared to the conventional loading.[7] It was also found in their study that immediate implant loading was associated with slightly, although not statistically significant, worse outcomes compared to the conventional loading. On the other hand, some prospective studies showed early-loaded implants occasionally rotated at the time of abutment connection.[8,9]

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Marginal bone resorption around dental implants can jeopardize the stability of peri-implant tissue which may lead to peri-implantitis or unesthetic implant restorations. Vercruyssen and Quirynen showed, in their long-term study, that some factors such as smoking, guided bone regeneration, the presence of dehiscence and bone quantity clearly showed a significant impact on the marginal bone loss around the dental implants.[10] There are few controlled studies evaluating the effect of loading time on marginal bone resorption around the dental implants.

The purpose of the present study was to investigate the effect of early implant loading on the implant survival rate. The null hypothesis was that there was no effect of early implant loading on implant survival. Anodic oxidized implants has been researched for expediting the osseointegration and reducing the healing time.[11-17] Thus, the present study examined the effect of early prosthetic loading on implant survival, periimplant bone loss, and periodontal parameters of anodic oxidized implants placed in posterior mandible.

MATERIALS AND METHODS

Study design/sample

To address the research purpose, the investigators designed and implemented a prospective study that was conducted in one dental hospital and one private practice in Korea. The study population was composed of fifty patients (24 males, 26 females, 17 to 75 years of age) presented for evaluation and management of missing edentulous areas in the posterior mandible between November, 2007 and March, 2008. To be included in the study sample, patients had to have missing mandibular premolars or molars with the presence of occluding dentition. Patients should have adequate width and height of the alveolar bone in the mandible to allow placement of implants with more than 3.5 mm in diameter and 7.0 mm in length, and be a nonsmoker or smoker who signed to quit smoking during the study period. Simultaneous minor guided bony regeneration with implant placement can be allowed.

Patients were excluded as study subjects if they had radiation therapy in the maxillofacial area, pre-implantation bone grafts, uncontrolled systemic diseases such as hypertension or diabetes mellitus, or parafunctional habits.

Study design/variables

Anodic oxidized implants (GS II, Osstem Co., Busan, Korea) were prepared for insertion in the posterior mandibles of the patients who fulfilled the presurgical inclusion and exclusion criteria. The implant specimens were divided into two groups according to the prosthetic loading time: test (2 to 6 weeks) and control (3 to 4 months). Grouping was randomly done by the restorative dentist. Loading time was determined as the time between placement of the dental implants and loading by the definitive implant prostheses. Each patient was informed that different loading times of implants were applied and signed a written informed consent form prior to the surgical procedure. The study protocol was approved by the institutional review board for clinical research of each dental hospital. The clinical and radiographic observations of the dental implants were performed during the following year. The implant survival rates, the peri-implant marginal bone loss, gingival inflammation index, plaque index, and width of keratinized gingiva were obtained and statistically analyzed.

Surgical procedure

Prophylatic antibiotics and gargling solutions (0.2% chlorhexidine digluconate) were provided prior to the operations. The surgery was performed under a local anesthesia (2% lidocaine with 1: 100,000 epinephrine). A crestal incision was made and a full mucoperiosteal flap was raised. The implants were placed according to the manufacturer's recommendation. The primary stability of the dental implants was measured with Osstell Mentor (Integration Diagnostics AB, Göteberg, Sweden). The bone graft procedures were, if needed, performed with a xenograft (BioOss; Geistlich Pharma AG, Wolhusen, Switzerland) combined with or without a small amount of autograft. Submerged or nonsubmerged implant placements were determined based on the operator's judgment. Mucoperiosteal flaps were closed with simple interrupted and horizontal mattress sutures. Postoperative gargling solutions (0.2% chlorhexidine digluconate), antibiotics, and anti-inflammatory agents were given to patients for a week. Liquid diet was recommended postoperatively for two weeks if patients have been wearing removable dentures. A second surgery was, if indicated, carried out.

Prosthetic procedure

At the time of final impression for implant prostheses, the implant stability (ISQ: implant stability quotient) on each implant was measured with Osstell Mentor. Only implants with ISQ values above 65 were prepared for the impression procedures. Forty implants from twenty six patients were loaded early (2 to 6 weeks, test). Conventional loading (3 to 4 month, control) was applied to forty three implants in twenty four patients. Silicone rubber impressions were made with custom tray (open type). Full contour wax-up was made on the master cast. Metal frameworks were adapted on the implants after being cast and finished. Framework fit was confirmed with standard radiographs. Veneering porcelains were added on the framework, if needed. The definitive fixed implant prosthesis was cemented or screw-tightened to 30 Ncm with the torque controler (Osstem Implant Co., Busan, Korea).

Data collection methods

1) Implant Survival

The implant survival was evaluated during the 12-month post loading period. "Failed (not survived)" implants include implants with clinical mobility or pain on function as well as lost implants.[18]

2) Clinical Evaluation Procedure

Soft tissue conditions, such as plaque index and gingival inflammation index were evaluated on buccal and lingual gingivae, and the width of buccal keratinized mucosa was measured at the 12-month follow-up visit.

Plaque index evaluates the thickness of the plaque at the gingival margin as follows: plaque index 0: no plaque detected, 1: a little plaque detected by exploring around gingival margin, 2: visible plaque detected, 3: much plaque detected.[19,20]

Gingival inflammation index evaluates the gingival status in clinical trials including redness, swelling, bleeding on probing, and the degree of inflammation. It can be categorized into the followings: gingival inflammation index 0: no inflammation, redness, and bleeding of gingiva, 1: a little inflammation and redness, but no bleeding of gingiva, 2: moderate inflammation, redness, swelling, and bleeding on probing of gingiva, 3: severe inflammation, redness, swelling, and spontaneous bleeding of gingiva.[19,20]

The width of buccal keratinized gingiva was measured as the midbuccal distance between the mucogingival junction and the most coronal aspect of the free gingival margin.[21]

The resonance frequency analysis values (Implant Stability Quotient) for evaluating the primary stability of implants were measured with Osstell Mentor (Integration Diagnostics AB) at implant placement and second surgery.

3) Radiographic Evaluation Procedure[10,22]

Marginal bone loss was defined as the average radiographic bone level changes in mesial and distal sides around implants. It was measured as the vertical distance between the implant platform and the first bone-implant contact area. Crestal bone level measured on the periapical radiograph taken immediately after the prosthetic loading was compared with the one taken at the 12 month postloading visit. The radiographs were taken using digital periapical radiography with paralleling cone technique (Rinn alignment system, Dentsply Rinn, Elgin, IL The magnification power was adjusted using the length of the placed implants. The mesial and distal sides were measured, and the mean value was calculated.

Statistical analyses

The implant survival rates were compared between two groups by Kaplan-Meier survival analysis. The mean values of the crestal bone loss, the gingival inflammation index, the plaque index, and the width of keratinized gingiva were also compared between two groups by unpaired t-test. Statistical analyses were done using SPSS 18.0 for Windows (SPSS Inc., Chicago, IL, USA). It was considered statistically significant for P values <.05.

RESULTS

From November, 2007 to March, 2008, eighty three implants placed in the posterior mandibles of fifty patients were enrolled in the study. Fourteen implants (4 from test group and 10 from control group) of eight patients were excluded from the final sample due to loss of follow-up. The final sample was composed of forty two patients with a mean age of 53 and 48% were male. A total of sixty nine implants were placed (Table 1).

The distribution of implants in length and diameter is presented in Fig. 1 and 2. The non-submerged implant placement was dominant in test group, whereas the subemerged implant placement was dominant in control goup (Fig. 3). Based on the average value of the RFA, ISQ value was higher at the final impression

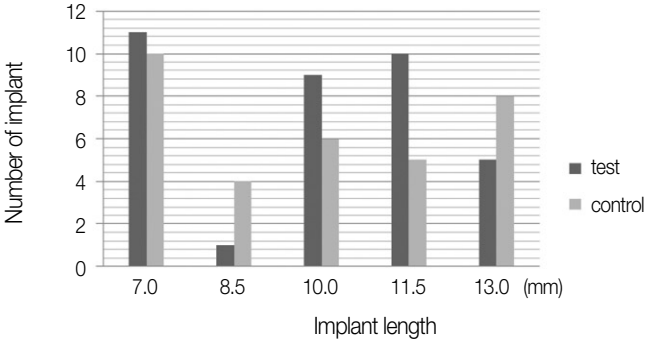

Fig. 1. Distribution of implant lengths.

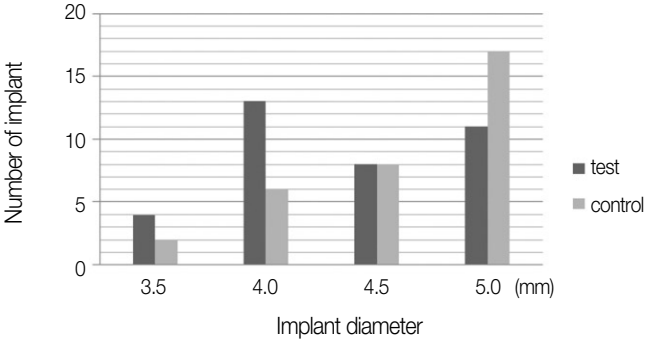

Fig. 2. Distribution of implant diameters.

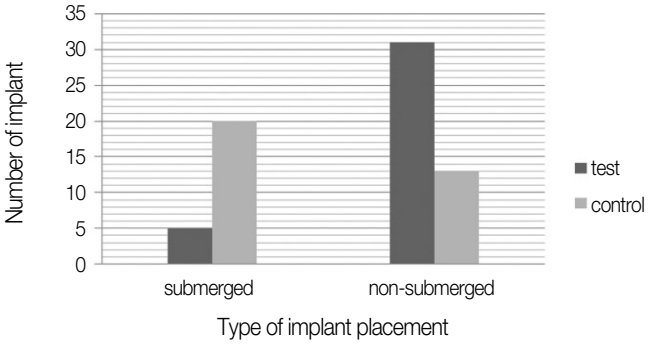

Fig. 3. Distribution of submerged and non-submerged placement.

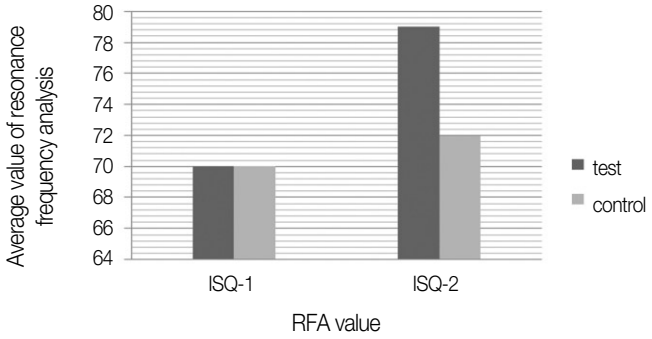

Fig. 4. Average value of resonance frequency analysis at implant placement (ISQ-1) and at the final impression (ISQ-2).

than the placement in all groups (Fig. 4).

The final implant prostheses in test group were 7 single implant crowns, 10 fixed partial dentures (FPDs) (21 implants) and 2 overdentures (4 implants). Control group had 11 single implant crowns and 10 FPDs (22 implants).

Implant survival and peri-implant condition were evaluated during 12-month prosthetic loading period. Test group had 4 failed implants during this time, while there was no failure in control group ($P<.05$) (Table 1). In test group, two single implant crowns from two male patients showed clinical mobility at 6-month postloading visit, and were removed and replaced. Another male patient had one implant presented with mobility and the other with severe bone resorption, both of which were eliminated and replaced (Table 2).

Average bone resorption rate was 0.27 ± 0.54 mm in test group, and 0.40 ± 0.55 mm in control group. They revealed no statistically significant differences (Table 3, $P>.05$). Gingival inflammation index, plaque index and the width of keratinized gingiva among the 3 groups also revealed no statistically significant differences (Table 4, $P>.05$).

Table 1. Number and ages of patients, number of implants placed, and survival rate

	Number of patients	Average age of patients	Number of implants	Survival rate (%)
Test	22	50	36	88.89*
Control	20	52	33	100.00

*Kaplan-Meier survival analysis: test vs control ($P<.05$) (Log-Rank test)

DISCUSSION

The present prospective clinical study investigated the effect of early loading on implant survival. The null hyposthesis claiming no influence was rejected because test group, 2 to 6 weeks loading group, presented 4 failed implants compared to control group showing no failures during the follow-up peri-

Table 2. Summary of failed implants in test group

Pt's age	Pt's sex	Placement site	Length of implant	Diameter of implant	Bone graft	Prosthesis type	Submerge
55	Male	#45	10.0	4.0	yes	FPD	Non-submerged
61	Male	#46	11.5	4.5	yes	FPD	Non-submerged
48	Male	#45	10.0	4.0	yes	Single crown	Non-submerged
48	Male	#37	10.0	4.0	No	Single crown	Non-submerged

Table 3. Amount of marginal bone loss around implant during 12-month prosthetic loading period

	Test	Control
Amount of bone loss (mm)	0.27 ± 0.54	0.40 ± 0.55

($P>.05$)

Table 4. Periodontal evaluation around implant

	Test	Control
Gingival inflammation index	0.43 ± 0.63^a	0.63 ± 0.71^a
Plaque index	1.21 ± 0.88^b	1.25 ± 0.92^b
Width of keratinized gingiva (mm)	2.64 ± 1.55^c	2.10 ± 1.40^c

The same letters indicate mean values with no statistically significant differences ($P>.05$).

od. This trial was also aimed for evaluating the effect of early prosthetic loading on the peri-implant marginal bone loss and some periodontal parameters. Early loading was not found to have any effect on the marginal bone loss or periodontal indices.

There were some different opinions about the time period of 'early loading', such as within 2 weeks, 35 days or 6 weeks from implant placement. In the present trial, the early loading period was set as 2 to 6 weeks.[4,7,8,23] According to the meta-analysis report of 13 prospective trials regarding immediate or early implant loading, survival rates of the implant under non-conventional loading such as immediate and early loading did not show any significant difference from the ones under conventional loading.[7,8,23,24-28]

There have been, nonetheless, some clinical studies reporting immediate loading showed lower survival rates of the implant than conventional loading.[29-31] Cochran suggested that implant stability was summed up by the decreasing primary stability and the increasing secondary stability after placement. He proposed the total implant stability reached the lowest point during 2 to 4weeks after placement, when implant osseointegration was likely to fail by any interfering forces.[32]

Regarding the association between the implant loading time and marginal bone loss around the implant, there were some different opinions. It was reported there was no significant difference in marginal bone loss of the implants between immediately loaded and conventionally loaded.[24,26,28] Early loaded implants were also claimed to have no significant difference in peri-implant marginal bone loss compared to conventionally loaded ones.[23,27] Difference in periodontal parameters between early and conventionally loaded implants were also revealed to have no significance.[4] In contrast, in 1 year follow-up research about maxillary full arch implants of 24 patients, Fischer and Stenberg found that 2-week early loading showed more alveolar bone resorption than the conventional loading.[6] It was noteworthy that in Fischer's study they collected only maxillary implant cases, while previous researches claiming no differences had mandibular implant overdenture cases.

The present trial included rough-surfaced microthreaded implant cases placed only in mandible so that the results did not show any significant difference in marginal bone loss under different loading times.[33-35] GS II implant, used in the present trial, was claimed to have a dual thread design composed of microthread and macrothread with anodized surfaces. The neck portion of the GS II implant with platform switching was claimed to have the effect of reducing marginal bone loss around implants.[36-41]

Some authors suggested that the implant placed in a non-reconstructed recipient site should survive better than the one placed in a reconstructed site.[42] Becktor *et al.*[43] discovered that bone graft in maxillary edentulous area generated a significant difference in the implant's survival rate as 75.1% vs 84.0%. Nonetheless, Woo *et al.* suggested that successful dentoalveolar reconstructive procedures were not an independent risk factor for implant failure.[44] Sbordone *et al.* reported similar implant cumulative survival rates were shown both in native and grafted sites.[45] In the present trial, three out of four failed implant cases in test group had minor bone graft procedures. It may be because surgical damage from the graft procedure can change the blood circulation around the implant and has negative influence on the recovery of the soft tissues and the bony tissues.

This trial researched the implants placed only on the posterior mandible for the purpose of controlling the bone quality, but did not evaluate the bone quality of each case. The small sample size from limited areas for implant placement was the limitation of this trial.

CONCLUSION

Within the limitations of the present clinical study, it was concluded that early implant loading could increase the possibility of implant failure in the posterior mandible. The periimplant marginal bone loss and periodontal parameters were not affected by early implant loading.

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