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A randomized clinical 1-year trial comparing two types of non-submerged dental implants

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Abstract

Objectives: This study compared the implant stability and clinical outcomes obtained with two types of non-submerged dental implants that have different thread designs and surface treatments.

Materials and methods: A randomized clinical trial with 1 year of follow-up was performed on 56 participants with 75 implants (control group, 36 implants in 28 subjects; experimental group, 39 implants in 28 subjects). The experimental group received the Osstem SSII Implant system; the control group received the Standard Straumann® Dental Implant System. The diameter and length of the fixture were uniform at 4.1 mm and 10 mm and all the implants restored the unilateral loss of one or two molars from the mandible. To compare implant stability, the peak insertion torque, implant stability quotient (ISQ), and periosteal value (PTV) were evaluated during surgery, and at 4 and 10 weeks after surgery. To compare marginal bone loss, standard periapical radiographs were obtained during surgery, and at 10 weeks and 1 year after surgery.

Results: This study showed statistically significant differences between the two groups in peak insertion torque ($P=0.009$) and ISQ ($P=0.003$) but not in PTV ($P=0.097$) at surgery. In contrast, there was no statistically significant difference in the pattern of change of ISQ during the 10 weeks after surgery ($P=0.339$). For marginal bone loss, no significant difference was observed between the control and the experimental groups before functional loading ($P=0.624$), but after 1 year of follow-up, a borderline difference was observed ($P=0.048$).

Conclusion: The success rate after 1 year of follow-up was 100% for both implant system despite the presence of a significant difference in implant stability during surgery. There was a borderline difference in marginal bone loss after 1 year of follow-up.

Thread design and surface treatment are two important elements that influence the long-term success of dental implants (Sykaras et al. 2000; Steigenga et al. 2003). Thread design has been shown to play an important role in achieving primary stability at the time of surgery and in preventing marginal bone loss through the dispersion of masticatory force to the surrounding bone (Chun et al. 2002; Geng et al. 2004;

O'Sullivan et al. 2004; Akkocaoglu et al. 2005). Surface treatment helps to enhance secondary stability after insertion by promoting osseointegration (Cochran et al. 1998; Albrektsson & Wennerberg 2004; Rocuzzo et al. 2008).

The two most widely used types of implants in current use are the two-piece submerged implant (Branemark et al. 1969), which is represented by the Branemark

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System[®] and the one-piece non-submerged implant (Schroeder et al. 1981), which is represented by the Straumann[®] Dental Implant System. Although a number of well-planned clinical trials yielded successful results with both systems of implants (Branemark et al. 1977; Astrand et al. 1996; Buser et al. 1997; Behneke et al. 2000; Akkocaoglu et al. 2005), no clinical trials have compared non-submerged implant systems with different thread designs and surface treatments. Therefore, this study was designed to compare the Standard Straumann[®] Dental Implant system with an alternative commercial non-submerged implant system. The aim of study was to compare the implant stability and clinical outcomes, including marginal bone loss and success rate, between two types of non-submerged implants with different thread designs and surface treatments.

Materials and methods

Experimental design

A randomized clinical trial with a parallel-group design and 1 year of follow-up was conducted to test the following null hypotheses: The two types of non-submerged implants are not associated with a statistically significant difference in (1) primary stability; (2) the pattern of change in secondary stability during the first 10 weeks after surgery; (3) marginal bone loss 1 year after surgery; and (4) the success rate 1 year after surgery. The Osstem SSII Implant system (Osstem Implant Co., Seoul, Korea) was used in the experimental group and the Standard Straumann[®] Dental Implant system (Institut Straumann AG, Basel, Switzerland) was used in the control group. The diameter (4.1 mm), length (10 mm), and collar height (2.8 mm) of all the implants were the same. Primary stability was compared using the peak insertion torque, implant stability quotient (ISQ), and periotest value (PTV) as outcome variables. To compare the changes in secondary stability, the pattern of changes in ISQ was evaluated. A periapical radiograph was taken to enable comparison of marginal bone loss.

Study population and entry criteria

A required sample size of 23 participants for each implant system was calculated

according to the average peak insertion torque and its standard deviation that were obtained from a previous experiment. In this earlier pilot study, 10 of each type of implant had been inserted into a solid rigid artificial bone block made of polyurethane foam (Biomechanical Test Blocks, Pacific Research Laboratories Inc., Washington, WA, USA). The required sample size was estimated on the basis of $\alpha = 0.05$, power = 0.80, $\delta = 5$, and $\sigma = 6$ ($N = [2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2] / \delta^2 = [2(1.96 + 0.84)^2 (6)^2] / 5^2 \approx 22.58$). A dropout rate of 20% was assumed, and this increased the number of participants required in each group to 28. A total of 93 potential participants visited the Department of Oral and Maxillofacial Surgery at Seoul National University Dental Hospital in response to an advertisement published in a major daily newspaper that called for subjects for the trial. Of these, 56 participants satisfied the following inclusion criteria and were selected for this study. All participants had unilateral loss of one or two molars from the mandible; the tooth had been extracted > 6 months back; the recipient bed had sufficient bone width (≥ 6 mm) and height (≥ 12 mm) to house the 4.1×10 mm implant; and the antagonist teeth were natural or had been repaired with fixed prostheses. The participants were generally healthy and had good plaque control. The study protocol and consent form were reviewed and approved by the Institutional Review Board of Seoul National University Dental Hospital (CCE06001), and the study was performed according to the Declaration of Helsinki on experimentation involving human subjects.

From June 2, 2007 to September 28, 2007, implants were installed consecutively. On each day of surgery, two participants were operated on simultaneously by one of two surgeons. The system of implant was assigned by drawing lots; the randomization was implemented by a research nurse. The two surgeons were familiar with both systems and JHL and JCP installed 36 (16 Standard Straumann[®] and 20 Osstem SSII) and 35 (17 Standard Straumann[®] and 18 Osstem SSII) implants, respectively. The implant system assigned was concealed from the participant until the end of the trial and from the surgeons until the time of the surgical procedure.

The two types of implant systems

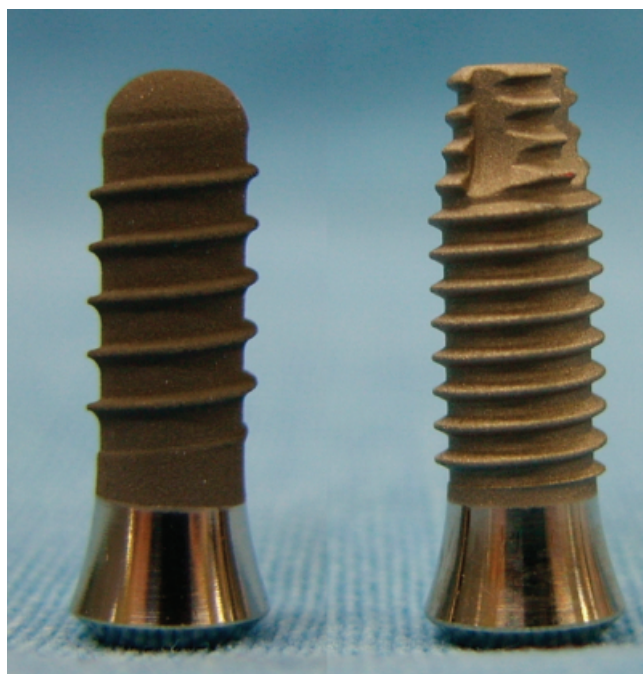
The two implant systems varied in thread shape, pitch height, inclination angle of the thread flank, and surface treatment, as shown in Fig. 1. The Osstem SSII Implant system has a V-shaped thread with a 30° angle of inclination of the thread flank. The Standard Straumann[®] Dental Implant system uses a reverse buttress V-thread with a 15° inclination angle. The RBM treatment involved spraying hydroxyapatite- $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ on the surface of the implant to set the surface roughness (R_a) to 1.2–1.8 μm (Jeon et al. 2009).

Installation of implant and evaluation of implant stability

All the implants were installed without tapping. The drilling sequence used in the control group involved drilling to the designated depth with 2.2, 2.8, and 3.5 mm twist drills, after perforation of the cortical bone with 1.4 and 2.3 mm round drills. For the experimental group, drilling with the lance drill was followed by the use of a 2 mm twist drill, a 2/3 pilot drill, a 3 mm twist drill, and a 3.6 mm twist drill. For all implants, the depth of insertion of the surface-treated portion at the buccolingual and mesiodistal surfaces was checked during each operation.

The stability of the implant was evaluated by measurement of the insertion torque, resonance frequency analysis (RFA), and assessment of the damping capacity. The machine used for insertion of the implants was an IntraSurg 300 Plus (KaVo, Biberach, Germany), which can measure peak insertion torques of up to 40 N cm automatically. When automatic insertion to the designated depth with 40 N cm was impossible, the surgeon used a hand wrench appropriate to each system to insert the implant to the designated depth. In these cases, the torque was recorded as 40 N cm or higher (Al-Nawas et al. 2006).

The magnetic RFA was measured using a Mentor[™] device (Ostell AB, Göteborg, Sweden). To increase the reliability of the measurements and reduce the magnitude of the differences in ISQ, the evaluators practiced matching 4 N cm of insertion torque by rotating the SmartPeg[™] in a digital torque gauge (MGT; MARK-10, Copiague, NY, USA) using a plastic mount for the metal peg in advance of the full-scale clinical trial. In the clinical trial, the Type 4 Smartpeg[™]



| | Control group: Standard Straumann® Dental Implant System | Experimental group: Osstem SSII Implant system |
|--|--|--|
| Thread shape | V- shape with reverse buttress | V – shape with isosceles triangle |
| Pitch height | 1.25 mm | 0.8 mm |
| Thread height | 0.35 mm | 0.35 mm |
| Inclination angle of the thread flank | 15° | 30° |
| Surface treatment | SLA(Sandblasted Large -grit, Acid -etched) | RBM (Resorbable Blast Media) |

Fig. 1. Comparison of the two implant systems with respect to thread design and surface treatment.

was connected to a plastic mount and inserted manually into the implant fixture. The plastic probe of the measuring instrument was brought to a distance of approximately 2–3 mm from the peg, and the ISQ could be read automatically.

The damping capacity was assessed using a Periotest™ device (Siemens, Bensheim, Germany). When using the Periotest™, measurements may be influenced by the distance of the striking point from the marginal bone and the surface slope of the struck superstructure (Meredith et al. 1998; Gomez-Roman & Lukas 2001). Therefore, the same size of healing abutment (∅4.8 × 4 mm; Osstem Implant Co.) was used for each implant, and this was connected to the implant fixture with a torque of 10 N cm using a manual torque wrench.

The ISQ and PTV were measured during surgery, and at 4 and 10 weeks after surgery. The measurements were taken twice

in the buccolingual direction on the buccal side, and the mean of the two values was used to compare stability. To verify the reliability of the measurements, the intraclass correlation coefficient was calculated; this corresponded to 0.991 for the ISQ and 0.884 for the PTV.

Prosthetic procedure

The commercially available solid abutments from each implant system were connected to the fixture at 10 weeks after surgery at the torques suggested by the manufacturer (control group: 35 N cm; experimental group: 30 N cm). An impression was obtained at the time of connection, and the final prostheses were attached at 12 weeks after surgery using resin cement (C&B™ CEMENT; Bisco, Schaumburg, IL, USA). In participants who had lost two molars, two-unit fixed prostheses were used.

Measurement of marginal bone loss

Standard periapical radiographs were taken during surgery, at the time of connection of the solid abutment (10 weeks after surgery), and at 1 year after surgery to measure the marginal bone level. A paralleling technique was used, with an impression bite block that was fabricated for the individual participant attached to the aiming device (Rinn Corp, Elgin, IL, USA). This technique was chosen to reduce possible errors in measurement between pairs of images, which were acquired serially at planned intervals (Huh et al. 2005; Romeo et al. 2007).

Before calculating the marginal bone loss, the enlargement ratio of the image was determined using the thread pitch height that is specific to each implant system (Standard Straumann® Dental Implant system = 1.25 mm, Osstem SSII Implant system = 0.8 mm). The distance from the implant shoulder (reference point) to the margin of the alveolar bone in the mesial and distal areas was calculated using the enlargement ratio. This distance was then compared with the distance measured at surgery (the baseline level) (Astrand et al. 1996). Given that values recorded by one evaluator gave better reproducibility than the mean of two values recorded by different evaluators, one evaluator, JCP, made two measurements at 2-week intervals, and the mean was calculated (Batenburg et al. 1998). The reliability of the measurement of marginal bone loss was verified with an intraclass correlation coefficient of 0.878.

A FOCUS X-ray machine (Instrumentarium Corp., Tuusula, Finland) was used in the study at 70 kVp, 7 mA, with a focal spot of 0.7 × 0.7 mm and a 0.26-s exposure time. The digital radiographic images were acquired using a charge-coupled device detector (Suni Corp., San Jose, CA, USA) in combination with SDR™ software (Mjrad Co., Seoul, Korea) (Heo et al. 2008).

Evaluation of the status of the mucosa and implant success after 1 year of follow-up

Soft tissue parameters, such as plaque index, sulcus bleeding index, and width of keratinized mucosa (KM), were assessed according to the criteria described in a previous report (Buser et al. 1990). All the parameters except KM were determined at the mesial, facial, distal, and lingual surfaces of the implant fixture, and the mean

of the four estimates was regarded as the representative value for the parameters of each implant. For KM, the mean of two values, measured at the midfacial and mid-

lingual surfaces, was regarded as the representative value.
The success of the implant was measured according to the criteria described by Buser

et al. (1997): (1) there must be no clinical mobility; (2) there must be no pain or other symptoms of discomfort; (3) there must be no recurrence of peri-implantitis with

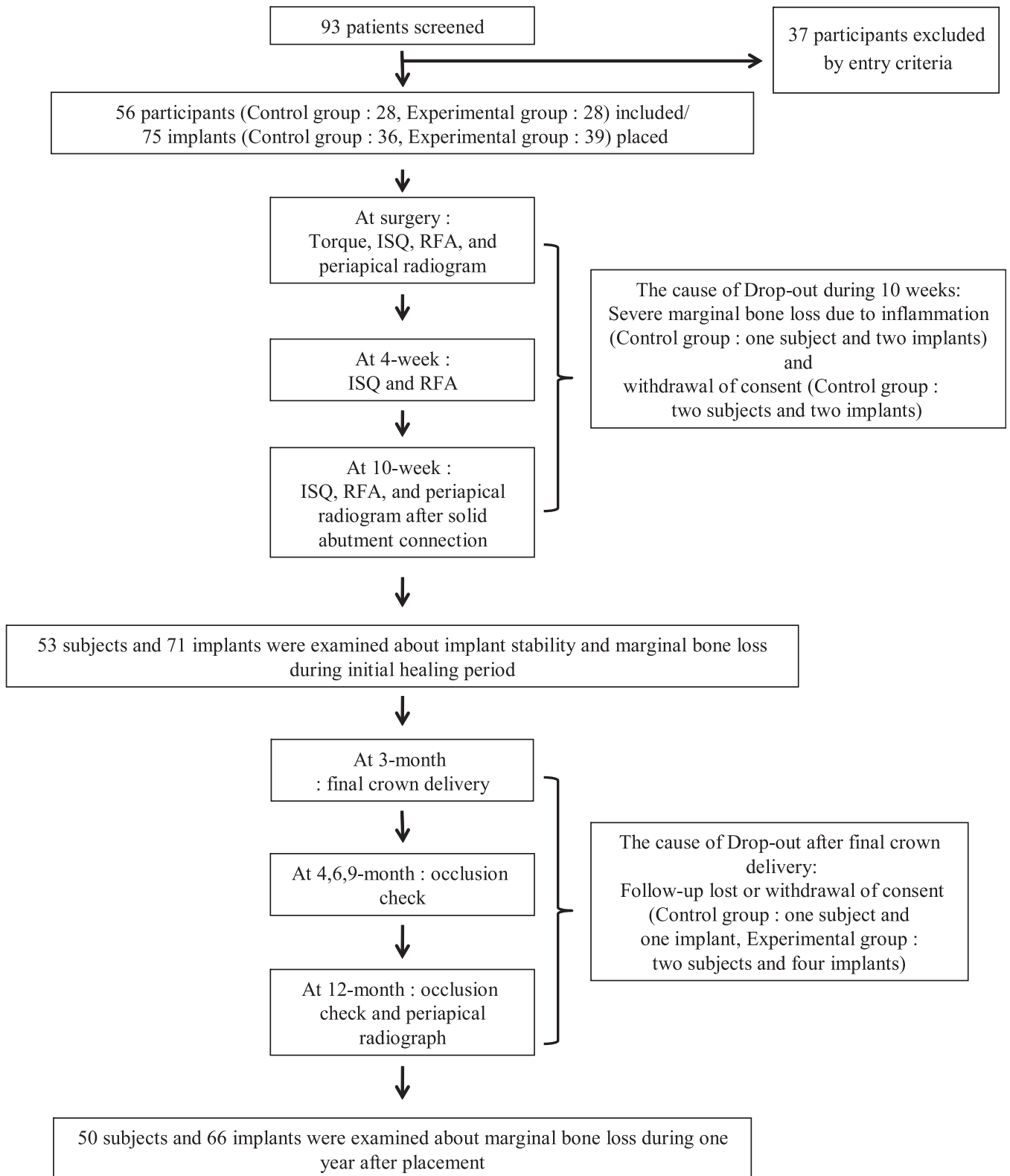


Fig. 2. Flow diagram of participants and implants placed.

suppuration; and (4) there must be no continuous radiolucency around the implant.

Statistical analysis

The statistical tests were based on the patient as the unit. If two implants had been used to replace missing molars in a participant, only the implant for the first molar was included in the analysis. The comparative evaluation of the two implant systems was performed by statistical analysis using the χ^2 test for categorical variables and the independent two-sample *t*-test or the Mann–Whitney test for continuous variables, depending on the normality of the distribution. The latter was examined using the Shapiro–Wilk method. For continuous variables, the mean and standard deviation for each implant system were calculated, and repeated measure analyses of variance in the generalized linear model were performed after the verification of normal distribution, homogeneity of variance, and Mauchly’s test of sphericity to evaluate differences in the patterns of change over time. A significant difference was assumed when the *P*-value was <0.05.

Results

Participants and implants placed

No participants dropped out at the time of surgery. However, one participant in the control group was excluded from the study due to a local inflammatory reaction around the implant 1 month after the operation (Fig. 2). Two additional subjects in the control group withdrew their consent to continue participating in the study before delivery of the final prostheses. After the prosthesis had been attached, three more subjects dropped out of the study because of failure to attend follow-up appointments or the withdrawal of consent. As a result, a total of six subjects and nine implants were excluded from the analysis at 1 year of follow-up.

Demographic characteristics of the participants

The demographic and clinical characteristics for each implant system before connection of the solid abutment are presented in Table 1. No significant differences were observed in age, sex, smoking status, and the location of the implant between

Table 1. Demographic data of study participants

| | | Type of implant | | |
|------------------------------------|--------------------|---|---|------------------|
| Variable | | Control (Standard Straumann® Dental Implant system) | Experimental (Osstem SSII Implant system) | <i>P</i> -value* |
| Implant based (<i>N</i> = 71) | Implant number | 32 | 39 | |
| | Age (mean ± SD) | 47.13 ± 12.03 | 48.24 ± 12.56 | 0.456 |
| | 20–50 | 19 | 17 | 0.236 |
| | Over 50 | 13 | 22 | |
| | Sex | | | |
| | Male | 22 | 22 | 0.333 |
| | Female | 10 | 17 | |
| | Smoker | | | |
| | Yes | 15 | 15 | 0.630 |
| | No | 17 | 24 | |
| | Location | | | |
| | 1st molar | 16 | 20 | 1 |
| | 2nd molar | 16 | 19 | |
| | Bone quality† | | | |
| Type I | 8 | 7 | 0.690 | |
| Type II | 15 | 18 | | |
| Type III | 9 | 14 | | |
| Type IV | 0 | 0 | | |
| Participant based (<i>N</i> = 53) | Participant number | 25 | 28 | |
| | Age (mean ± SD) | 46.84 ± 11.44 | 49.50 ± 12.47 | 0.289 |
| | 20–50 | 15 | 11 | 0.132 |
| | Over 50 | 10 | 17 | |
| | Sex | | | |
| | Male | 17 | 15 | 0.284 |
| | Female | 8 | 13 | |
| | Smoker | | | |
| | Yes | 11 | 9 | 0.374 |
| | No | 14 | 19 | |

‘Control’ indicates the Standard Straumann® Dental Implant system and ‘Experimental’ the Osstem SSII Implant system.
 Data, except for age are presented as the number of implants or participants. The units of age are year.
 **P*-values were calculated using the χ^2 test for all variables except age. The *P*-value for age was calculated using the Mann–Whitney test.
 †Bone quality was assessed based on the classification system of Lekholm and Zarb (1985) during the drilling sequence.
 SD, standard deviation.

the control and the experimental groups. The thickness of the cortical bone and bone quality in the implant bed also showed no significant differences between the two groups.

Depth of implant insertion

To determine whether the condensation effect of the tapered machined collar of the two systems affected the peak insertion torque, standard periapical radiographs taken at surgery were used to measure the depth of insertion of the two implant systems at surgery. The length from the implant shoulder to the upper border of the alveolar bone was 1.71 ± 0.53 mm for the control group and 1.74 ± 0.74 mm for the experimental group at the proximal side. The length at the distal side was

2.04 ± 0.71 mm for the control group and 2.05 ± 0.56 mm for the experimental group. There was no significant difference in the depth of insertion on either side (*P* = 0.455 for the proximal side and *P* = 0.543 for the distal side by the Mann–Whitney test).

Comparison of implant stability at surgery and at 4 and 10 weeks after surgery

Table 2 shows the comparison of primary stability according to the peak insertion torque, ISQ, and PTV. No significant differences were observed between the two surgeons with regard to the peak insertion torque, ISQ, and PTV at surgery (*P* = 0.358 for torque, *P* = 0.823 for ISQ, and *P* = 0.097 for PTV by the Mann–Whitney test). There was a significant difference between the two

systems with respect to insertion torque ($P=0.009$ by the Mann–Whitney test). When ISQ and PTV were compared at surgery, only ISQ showed a significant difference ($P=0.003$ for ISQ by a t -test, $P=0.097$ for PTV by the Mann–Whitney test).

The evaluation of ISQ and PTV at 4 and 10 weeks after surgery showed significantly higher ISQ values in the experimental group at both times ($P=0.004$ at 4 weeks and $P=0.006$ at 10 weeks by t -test), but no significant differences in PTV

($P=0.840$ at 4 weeks and $P=0.084$ at 10 weeks by Mann–Whitney test), as shown in Fig. 3. These results did not reveal any significant difference in the pattern of change of ISQ between the two systems ($P=0.339$ by repeated ANOVA),

Table 2. Comparison of primary stability between the two implant systems

| | Type of implant | | | | P-value* |
|---------------------|---|--------------|----------------------------|--------------|----------|
| | Standard Straumann® Dental Implant system | | Osstem SSII Implant system | | |
| | Number | Mean ± SD | Number | Mean ± SD | |
| Torque (N cm) | | 23.76 ± 8.23 | | 29.54 ± 6.84 | 0.009 |
| ISQ | 25 | 73.28 ± 6.36 | 28 | 78.45 ± 5.82 | 0.003 |
| PTV | | -3.56 ± 1.47 | | -4.20 ± 0.98 | 0.097 |
| Torque range (N cm) | | | | | |
| 10–20 | | | | | |
| ISQ | 9 | 66.83 ± 4.96 | 1 | 65.50 ± 0 | |
| PTV | | -2.83 ± 1.64 | | -3 ± 0 | |
| 20–30 | | | | | |
| ISQ | 9 | 76.28 ± 3.66 | 11 | 77.32 ± 3.72 | |
| PTV | | -3.33 ± 1.09 | | -4.05 ± 0.79 | |
| 30–40 | | | | | |
| ISQ | 6 | 76.83 ± 3.04 | 13 | 78.73 ± 5.62 | |
| PTV | | -4.58 ± 0.80 | | -4.31 ± 1.18 | |
| > 40 N cm | | | | | |
| ISQ | 1 | 83 ± 0 | 3 | 85.67 ± 5.51 | |
| PTV | | -6 ± 0 | | -4.67 ± 0.58 | |

*The P-values for ISQ were calculated by t -test and those for torque and PTV by Mann–Whitney test. ISQ, implant stability quotient; PTV, periosteal value; SD, standard deviation.

Comparison of marginal bone loss between the two implant systems

Marginal bone loss after insertion of the implant was analyzed for the 53 subjects at 10 weeks after surgery and the 50 subjects at 1 year after surgery (Table 3). The results of the evaluation of marginal bone loss showed no significant difference between the two systems from the time of surgery to the connection of the solid prosthetic abutment with respect to the mean values of proximal and distal bone loss ($P=0.624$ by the Mann–Whitney test). After 1 year of follow-up, the two groups showed a borderline difference in marginal bone loss ($P=0.048$ by the Mann–Whitney test) if calculated from the mean value.

To examine the possibility that marginal bone loss is aggravated according to the depth of insertion (Hammerle et al. 1996), the distances from the implant shoulder to the upper border of the alveolar bone at

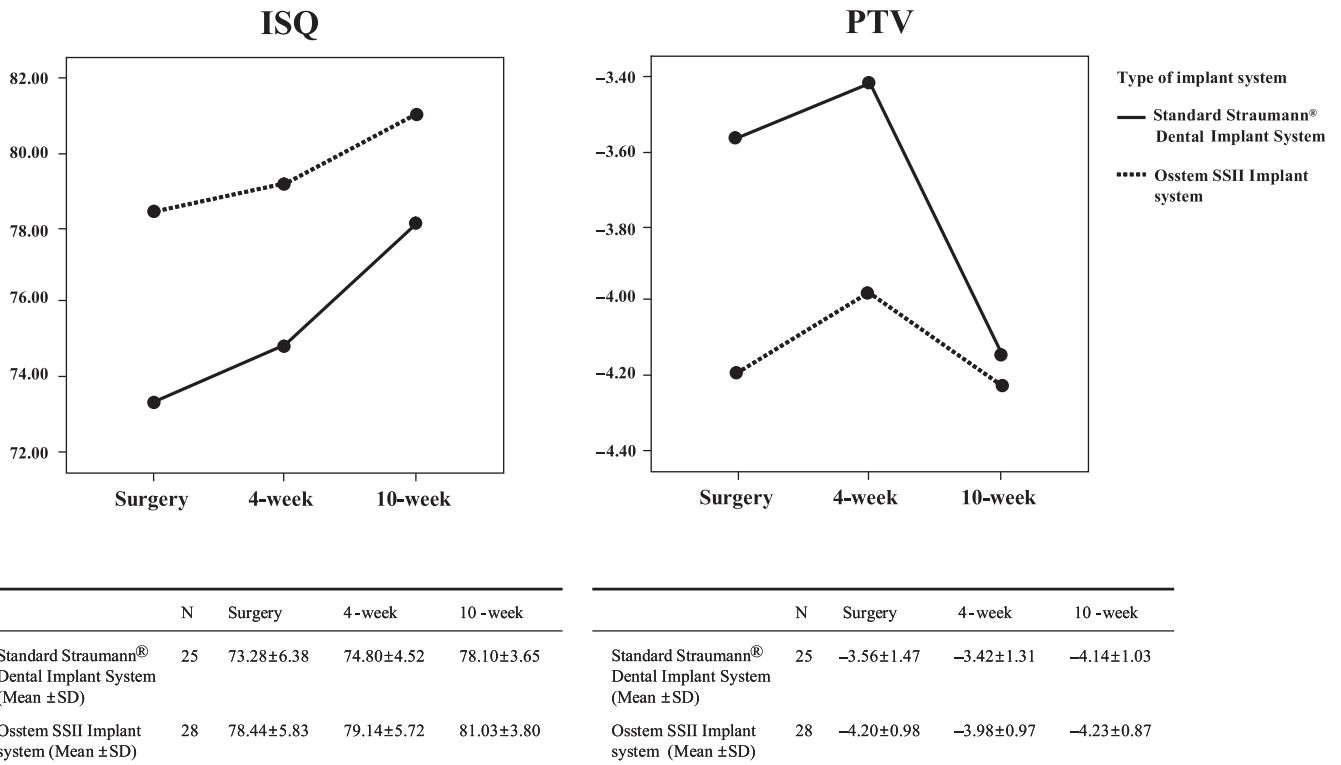


Fig. 3. Comparison of secondary stability according to the pattern of change in implant stability quotient (ISQ) and periosteal value (PTV) during the 10 weeks after implant surgery.

Table 3. Comparison of marginal bone loss between the two implants

| Duration | Area | Type of implant | | | | P-value* |
|-----------------------------------|----------|---|----------------|----------------------------|----------------|----------|
| | | Standard Straumann® Dental Implant system | | Osstem SSII Implant system | | |
| | | N | Mean ± SD (mm) | N | Mean ± SD (mm) | |
| During the 10 weeks after surgery | Proximal | 25 | 0.96 ± 0.64 | 28 | 0.75 ± 0.49 | 0.273 |
| | Distal | 25 | 0.62 ± 0.44 | 28 | 0.60 ± 0.51 | 0.722 |
| | Avg | 25 | 0.79 ± 0.51 | 28 | 0.67 ± 0.43 | 0.624 |
| 1 year follow-up | Proximal | 24 | 1.21 ± 0.57 | 26 | 0.92 ± 0.68 | 0.066 |
| | Distal | 24 | 0.93 ± 0.39 | 26 | 0.65 ± 0.37 | 0.013 |
| | Avg | 24 | 1.07 ± 0.46 | 26 | 0.79 ± 0.42 | 0.048 |

*The P-values were calculated using Mann–Whitney test.
Area, the radiographic measurement area for calculation of marginal bone loss; Avg, the average value of proximal and distal bone loss; SD, standard deviation.

Table 4. Comparison of mucosal status between the two implant systems after 1 year of follow-up

| Parameters | Type of implant | | | | P-value* |
|----------------------------------|---|-------------|----------------------------|-------------|----------|
| | Standard Straumann® Dental Implant system | | Osstem Implant SSII system | | |
| | Number | Mean ± SD | Number | Mean ± SD | |
| Plaque index† | 24 | 0.13 ± 0.34 | 26 | 0.35 ± 0.56 | 0.114 |
| Sulcus bleeding index‡ | 24 | 0.17 ± 0.48 | 26 | 0.30 ± 0.47 | 0.246 |
| Width of keratinized mucosa (mm) | 24 | 2.54 ± 1.17 | 26 | 2.58 ± 1.23 | 0.968 |

*The P-values were calculated using Mann–Whitney test.
†Plaque index: score 0, no detection of plaque; score 1, plaque only recognized by running a probe across the smooth marginal surface of the implant; score 2, plaque can be seen by the naked eye; score 3, abundance of soft matter.
‡Sulcus bleeding index: score 0, no bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant; score 1, isolated bleeding spot visible; score 2, blood forms a confluent red line on margin; score 3, heavy or profuse bleeding.
SD, standard deviation.

surgery were compared between the two implant systems and showed no significant differences (proximal: $P=0.455$; distal: $P=0.543$ by the Mann–Whitney test). Additional occlusal adjustment was not required at 1 year of follow-up after surgery, which ruled out the possibility of marginal bone loss caused by a disorder of occlusion.

Evaluation of mucosal status and the success rate of the two implant systems

There were no significant differences between the two implant systems for all parameters that evaluated soft tissue (Table 4). The success rate after one year of follow-up was 100% for both types of implants, according to the criteria proposed by Buser et al. (1997), after excluding the subjects who dropped out of the study.

Discussion

Primary stability of the two implant systems

Although no baseline level of insertion torque has been established previously to indicate an appropriate level of primary stability for each implant (Rabel et al. 2007), it is important to minimize the implant mobility to apply early or immediate loading. A recent prospective clinical trial using the Straumann® Dental Implant System applied loading 1 week after surgery. The authors reported a 100% survival rate for the implant after 1 year when the solid prosthetic abutment did not spin after fastening with a torque of 35 N cm (Salvi et al. 2004).

In our study, three variables related to primary stability were measured at the time of surgery: the peak insertion torque, ISQ, and PTV. It was found that the peak

insertion torque of the control group was, on average, 6 N cm lower than that of the experimental group and that the ISQ of the experimental group was significantly higher than that of the control. On the other hand, there was no statistically significant difference in the PTV of the two types of implant. The lack of significance in the difference in PTV may be attributed to a smaller range of measured values when compared with other methods (Lachmann et al. 2006). The PTV in each measurement period ranged between -7 and 0 , with a median of -4 for both types of implants. This is consistent with other studies that describe the limitations of PTV in the measurement of implant stability (Olive & Aparicio 1990; Cehreli et al. 2004). Given these results, the experimental group may be assumed to have better primary stability than the control group.

To compare the primary stability between the two systems of non-submerged dental implants, the condensation effect of the tapered machined collar and the press-fit effect by differences in the diameter of the final drill should be taken into consideration. In our study, no difference was found in insertion depth between the two systems; hence, the condensation effect could be excluded. For the press-fit effect, the diameter of the final twist drill in the experimental group was 0.1 mm larger than in the control group, which means that the control group may have experienced a greater press-fit effect. On the other hand, some studies have provided evidence that primary stability is related closely to implant design, more specifically, to the design and geometry of the thread (Meredith 1998; O'Sullivan et al. 2000). The number of threads increases as the pitch height decreases, and an increased number of threads improves the mechanical properties of the implant substantially (Akkocaoglu et al. 2005). The pitch height of the two implant systems used in this study is different (Standard Straumann® Dental Implant system, 1.25 mm; Osstem SSII Implant system, 0.8 mm). Thus, it might be that the difference in the primary stability between the two implant groups can be explained by the differences in the thread design. To confirm this hypothesis, the primary stability of implants with different thread designs and the same surface treatment should be compared.

Secondary stability during the initial healing period

The arithmetic average of the roughness profile (R_a) of resorbable blast media, which were used for the surface treatment of the experimental implant, was 1.2–1.8 μm (Jeon et al. 2009); the R_a of the sandblasted large-grit, acid-etched surface treatment for the control implant was 3.22 μm (Rupp et al. 2006). We found no significant difference between the two types of implants in the pattern of change in ISQ for 10 weeks after surgery. This may indicate no significant difference in the pattern of change in secondary stability during the initial healing period, despite the arithmetic difference in the R_a .

Marginal bone loss

The marginal bone loss associated with the Standard Straumann® Dental Implant system was 0.79 mm, on average, until the solid abutment was connected, and 1.07 mm a year after surgery. This was consistent with the amounts of marginal bone loss reported in a previous study of this implant (0.9 and 1.2 mm, respectively) (Behneke et al. 2000).

It is a matter of debate whether the degree of marginal bone loss is due to the thread design or due to the surface treatment of each type of implant. Although one report showed a difference in marginal

bone loss between an implant with surface treatment and one without (Jungner et al. 2005), implants of intermediate roughness showed no significant differences in marginal bone loss after connection of the prosthesis (Cochran et al. 1998; Albrektsson & Wennerberg 2004). Moreover, a 5-year clinical study of implants with the same thread design showed no difference in marginal bone loss between two methods of surface treatment (Rocuzzo et al. 2008). This shows that the design of the thread may have a greater influence on marginal bone loss than the surface treatment, by modifying the dispersion of masticatory force to the surrounding bone. However, a comparative clinical study on the influence of the structure of the screw thread on marginal bone loss has yet to be performed (Steigenga et al. 2003, 2004).

The thread design is affected by the shape of the thread end, the screw pitch, the width of the thread end, and the height of the thread (Dixon et al. 1995). Finite element analysis that compared different thread designs with the same pitch height but different configurations did not show statistically significant differences in dispersion of the stress to cortical bone (Geng et al. 2004). However, with the same thread configuration, the distribution of stress increased as the pitch decreased.

Analysis suggests that the dissipation of stress is most effective when the ratio of thread height to pitch height is 0.46 (Chun et al. 2002). In our study, the ratio in the experimental group was 0.44 (0.35/0.8), and that in the control group was 0.28 (0.35/1.25). The borderline difference in marginal bone loss after 1 year of follow-up may have been influenced by the difference in pitch height between the two systems. However, the difference in marginal bone loss was very small and may be related to the surface, or to the thread design, or to both. Further studies are required to determine the exact reasons for the difference in marginal bone loss between the two types of implants.

Conclusion

The success rate after 1 year of follow-up was 100% for both systems of implants, despite the presence of a significant difference in implant stability during surgery. There was a borderline difference in marginal bone loss after 1 year of follow-up.

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