CLINICAL ORAL IMPLANTS RESEARCH

Jung-Joo Kim* Dong-Won Lee* Chong-Kwan Kim Kwang-Ho Park Ik-Sang Moon Effect of conical configuration of fixture on the maintenance of marginal bone level: preliminary results at 1 year of function

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Abstract

Objectives: To evaluate and to compare the effect of the conical neck design on marginal bone loss around the fixtures, when both implants were provided with micro-threads to the top of the fixture.

Materials and methods: Two types of implant, one with a straight shape (S) and the other with a conical neck design (C) provided with a retentive element to the top of the fixture, were placed adjacent to each other in the partially edentulous areas of 12 patients. Bone loss around each implant was analyzed after 1 year of functional loading. The bone losses after loading were compared using Wilcoxon's signed-rank test.

Results: The mean marginal bone losses (5, 0.05 ± 0.09 mm; C, 0.07 ± 0.14 mm) were not statistically significant between the two groups (P = 0.578).

Conclusions: There was no significant difference between conical and straight neck implants in terms of marginal bone loss after 1 year of loading.

Previous study by our group regarding the effect of micro-thread on the marginal bone level concluded that implants with microthread showed favorable marginal bone maintenance compared with the implants without micro-thread (Lee et al. 2007). However, concerns regarding the design of the study reported (Abrahamsson & Berglundh 2009; Bratu et al. 2009) that the two implants compared not only differ with regard to the presence of microthread, but also with the gross configuration of the fixture: one with a conical neck and the other with a cylindrical design. Thus, in order to rule out the possible effect of conical configuration of the fixture on the marginal bone level, comparison between conical neck and straight implants appears to be mandatory.

Conical neck implants were developed with the goal of achieving improved adapta-

tion to the alveolar margins of fresh extraction sites (Quirynen et al. 1992). However, the effects of the gross fixture design (e.g. conical neck design vs. straight design) on peri-implant marginal bone maintenances are controversial (Quirynen et al. 1992; Malevez et al. 1996; Nordin et al. 1998; Huang et al. 2007). Marginal bone levels around Brånemark Conical Implants that had a machined conical surface, were reported to be positioned more apically (Quirynen et al. 1992) and resulted in increased marginal bone loss compared with standard or self-tapping implants (Malevez et al. 1996). Thus, Quirynen et al. (1992) and Malevez et al. (1996) concluded that such an implant design was not ideal for singletooth replacement where the conical part is placed into a sub-crestal location.

In contrast, studies with Astra Single Tooth implants have shown stable bone-level

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Date:

Accepted 8 October 2009

To cite this article:

Kim J-J, Lee D-W, Kim C-K, Park K-H, Moon I-S. Effect of conical configuration of fixture on the maintenance of marginal bone level: preliminary results at 1 year of function.

Clin. Oral Impl. Res. 21, 2010; 439–444. doi: 10.1111/j.1600-0501.2009.01871.x

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maintenance (0.05 \pm 0.11 mm, Nordin et al. 1998) after 1 year or minimal marginal bone loss (0.24 \pm 0.13 mm, Lee et al. 2007) after 3 years of loading.

These contradictory results might be due to surface treatment in the former or the use of micro-thread on the conical part of the implant in the latter studies. Brånemark System implants had a machined conical neck, without any retentive factors, which could result in marginal bone loss. In contrast, Astra Single Tooth implants had a rough surface and micro-thread, which could prevent marginal bone loss (Hansson 1999). Thus, direct comparison between the two systems is not logical in terms of the gross fixture design. In order to investigate the pure effect of conical neck design on marginal bone-level maintenance, it is necessary to use equivalent conditions, such as loading, thread configuration, fixture-abutment interface, presence of a retentive factor, and surface treatment.

The aim of the present 1-year post-loading, prospective clinical study was to evaluate the effect of the conical neck design with micro-thread on the marginal bone level of the fixture, by comparing the amount of marginal bone loss between the implant with straight shape and the other with conical neck design, both provided with micro-thread at the coronal side of fixture.

Material and methods

This study was approved by the Institutional Review Board of Yonsei University. Patients were informed of the study procedures and all gave written informed consent.

Patients

At the time of selection, all patients showed good general health and had been treated for existing moderate to severe chronic periodontal disease. The diagnostic criteria followed the 1999 classification standards for periodontal disease (Armitage 1999). The patients received initial therapy including oral hygiene instruction, scaling and root planing, and subsequent corrective therapy including extraction and periodontal flap surgery at the Department of Periodontology at Gangnam Severance Hospital (College of Dentistry, Yonsei

Table 1. Characteristics of the subject population, position and type of the implants

| Subject | Age | Gender | Tooth no. | Fixture type | Subject | Age | Gender | Tooth no. | Fixture type |
|---------|-----|--------|--------------|-----------------|---------|-----|--------|--------------|-----------------|
| 1 | 69 | М | 36 | S | 7 | 60 | F | 16 | S |
| | | | 37 | C | | | | 17 | C |
| 2 | 62 | F | 24 | S | 8 | 62 | M | 36 | S |
| | | | 25 | C | | | | 37 | C |
| 3 | 71 | M | 25 | S | 9 | 61 | F | 16 | S |
| | | | 26 | C | | | | 17 | C |
| 4 | 55 | M | 26 | S | 10 | 60 | F | 26 | S |
| | | | 27 | C | | | | 27 | C |
| 5 | 62 | M | 25 | S | 11 | 60 | F | 15 | S |
| | | | 26 | C | | | | 16 | C |
| 6 | 49 | F | 35 | C | 12 | 53 | M | 44 | S |
| | | | 36 | S | | | | 45 | С |

University, Seoul, Korea). Patients had received implant surgeries from November 2006 to October 2007. In total, six males and six females participated in the present study with a mean age of 60.3 years (range 49–71 years, Table 1).

Implants

Astra Tech Osseospeed™ Implants (Astra Tech AB, Mölndal, Sweden) were used in this study. The Osseospeed™ 4.0 s fixture (S) has a straight shape with a 4 mm diameter. The coronal portion of the Osseospeed™ 5.0 fixture (C) is tapered with Micro-thread™. The apical part of the C has 4 mm diameter, which increases at the marginal collar resulting in a coronal diameter of 5 mm. Both fixtures have micro-thread (Micro-thread™, Astra Tech AB) at their coronal collar and a fluoride-modified TiO-blast surface (Osseospeed™, Astra Tech AB).

Treatment procedure

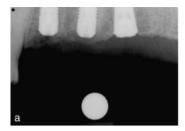
The two fixture types (C and S) were installed adjacent to each other at the same edentulous area. The mesiodistal location of each implants were randomly determined. However, because of the difference in coronal diameter of fixtures, mostly S were implanted mesial to C (Table 1). All implants were installed using the two-stage submerged surgical technique. The implants were placed at or slightly below the marginal bone level, following the manufacturer's guidelines. Special attention was paid to ensure that there was at least 1 mm of bone remaining both buccally and lingually. A second surgery was performed after a healing period of 3 months in the mandible and 6 months in the maxilla. Three weeks after the second

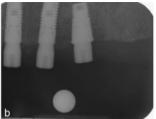
surgery, the prostheses were delivered. During waxing of bridges, the width of the embrasures was matched with the size of the inter-dental cleaning device recommended to the patients (Glantz & Nyman 1998). All the patients had undergone specific oral hygiene instruction for the individual implant prosthesis right after delivery, using interproximal brushes of various sizes (Lee et al. 2006). Patients were recalled every 3 months after prosthesis delivery, and clinical examination, professional plaque control, and oral hygiene instruction were performed at every visit.

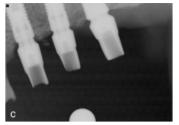
Radiographic examination

Taking radiograph and measurements followed previous protocols of our group (Lee et al. 2005, 2006, 2007). In brief, periapical radiographs (Kodak Insight, film speed F, Rochester, NY, USA) were taken (70 KVp, 10 mA, Yoshida REX 601, Tokyo, Japan, Wyatt et al. 2001) I day after the first surgery, second surgery, prosthesis delivery, and I year after functional loading (Fig. 1). The parallel cone technique with an XCP device (XCP Kit, Ran, Elgin, IL, USA) was used. Films were developed using the same automatic processor (Periomat, Dürr Dental, Bietigheim-Bissingen, Germany) following the manufacturer's manual.

All radiographs were scanned (EPSON GT-12000, EPSON, Nagano, Japan) at 2400 dpi with 256 gray scale. After digitization, the files were transferred to a personal computer (Processor, Intel Celeron D, Santa Clara, CA, USA; Windows XP Professional 2002 operating system, Redmond, WA, USA) and radiographic measurements were taken in the dark using the







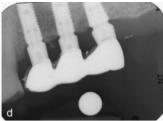


Fig. 1. Intra-oral radiographs of implants. (a) First surgery; (b) second surgery; (c) prosthesis delivery; (d) 1-year follow-up.

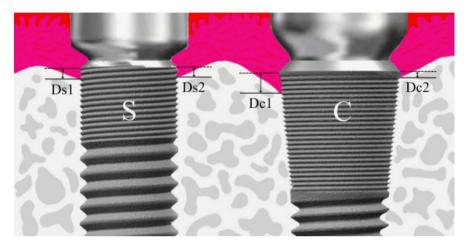


Fig. 2. Schematic representation of site and reference point measurements. S, Astra Tech Osseospeed $^{\text{m}}$ 4.0 s implant; C, Astra Tech Osseospeed $^{\text{m}}$ 5 implant. Dotted line, reference point; solid line, measuring site; Ds1 and Ds2, distance from the reference point to marginal bone at 4.0 s implant; Dc1 and Dc2, distance from the reference point to marginal bone at 5.0 implant.

same monitor (Flatron 775FT Plus, LG, Seoul, Korea, 1024×768 pixel resolution).

Marginal bone-level change measurements

The marginal bone level was measured from the reference point to the lowest contact point of the marginal bone and implant fixture observed. The border between the machined surface and rough surface was considered as the reference point (Fig. 2). Calibration was performed with the thread pitch distance of the fixture. A known diameter of the metal ball was used for calibration in case the threads were not clearly visible. UTHSCSA Image Tool (version 3.00, The University of Texas Health Science Center in San Antonio) was used to measure the distance from the reference point to the marginal bone level to the nearest 0.01 mm. The bone level of each fixture was measured on both the mesial and distal sides, and the average value was used. In the case of bone gain, the amount of bone loss was considered zero. Also, mesiodistal distance (inter-implant distance) between C and S implants were recorded by measuring the shortest distance between the reference points (ID).

Measurements were made by a single operator (J.-J.-K.). To test intra-observer variability, marginal bone losses on 40 randomly selected radiographs of S and C, which were not included in the present study, were measured twice with a 1week interval. Pearson's correlation coefficient was calculated to analyze the correlation between the two sets of measurements. 95% confidence interval for the differences of the paired data showed 0.02-0.06 mm, with a Pearson's correlation coefficient of 0.89 (P < 0.0001, 95%confidence interval 0.8-0.94). The intraobserver variability and correlation coefficients were similar to those reported previously (Webber et al. 1992; Wyatt et al. 2001).

Follow-up parameters

At the I-year follow-up, the presence/ absence of pain, discomfort, or infection associated with the implants were recorded. The clinical immobility of each implant was also checked after bridge removal. A surviving implant was defined as an implant that was stable, functional, and symptom-free. The modified plaque index (mPI) and modified sulcus bleeding index (mBI) were measured at four aspects around the each implant (Mombelli et al. 1987). The average of the four mPI and mBI values obtained was calculated to represent the respective values for each implant.

Statistical analysis

The null hypothesis was that there would be no difference between the marginal bone loss of S and C during the examination period. After collecting all data (12 pairs), data distribution normality was tested using D'Agostino-Pearson test. As the normality of the distribution of both groups were rejected, Wilcoxon's signed-rank was used for comparison of the median of the pair-wise differences between marginal bone losses, mPI and mBI of the two groups. In order to study the possible correlation between the ID and marginal bone loss between fixtures, Spearman's rank correlations were calculated between ID and marginal bone loss at the proximal implant surfaces facing implant/implant unit (Si [Ci], marginal bone loss at interimplant side of fixture S [C]). Computer software (MedCalc Software, version 11.0, Mariakerke, Belgium) was used to process data. The value was deemed statistically significant if the P-value was < 0.05.

Results

Clinical examination

During the observation period, no remarkable complications were found. No patient suffered from pain or implant mobility, and no prosthetic complications were observed.

Marginal bone-level changes

The marginal bone loss for each implant is illustrated in Table 2. The mean marginal bone losses (S, 0.05 \pm 0.09 mm; C, 0.07 \pm 0.14 mm) were not statistically significant between the two groups (P = 0.578).

Table 2. Marginal bone loss of S and C implants after 1 year of loading

| Subject | Type of imp | olant | Inter-implant distance (ID) | | | |
|---|--|-------|------------------------------------|-------|-------------------------------------|--|
| | S | | | | С | |
| 1 | 0 0.05 | 0.025 | 0 | 0 | 2.7 | |
| 2 | 0.24 0.38 | 0.31 | 0.46 0.48 | 0.47 | 2.7 | |
| 3 | 0 | 0 | 0 | 0 | 3.5 | |
| 4 | 0 | 0 | 0 | 0 | 2.7 | |
| 5 | 0 0.13 | 0.065 | 0 | 0 | 5.2 | |
| 6 | 0 | 0 | 0 | 0 | 6.7 | |
| 7 | 0 | 0 | 0 | 0 | 4.7 | |
| 8 | 0 0.17 | 0.085 | 0 | 0 | 4 | |
| 9 | 0 | 0.1 | 0.37 0 | 0.185 | 3.4 | |
| 10 | 0 | 0 | 0 0.03 | 0.015 | 4.1 | |
| 11 | 0.02 0 | 0.01 | 0 0.35 | 0.175 | 3 | |
| 12 | 0 | 0 | 0 | 0 | 3.3 | |
| Mean Median | 0.05 0.01 | | 0.07 0 | | 3.83 3.45 | |
| Standard deviation | 0.09 | | 0.14 | | 1.21 | |
| Coefficient of skewness 95% CI for the median 95% CI for the median of difference | 2.56 (P=0.0005) 0-0.082 e - 0.07 to 0.02 | | 2.34 (<i>P</i> = 0.001) 0-0.15 | | 1.33 (<i>P</i> = 0.04) 2.75–4.6 | |
| D'Agostino–Pearson test Wilcoxon test (<i>P</i> -value) | Reject normality (<i>P</i> <0.0001) 0.578 | | Reject normality ($P = 0.0001$) | | Reject normality (P = 0.0495 | |

S, Astra Tech Osseospeed™ 4.0 s implant; C, Astra Tech Osseospeed™ 5.0 implant.

Table 3. Correlation between inter-implant distance and marginal bone loss

| ID | Si | Ci |
|--|-----------------------------------|----------------------------|
| Spearman's coefficient of rank correlation (ρ) Significance level Sample size | − 0.204 <i>P</i> = 0.498 12 | - 0.346 P = 0.251 12 |

ID, inter-implant distance; Si, marginal bone loss at inter-implant side of fixture S; Ci, marginal bone loss at inter-implant side of fixture C.

Inter-implant distances

The inter-implant distances are depicted in Table 2. Also, the correlations between ID-Si, ID-Ci were not statistically significant (P = 0.498 [ID-Si], 0.251 [ID-Ci], Table 3).

Evaluation of the peri-implant soft tissue

The peri-implant soft tissues revealed little tendency to bleed following probing and were clinically healthy. The average mPI of group S and C was 0.833 and 0.771, respectively (Table 4). The average mBI of group S and C was 0.667 and 0.729, respectively (Table 5). No statistically significant differences were found between

the two groups for either index (P = 0.426)[mPI], 0.563 [mBI]).

Discussion

The purpose of the present study was to evaluate the effect of conical neck design with micro-thread on the marginal bone level at the fixture, by comparing the amount of marginal bone loss between two implant types (group C and S) installed adjacent to each other for equal occlusal load application on the fixtures. The implant fixtures used in present study had the same surface treatment (Osseospeed™,

Astra Tech AB), implant-abutment interface (Conical Seal Design™, Astra Tech AB), and thread characteristics; thus, all possible effects of implant design except the gross shape could be minimized. Lee et al. (2007) suggested that aligning fixtures of different types and connecting them facilitates the matching of the individual load to each tested fixture. In the present study, each implant type was aligned adiacent to and connected with the other in the same edentulous area to minimize the effects of variables such as load and bone quality. To minimize the possible effects of plaque, repeated professional plaque control and oral hygiene instruction were performed throughout the examination period, and statistically compared with regard to the plaque accumulation and sulcus bleeding between each tested groups.

In present study, the mean marginal bone losses were $0.05 \pm 0.09 \,\mathrm{mm}$ (S) and $0.07 \pm 0.14 \,\text{mm}$ (C). In group C, the amount of peri-implant marginal bone loss

Table 4. mPI of S and C implants

| Subject | Type of implant | | |
|--------------------|-----------------|------|--|
| | S | С | |
| 1 | 0 | 0 | |
| 2 | 1 | 0.75 | |
| 3 | 2.25 | 2.5 | |
| 4 | 0.5 | 0.25 | |
| 5 | 0.25 | 0.5 | |
| 6 | 0.5 | 0.25 | |
| 7 | 1 | 1 | |
| 8 | 1 | 0.75 | |
| 9 | 0.75 | 0.5 | |
| 10 | 0.75 | 0.75 | |
| 11 | 1 | 0.75 | |
| 12 | 1 | 1.25 | |
| Mean | 0.83 | 0.77 | |
| Median | 0.88 | 0.75 | |
| Standard deviation | 0.56 | 0.64 | |
| <i>P</i> -value | 0.426 | | |

Level of significance (P<0.05). S, Astra Tech OsseospeedTM 4.0 s implant; C, Astra Tech OsseospeedTM 5.0 implant; mPI, modified plague index.

Table 5. mBI of S and C implants

| Subject | Type of implant | | |
|--------------------|-----------------|------|--|
| | S | С | |
| 1 | 0 | 0.25 | |
| 2 | 1.25 | 1.25 | |
| 3 | 1.5 | 1.5 | |
| 4 | 1.25 | 0.5 | |
| 5 | 0.25 | 0.75 | |
| 6 | 0 | 0 | |
| 7 | 0 | 0 | |
| 8 | 0.5 | 1 | |
| 9 | 0 | 0.5 | |
| 10 | 0.25 | 0 | |
| 11 | 1 | 1 | |
| 12 | 2 | 2 | |
| Mean | 0.67 | 0.73 | |
| Median | 0.38 | 0.63 | |
| Standard deviation | 0.7 | 0.64 | |
| <i>P</i> -value | 0.563 | | |

Level of significance (*P*<0.05). S, Astra Tech Osseospeed™ 4.0 s implant; C, Astra Tech Osseospeed™ 5.0 implant; mBI, modified sulcus bleeding index.

was much smaller than that observed in some previous studies using machined implants without any retentive element in the conical portion of the fixture (3.3 \pm 1 mm, Quirynen et al. 1992; 1.14 \pm 0.54 mm, Malevez et al. 1996), but consistent with the results of marginal bone loss after 1 year of loading (0.05 \pm 0.11 mm, Nordin et al. 1998; 0.14 \pm 0.11 mm, Lee et al. 2007, 0.06 \pm 0.67 mm, Wennström et al. 2005). Because the implants used in Quirynen et al. (1992) and Malevez et al. (1996) had a flat top interface and machined conical surface, differences from our results might be due to

differences in the implant-abutment interface, surface topography, and/or the use of a minute thread to the top of the fixture. Indeed, the thread on the neck portion might be considered as the major contributor to the observed differences (Jung et al. 1996).

Hansson (2000, 2003) concluded that the conical interface transfers the load deeper into the bone, thus reducing the peak stress at the peri-implant marginal bone compared with a flat top interface. The results of some clinical studies indicate that the conical seal design offers advantages in the marginal bone-level maintenance (Norton 1998, 2006; Engquist et al. 2002). With retention elements at the implant neck, the marginal bone is reportedly stimulated mechanically by axial loads on the implant, and retention elements such as a rough surface, and micro-thread at the neck portion help maintain the marginal bone level (Hansson 1999). Finite-element analyses indicate that threads of small dimensions are quite effective at preserving the marginal bone (Hansson & Werke 2003). Finally, experimental studies have verified the advantages of micro-thread compared with a smooth neck, in terms of established bone-to-implant contact and marginal bone-level maintenance (Rasmusson et al. 2001; Berglundh et al. 2005; Abrahamsson & Berglundh 2006).

Misch & Bidez (1999) claimed that an angled crest module of > 20° with a surface texture that increases bone contact might impose slightly beneficial compressive and tensile components to the contiguous bone and decrease bone loss risk. Because the conical neck design transmits the compressive forces to the bone, this could help maintain the marginal bone level (Guo 2001). Using a three-dimensional finiteelement analysis, Huang et al. (2007) demonstrated that the tapered body reduces stresses in both the cortical and trabecular bone, potentially due to the increased interfacial area. Also, Kong et al. (2008) proposed that the taper of the implant neck favors stress distribution in the cortical bone and affects implant stability. However, in the present study, we found no significant differences between conical and straight neck implants in terms of marginal bone loss, which could not support the aforementioned studies (Misch & Bidez 1999; Guo 2001; Huang et al. 2007; Kong et al. 2008). It is possible that the beneficial effects of the conical implantabutment interface, micro-thread, and rough surface on marginal bone-level maintenance overwhelmed the additional effects of conical neck design.

One of the drawbacks of the present study is the short-term follow-up period. However, when we analyze a previous study comparing straight/non-micro-threaded implant and conical/micro-threaded implant (Lee et al. 2007), the most critical period regarding the marginal bone-level changes occurred I year after loading. After I year, both groups showed stable marginal bone reaction, which did not show statistically significant additional marginal bone resorption. Thus, this 1-year interim result would be worth considering. This study is an interim report of the 5-year prospective study, and further evaluation and patient recruitment is still ongoing. Also, the interimplant distance was not standardized. The possible influence of inter-implant distance on the level of mid-proximal bone level between implants as previously addressed (Cardaropoli et al. 2003). However, the marginal bone levels between implants were reported to be unrelated with the horizontal distance between implant (Cardaropoli et al. 2003). The results of our study confirm this, as ID did not correlate with Si and Ci. Thus, the effect of unstandardized inter-implant distance in the present study seems to be negligible, as far as the marginal bone levels around implants are concerned. Additional limitations, such as small sample sizes, skewness of data, and possible false diagnosis in analyzing small peri-implant bone-level changes (Brägger et al. 1998) exist, and further additional research is necessary to investigate the mechanism and the relationship between implant design and crestal bone loss.

In conclusion, difference in gross fixture design, such as conical neck vs. straight implant did not result in statistically significant difference of marginal bone loss after I year of loading.

Acknowledgement: There were no financial relationships between any of the authors and the manufacturers of products involved in the study. This study was supported by a faculty research grant of Yonsei University College of Dentistry for 2009(6-2009-0043).

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