# Prospective randomized clinical trial of hydrophilic tapered implant placement at maxillary posterior area: 6 weeks and 12 weeks loading

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**PURPOSE.** Early loading of implant can be determined by excellent primary stability and characteristic of implant surface. The implant system with recently improved surface can have load application 4-6 weeks after installing in maxilla and mandible. This study evaluated the effect of healing period to the stability of hydrophilic tapered-type implant at maxillary posterior area. **MATERIALS AND METHODS.** This study included 30 patients treated by hydrophilic tapered-type implants (total 41 implants at maxilla) and classified by two groups depending on healing period. Group 1 (11 patients, 15 implants) was a control group and the healing period was 12 weeks, and Group 2 (19 patients, 26 implants) was test group and the healing period was 6 weeks. Immediately after implant placement, at the first impression taking, implant stability was measured using Osstell Mentor. The patients also took periapical radiographs after restoration delivery, 12 months after restoration and final followup period. The marginal bone loss around the implants was measured using the periapical radiographs. **RESULTS.** All implants were survived and success rate was 97.56%. The marginal bone loss was less than 1mm after 1 year postoperatively except the one implant. The stabilities of the implants were not correlated with age, healing period until loading, insertion torque (IT), the diameter of fixture and the location of implant. Only the quality of bone in group 2 (6 week) was correlated with the stability of implant. **CONCLUSION.** Healing period of 6 weeks can make the similar clinical prognosis of implants to that of healing period of 12 weeks if bone quality is carefully considered in case of early loading. *[J Adv Prosthodont 2016;8:396-403]*

**KEYWORDS:** Hydrophilicity; Dental implant; Survival rate

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## INTRODUCTION

At implant placement, having good primary stability and being without micromotion at the secondary bone healing are a very important factors for the successful implant placement.[1] In the past, early application of load on the implant was considered to be a factor inhibiting osseointegration of the implant. Therefore, delayed loading has been used, in which the load is applied gradually at 3 - 6 months after the implant placement.[2,3] Surface treatment is one of the factors affecting on early load application. The surface area is increased by making the surface of the implant rough, and this facilitates the osseointegration rate. Various techniques such as blasting and acid etching, resorbable

blast media (RBM), SLA, oxidation, and hydroxyapatite coating have been developed and are being clinically applied. Such implant surface treatment and design improvement reduced the healing period and brought changes to the past concept of Branemark.[4,5]

Calcium phosphate (CaP) has been reported to have a greater adhesion compared to that of hydroxyapatite (HA) coating.[6] The latest methods for CaP coating have been introduced as electron-beam evaporation process and Ion-beam-assisted deposition. They have been reported to have new bone formation and excellent osseointegration after implant placement.[6-8] The primary stability can be affected by bone mass, bone quality, implant design, and surgical technique, which are very important factors for successful osseointegration. Secondary stability is affected by bone reaction to implant surface and surgical trauma. Early loading of implant can be determined by excellent primary stability and characteristic of implant surface. The implant system with recently improved surface can have load application 4 - 6 weeks after installing in maxilla and mandible. Early loading is defined as loading between 2 weeks and 2 months after implant placement.[9-11] The Osstem TS III CA implant used in this study has super-hydrophilic rough surface and 1.5° taper body and cork-screw thread design. It is expected that this system has excellent primary and secondary stability and early loading is possible. The methods for clinically evaluating osseointegration are periotest, resonance frequency analysis (RFA), percussion, palpation, and periapical radiograph. However, it is clear that they are not accurate.[12,13] There have been many controversies regarding the accuracy of RFA, and many scholars have given negative opinions.[14,15] However, there have been many reports that RFA is effective in measuring implant primary stability and evaluation of healing process, and it is thought as the most effective method which can be clinically applied.[16,17]

In this study, CaP-coating hydrophilic tapered implant was placed using one-stage method, in the maxillary posterior area with poor bone quality. Through the measurement of RFA with Osstell mentor, the changes in ISQ value from the initial and secondary stability and healing period were evaluated; and the possibility of early loading was evaluated. After 6 weeks and 12 weeks, clinical score for early loading was evaluated after the final prosthesis is installed.

## MATERIALS AND METHODS

This study was conducted after obtaining approval (E-1210-174-001) from Seoul National University Bundang Hospital Institutional Review Board.

The following patients were included in this study. 1) Adult patients over the age of 20 years whose maxillomandibular growth has completed. 2) Maxillary posterior edentulous ridge 3) Patient with 1 or 2 consecutive posterior teeth missing with residual bone height of 6mm or above. 4) Patient with enough mesiodistally and buccolingually available bone 5) Patient with opposite tooth (natural toothe, prosthetic treated tooth, and plant) 6) Patient who

consented to participate in clinical trial and signed informed consent form 7) GBR regarding the sinus lifting through crestal approach and small defects (less than 3 - 4 mm dehiscence defects) around implant is permitted. The following patients were excluded. 1) Pregnancy 2) Myocardial infarction within the last 3 years 3) Uncontrolled medical conditions 4) Bleeding disorder or being on anticoagulants 5) Allergies to implant materials 6) Requiring extensive bone grafting 7) Having no opposite tooth or having dentures 8) Severe oral parafunction (bruxism and clenching) 9) Moderate to severe periodontal disease 10) Patients determined to be unsuitable for participation due to ethical reasons or for having potential influence to the result of clinical trial 11) Difficulty in receiving implant placement surgery (uncooperative, very poor oral hygiene)

The patients who lost teeth in the maxillary posterior area and have been treated at Seoul National University Bundang Hospital from May 2012 to May 2013 were screened to select those who met prospective clinical trial inclusion criteria. The target number of subjects was 52, and they were randomly assigned to control group (Group 1, 12-week loading) and experimental group (Group 2, 6-week loading). Treatment assignment chart was created and managed by dental hygienist involved in this study, so that when the subjects were finally selected, they were assigned to the groups according to the chart and were given the identification codes. The assigned groups were announced to the researchers on the day of the surgery, and the researchers were not aware of the subjects' group.

According to the manufacturer's instructions, drilling was performed followed by Osstem TS III CA implant (Osstem implant Co., Busan, Korea) installed in a non-submerged type, and the insertion torque value was recorded. Immediately after the installation, Osstell SmartPeg was connected with 5 Ncm, and primary stability was measured four times (buccolingual and mesiodistal side) using Osstell Mentor and was recorded (Implant stability quotient 1: ISQ 1)(Fig. 1). The diameter of the implant was 4.5 mm or 5.0 mm, and the length was 10mm. The diameter of the most recently used drill was recorded. By comparing to the diameter of the installed implant, drilling was distinguished as 0.5 mm, 0.5 - 1 mm, and 1 mm smaller in diameters. The bone quality was subjectively determined from D1 - D4, by the surgeon at the time of surgery.[18] Panoramic and periapical radiography were taken immediately after the surgery. After suturing the wound, antibiotic and anti-inflammatory painkillers were prescribed for 5 days. After 10 days, suture stitches were removed and periapical radiography was taken. Experimental group (group 2) was installed with the final prosthesis after 6 weeks, and the control group (group 1) was installed after 12 weeks. Osstell Mentor was used in the implant prosthesis impression test (ISQ 2) and prior to final prosthesis installation (ISQ 3) to measure secondary stability. Also, panoramic and periapical views were taken. After the implant installation, if ISQ < 65, the patients with osseointegration failure during healing period, patients with delayed healing period due to sensitive reactions at

impression taking, and those who failed to follow up according to study schedule were all considered to have withdrawn from this study.

ISQ values were recorded immediately after implant placement on the control group and the experimental group, at the impression taking, and at final prosthesis installation. The changes according to time, difference in ISQ between each group, bone quality, final implant drill size, implant diameter, and difference in ISQ value according to installation area were compared. SPSS program (SPSS, version 12.0, SPSS, Inc., an IBM Company, Chicago, IL, USA) was used for statistical analysis.

For the measurement of marginal bone loss, periapical view was taken by using parallel cone technique so that it is perpendicular to the length of the implant. When taking periapical view, putty on positioner for fastening the film was used to make frame as if taking impression of the location when patient takes a bite. Using this frame, periapical view was taken when observing the same patient (Fig. 2). On the first obtained film, the angle or distance between the film and the x-ray tube head was indicated to maintain unchanged. With these, every x-ray imaging was reproducible. The periapical radiograph obtained immediately after placing upper prosthesis implant was set as baseline, and marginal bone loss was measured at 6 months and 12 months. The distance between implant platform and the first converging point of implant and alveolar bone was measured. The radiological magnification was applied to find the actual distance. The magnification on the radiograph was found by using proportion of the length on radiograph and the actual implant length. The average value for change was measured in the mesial and distal marginal bone level around the implant.

The implant survival was defined as the implant remaining with function at the final observation. The success rate was determined with the following standards.[19]

- Having no lasting pain, discomfort, or paresthesia
- Having no peri-implant accompanied by abscess
- Having no mobility
- Having no radiation penetration around the implant
- Having marginal bone loss of 1 mm or below 1 year after prosthesis

## RESULTS

There were 68 subjects recruited initially and 16 subjects were excluded from this study, because they had insufficient residual bone or missing opposite teeth. Therefore, a total of 52 subjects who met the inclusion criteria were enrolled in this study. The subjects were randomly assigned into control group and experimental group with 26 in each group. During the trial, 22 patients (Group 1: 15 subjects and Group 2: 7 subjects) were withdrawn from this study due to the following reasons: 14 subjects withdrew under agreement (Group 1: 9 subjects and Group 2: 5 subjects); loss of contact with 2 subjects (Group 1); and 6 patients (Group 1: 4, Group 2: 2) whose healing period was delayed due to implant osseointegration failure, primary stability with ISQ of 65 or below, and sensitive reaction at impression taking. Therefore, there was a total of 30 subjects (41 implants) included in the final analysis. Group 1 had 11 subjects (4 males and 7 females), 15 implants were included in the analysis, and the average age of the patients was 66.5 years. For the distribution by region, there were 5 in the premolar region and 10 in the molar region. In Group 2, there were 19 patients (9 males and 10 females), total of 26 implants were included in the analysis, and the average age was 59 years. For the distribution by region, there were 8 in the premolar region and 18 in the molar region (Table 1). The distribution of gender, installed implant diameter, and placement area between the control group and the experimental group did not show any statistically significant difference (Fig. 3).



**Fig. 1.** Osstell SmartPeg was connected with 5 Ncm using hand torque wrench.
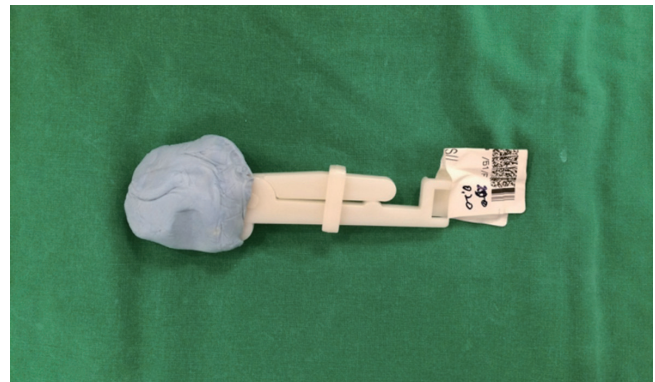


**Fig. 2.** Film positioner with putty jig.

At the implant placement, the average torque for Group 1 was 37.84 Ncm and for Group 2 was 35.74 Ncm; there was no significant difference between the two groups. The ISQ values were measured at the installation, at impression taking, and at the placement of prosthesis. However, ISQ values for 1 case in Group 1 and 3 cases in Group 2 were missing at the prosthesis placement. Therefore, statistical analysis was performed without these measurements.

As the result of the analysis, ISQ values at the installation, at impression taking, and at prosthesis placement did not show statistically significant difference between the two groups. The ISQ3-ISQ1, which is changing value of ISQ at the final prosthesis placement and immediately after the placement, were shown as follows: Group 1 had 3.04 ± 4.25 ISQ and Group 2 had 3.03 ± 5.71 ISQ. The two

groups did not show statistically significant difference ($P$ = .999) (Table 2).

In Group 1, the implants with the following bone qualities were installed: 5 implants with D2 bone quality, 7 implants with D3, and 2 implants with D4. The ISQ value according to the bone quality did not show statistically significant difference (Table 5). In Group 2, the following were installed: 8 implants with D2, 15 implants with D3, and 2 implants with D4. The ISQ1 showed significant difference between the bone qualities ($P$ = .01). However, ISQ 2 and 3 did not show statistically significant difference according to bone quality (Table 3).

When drilling was performed with the diameters smaller than the finally installed implant, by 0.5 mm, 0.5 - 1 mm, and 1 mm, the primary and secondary stability values were

**Table 1.** The distribution of the patients

| | | Group 1 (11 patients, 15 implants) | Group 2 (19 patients, 26 implants) | Chi-square | $P$ value |
|---|---|---|---|---|---|
| Sex | Male | 4 | 9 | 0.344 | .558 |
| | Female | 7 | 10 | | |
| Implant diameter | 4.5 mm | 5 | 14 | 1.610 | .205 |
| | 5.0 mm | 10 | 12 | | |
| Implant location | Premolar | 5 | 8 | 0.029 | .865 |
| | molar | 10 | 18 | | |
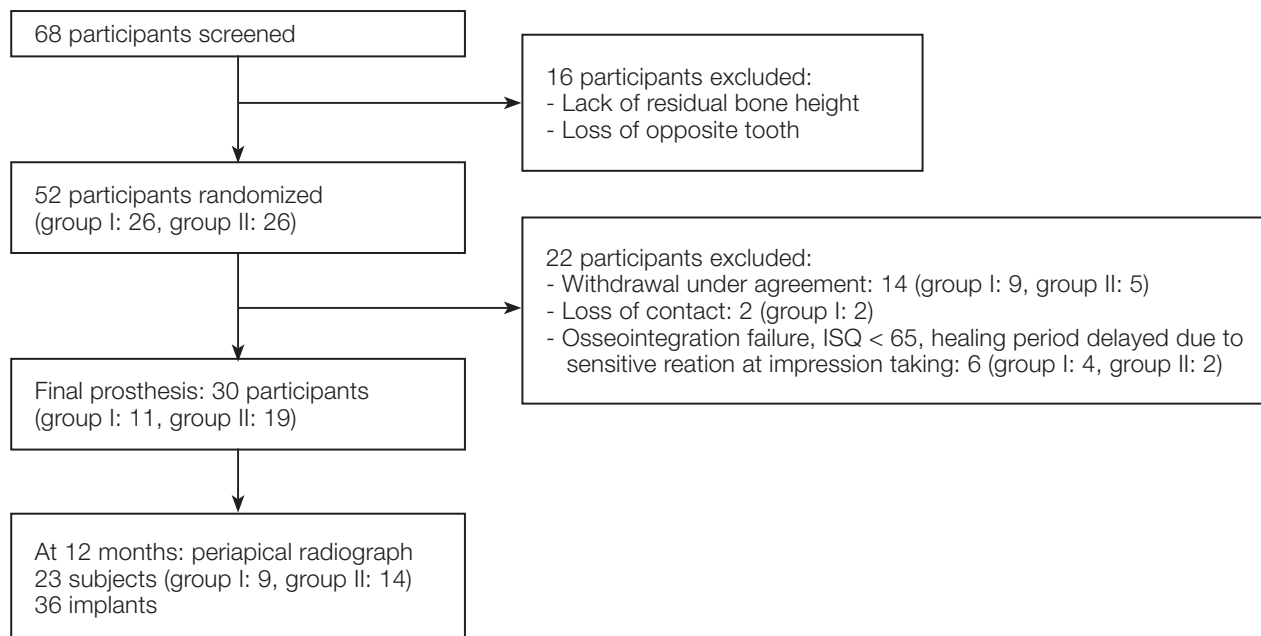


**Fig. 3.** CONSORT study flow chart.

**Table 2.** Insertion torque and ISQ

|  | Group 1 (n = 15) | Group 2 (n = 26) | t | P value |
|---|---|---|---|---|
| Age | 66.64 ± 8.80 | 59.00 ± 9.31 | 0.151 | .700 |
| Torque | 37.84 ± 15.62 | 35.74 ± 14.70 | 0.431 | .669 |
| ISQ 1 | 76.80 ± 5.95 | 79.30 ± 5.73 | -1.326 | .193 |
| ISQ 2 | 77.43 ± 4.99 | 79.38 ± 4.73 | -1.247 | .220 |
| ISQ 3 | 79.75 ± 3.61 (1 case missing) | 81.57 ± 4.84 (3 cases missing) | -1.211 | .234 |
| ISQ 3 – ISQ 1 | 3.04 ± 4.25 (1 case missing) | 3.03 ± 5.71 (3 cases missing) | 0.002 | .999 |

ISQ: implant stability quotient

**Table 3.** ISQ of group 1 and group 2

|  | RFA value | D2 (n = 5) | D3&D4 (n = 10) | P value |
|---|---|---|---|---|
| Group 1 | ISQ 1 | 79.40 ± 5.65 | 75.50 ± 5.93 | .245 |
|  | ISQ 2 | 78.60 ± 5.21 | 78.85 ± 5.05 | .542 |
|  | ISQ 3 | 80.10 ± 4.47 | 79.56 ± 3.32 | .799 |
|  | RFA value | D2 (n = 8) | D3&D4 (n = 18) | P value |
| Group 2 | ISQ 1 | 83.06 ± 2.09 | 77.63 ± 6.07 | .01* |
|  | ISQ 2 | 80.41 ± 4.88 | 78.93 ± 4.74 | .436 |
|  | ISQ 3 | 81.93 ± 4.28 | 81.41 ± 5.19 | .92 |

* Mann-whitney analysis

**Table 4.** ISQ of group 1 and group 2 according to the difference between final drilling size and implant diameter

|  | RFA value | Diff ≤ 0.5 mm (n = 3) | 0.5 mm < Diff ≤ 1.0 mm (n = 6) | Diff > 1.0 mm (n = 6) | P value |
|---|---|---|---|---|---|
| Group 1 | ISQ 1 | 83.33 ± 3.06 | 75.33 ± 5.50 | 75.00 ± 5.74 | .057 |
|  | ISQ 2 | 81.50 ± 1.50 | 77.42 ± 5.20 | 75.42 ± 5.20 | .161 |
|  | ISQ 3 | 82.67 ± 2.76 | 79.75 ± 3.79 | 78.00 ± 3.22 | .136 |
|  | RFA value | Diff ≤ 0.5 mm (n = 3) | 0.5 mm < Diff ≤ 1.0 mm (n = 17) | Diff > 1.0 mm (n = 5) | P value |
| Group 2 | ISQ 1 | 83.50 ± 1.32 | 78.21 ± 5.90 | 80.70 ± 5.97 | .176 |
|  | ISQ 2 | 81.33 ± 3.51 | 78.50 ± 4.78 | 81.40 ± 5.03 | .424 |
|  | ISQ 3 | 82.00 ± 3.61 | 80.88 ± 5.44 | 84.00 ± 2.12 | .645 |

various in both the Group 1 and 2. The difference in ISQ value according to the difference in implant diameter and final drilling diameter was not observed (Table 4). The ISQ value of each group according to the installed implant diameter also did not show any significant difference (Table 5).

In Group 1 and 2, difference in ISQ value according to tooth location was not identified (Table 6).

During the investigation period, radiographs for 5 implants from 3 patients were missing, so they were excluded from the measurement. Therefore, 36 implants from the final 23 patients were measured for bone loss 1 year after the prosthesis. Group 1 had 0.28 ± 0.63 mm and Group 2 had 0.15 ± 0.30 mm. As the result of Mann-Whitney test, a nonparametric test, there was no statistically significant difference between the two groups (P = .597). For the survival

**Table 5.** ISQ of group 1 and 2 according to implant diameter

| | RFA value | 4.5 mm (n = 5) | 5.0 mm (n = 9) | P value |
|---|---|---|---|---|
| Group 1 | ISQ 1 | 80.50 ± 5.17 | 74.95 ± 5.63 | .057 |
| | ISQ 2 | 80.50 ± 3.32 | 75.90 ± 5.10 | .057 |
| | ISQ 3 | 81.70 ± 2.84 | 78.67 ± 3.66 | .141 |
| | RFA value | 4.5 mm (n = 14) | 5.0 mm (n = 12) | P value |
| Group 2 | ISQ 1 | 80.96 ± 4.24 | 77.35 ± 6.76 | .129 |
| | ISQ 2 | 80.04 ± 4.09 | 78.52 ± 5.50 | .503 |
| | ISQ 3 | 81.73 ± 4.06 | 81.39 ± 5.77 | .782 |

**Table 6.** ISQ of group 1 and 2 according to tooth location

| | RFA value | Premolar (n = 5) | Molar (n = 10) | P value |
|---|---|---|---|---|
| Group 1 | ISQ 1 | 78.80 ± 5.13 | 75.80 ± 6.33 | .357 |
| | ISQ 2 | 79.80 ± 3.01 | 76.25 ± 5.48 | .158 |
| | ISQ 3 | 81.20 ± 2.54 | 78.94 ± 3.99 | .316 |
| | RFA value | Premolar (n = 8) | Molar (n = 18) | P value |
| Group 2 | ISQ 1 | 80.44 ± 4.89 | 78.79 ± 6.13 | .559 |
| | ISQ 2 | 80.19 ± 5.03 | 79.03 ± 4.70 | .54 |
| | ISQ 3 | 82.36 ± 4.69 | 81.22 ± 5.02 | .64 |

rate, all 41 implants were found to remain over the total observation period of 20.62 months, so the survival rate was 100%. However, the left maxillary 1st molar implant, which was installed in a 76 year-old male patient, showed bone resorption of 2.4 mm after 1 year. Therefore, the success rate was 97.56%.

## DISCUSSION

Radiofrequency analysis (RFA) is a non-invasive method for objectively measuring the implant stability. According to the study by Sennerby and Meredith, immediate load or early load is possible if RFA value is higher than ISQ of 60 - 65; and if it is lower than ISQ of 40, there is a higher risk of failure.[20] The RFA value can be afected by various factors. Kessler et al. investigated by using RFA value on the relationship between healing period after implant installation and the implant stability. There was no relationship between healing period and implant stability. Basically, implant width and height of attached gingiva had relationship to implant stability.[21] There has been a study on the relationship between the location of implant installation and primary stability, reporting that mandible and anterior region rather than maxilla and posterior region showed higher implant primary stability.[22] When drilling was performed using smaller diameter than the implant fixture, the RFA value was shown to be higher and the initial torque was also shown to be higher. Particularly, large initial torque was shown in the implants with wider diameter. Furthermore, relationship between the initial torque and RFA value was observed. Therefore, when smaller drilling was performed than the finally installed implant in the trabecular bone with poor bone quality, placing conical implant secured the primary stability.[23] Park et al. reported in the experimental study using models that when implant is placed and fixed in cortical bone, ISQ and removal torque value (RTV) were observed to increase; and in the region with poor bone quality, under-drilling can be performed to improve implant stability.[24] Ahn et al. reported that underpreparation and bicortical fixation in the maxillary posterior areas with poor bone quality can enhance primary stability of the implant.[25] On the other hand, Bayarchimeg et al. stated that there are variables such as thickness of cortical bone and bone density for the implant primary stability, so simply reducing the final drilling diameter would not enhance the primary stability.[26] As the result of determining the effect of implant diameter and the final drilling diameter, which were installed in this study, on the implant primary and secondary stability, statistically significant difference was not found.

In many times, the bone quality is evaluated by using senses of touch and sight of the surgeon when performing the drilling. This relies on the surgeon's subjective sense, and there is a limitation in the accuracy of the evaluation.

In the study by Delgidi, it was found that the subjective evaluation of the operating surgeon is likely to be measured weaker than the actual. Therefore, for more objective evaluation, computed tomography Hounsfield unit (HU) can be utilized, but there is a problem on routinely applying this in clinical setting.[27] In several studies on the relationship between bone quality and implant stability, it has been stated that bone quality is the most important factor affecting on primary stability of the implant.[28-30] Isoda et al. reported that bone quality evaluation by using CBCT provides a very useful information for predicting implant primary stability.[31] Farré-Pagés et al. stated that there is a high correlation between CT Hounsfield units (Hu) and implant primary stability.[32] In this study, bone quality D2, bone quality D3, bone quality D4, and implant stability were compared. Only the primary stability (ISQ1) of Group 2 showed difference according to the bone quality, and the others did not show any significant difference. Therefore, this was different from the theory introduced in recent studies that stability decreases when the bone quality is weak.

Other variables affecting on the implant stability include thickness of the alveolar bone and length of implant (increase in total surface area), in which the implant stability increases as these variables increases.[33,34] In this study, the length of the installed implants were all 10 mm, and the alveolar bone thickness was not measured; therefore, the relationship was deemed not to be tested.

The marginal bone loss measured 1 year after the prosthetic loading was $0.28 \pm 0.63$ mm in Group 1 and $0.15 \pm 0.30$ mm in Group 2. There was no statistically significant difference between the two groups. Therefore, the healing period of 6 weeks and 12 weeks did not affect on the amount of marginal bone loss around the implant. All implants survived (100% survival) over the average observation period of 20.62 months, and the success rate was 97.56%. With these results, when installing hydrophilic tapered implant (TSIII CA Fixture; Osstem Implant Co., Busan, Korea), 6 weeks of early loading can be expected to have the similar clinical prognosis as 12 weeks of delayed loading. However, in the case where primary stability is not good, the healing period should be delayed. The Osstem TS III CA implant used in this study maintains the surface form of the previously used TS III SA (Sandblasted with $Al_2O_3$ and Acid etched method) while chemically changing the surface. The substance which the implant is submerged in is $CaCl_2$ solution. It provides super-hydrophilic surface to eliminate carbon contamination, and it enhances blood affinity to increase protein absorption rate. The chemical activity due to Ca ions is increased which facilitates bone coherence, significantly reducing the healing period. TSIII CA Fixture has 1.5° taper body and cork-screw thread design, which was designed to secure sufficient initial fixation in the weaker bone quality as in maxilla. All implants in this study were installed in the maxillary posterior area where the bone quality is weak. At the installation of the final prosthesis and immediately after the installation, ISQ3-ISQ1 value which is the changing value of ISQ was

$3.04 \pm 4.25$ ISQ for Group 1 and $3.03 \pm 5.71$ ISQ for Group 2. Therefore, no statistically significant difference was shown between the two groups.

## CONCLUSION

This study can support the conclusion that there is no difference between the load time of 6 weeks and 12 weeks in implant stability if the primary stability after the installation is excellent.

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