A 1-year prospective clinical study of soft tissue conditions and marginal bone changes around dental implants after flapless implant surgery

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Background. Despite several reports on the clinical outcomes of flapless implant surgery, limited information exists regarding the clinical conditions after flapless implant surgery.
Objective. The objective of this study was to evaluate the soft tissue conditions and marginal bone changes around dental implants 1 year after flapless implant surgery.
Study design. For the study, 432 implants were placed in 241 patients by using a flapless 1-stage procedure. In these patients, peri-implant soft tissue conditions and radiographic marginal bone changes were evaluated 1 year after surgery.
Results. None of the implants were lost during follow-up, giving a success rate of 100%. The mean probing depth was 2.1 mm (SD 0.7), and the average bleeding on probing index was 0.1 (SD 0.3). The average gingival index score was 0.1 (SD 0.3), and the mean marginal bone loss was 0.3 mm (SD 0.4 mm; range 0.0-1.1 mm). Ten implants exhibited bone loss of >1.0 mm, whereas 125 implants experienced no bone loss at all.
Conclusion. The results of this study demonstrate that flapless implant surgery is a predictable procedure. In addition, it is advantageous for preserving crestal bone and mucosal health surrounding dental implants. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2010;xx:xxx)**

Flapless surgery as a method for dental implant placement is gaining popularity among implant surgeons. The increased use of this method can be attributed to improvements in radiologic technologies and dental implant treatment planning software, as clinicians can now acquire 3-dimensional images of potential implant sites before surgery.[1-4] Flapless surgery has numerous advantages, including preservation of the vessels around the implants,[5] maintainance of the original mucosal form around the implants,[6] and retention of hard tissue volume at the surgical site.[7] This method also shortens the length of the surgery, improves patient comfort, and accelerates recovery.[8]

In recent years, flapless implant surgery has been reported to have a predictable outcome with a high success rate, as long as patients are properly selected for the procedure and have an appropriate width of bone available for implant placement.[9-11] Other studies have shown that exclusion of the mucoperiosteal flap can prevent the potential postoperative bone resorption associated with flap elevation,[12-14] but limited controlled data are available to evaluate the clinical conditions after flapless implant surgery. Additionally, most crestal bone loss occurs in the early phase after implant placement.[15-17] Therefore, the purpose of the present study was to evaluate the soft tissue conditions and marginal bone changes around dental implants 1 year after flapless implant surgery.

MATERIALS AND METHODS

Two hundred forty-one consecutive patients (108 men and 133 women, aged 19-73 y, mean age 54 y) were enrolled in this study. All of the patients were treated at a single clinic associated with a Korean university, and all of them underwent flapless implant surgery. In all, 432 Osstem implants (GSII; Osstem Implant Co., Seoul, Korea) were inserted into different areas of the jaw. Inclusion criteria included subjects

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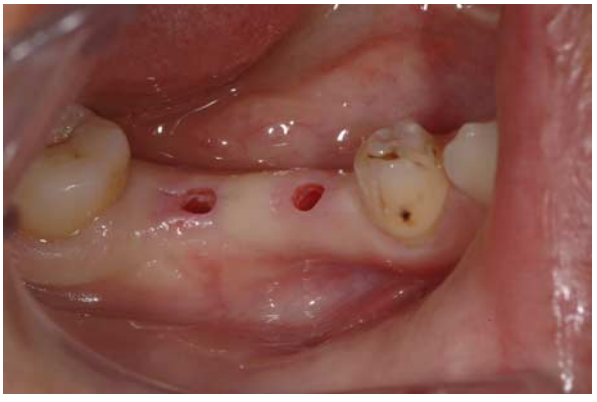

Fig. 1. Clinical features after punching the soft tissue at the proposed implant sites with a 3-mm soft tissue punch.

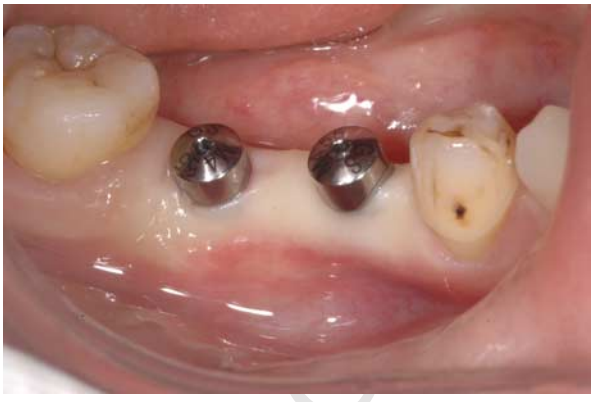

Fig. 2. Clinical features after healing abutments were connected to the fixtures.

undergoing full-arch, partial-arch, or single-tooth replacement procedures who were systemically healthy, presenting with good periodontal health or with mild to moderate gingivitis, and who were able and willing to provide informed consent. Patients requiring ridge augmentation with barrier membranes or bone grafts were excluded from the study.

Surgical procedure

Under local anesthesia with 2% lidocaine (1:100,000 epinephrine), the soft tissue of the proposed implant site was punched with a 3-mm soft tissue punch (Fig. 1). A core of soft tissue was then removed from over the crestal bone, and an implant osteotomy was performed at the core of the exposed bone. Before drilling, the soft tissue thickness was measured at the implant site using a periodontal probe. Implant osteotomy and placement were performed following the manufacturers' instructions. All of the patients received endosseous implants 3.5, 4.0, 4.5, or 5.0 mm in diameter and 8.5-15 mm in length via flapless surgery. After implant placement, healing abutments 4.5 or 5.5 mm in diameter and 3 or 5 mm in length were connected immediately to the fixtures, such that the coronal portion of the abutments remained exposed to the oral cavity (Fig. 2). Experienced senior physicians placed all implants. Immediately after implant placement, a plaque control procedure was performed daily.

Prosthetic reconstruction

After 3-4 months of healing, all fixtures were checked for stability using a manual tightening torque of 20 N · cm. Restorative dentists fabricated the final prostheses. These dentists produced screw-retained metal-ceramic or metal-resin reconstructions that were then adapted to the needs and demands of each patient.

Clinical evaluation

For each implant, a clinical evaluation was performed 12 months after the implant insertion. One clinician performed the clinical evaluation, which involved measuring the probing pocket depth, assessing the gingival index (GI), and recording the presence of bleeding on probing (BOP).[18] The presence or absence of keratinized gingiva around the implants was also recorded. Pocket depths were measured using probes (PDT, Zila, AZ) with a probing force of 0.2 N. The probe was calibrated for a 0.2-N probing force. The mean pocket probing depth for each implant site was obtained from averaging the measurements taken at 4 different sites around the implant.

To assess postsurgical changes in the crestal bone level, conventional dental radiographs were taken immediately after surgery and 12 months after implant placement (Fig. 3). The images were digitized, and the distance between the fixture shoulder and the apical level of the marginal bone that was in contact with the implant was measured at ×8 magnification using implant height (a known measurement) for calibration. Measurements were made at the mesial and distal aspects of each fixture, and the mean for each case was calculated. All measurements were performed by 2 examiners who were blinded to the methods used in the study; when these examiners disagreed, the values were rechecked and discussed until an agreement was made.

Statistical analysis

The data were processed using a statistical software package (SPSS for Windows; SPSS, Chicago, IL). Descriptive statistics were used to evaluate the soft tissue conditions and any bone changes. Bone loss was analyzed using the Student *t* test for comparison between the thick soft tissue (ε3 mm) and the thin soft tissue

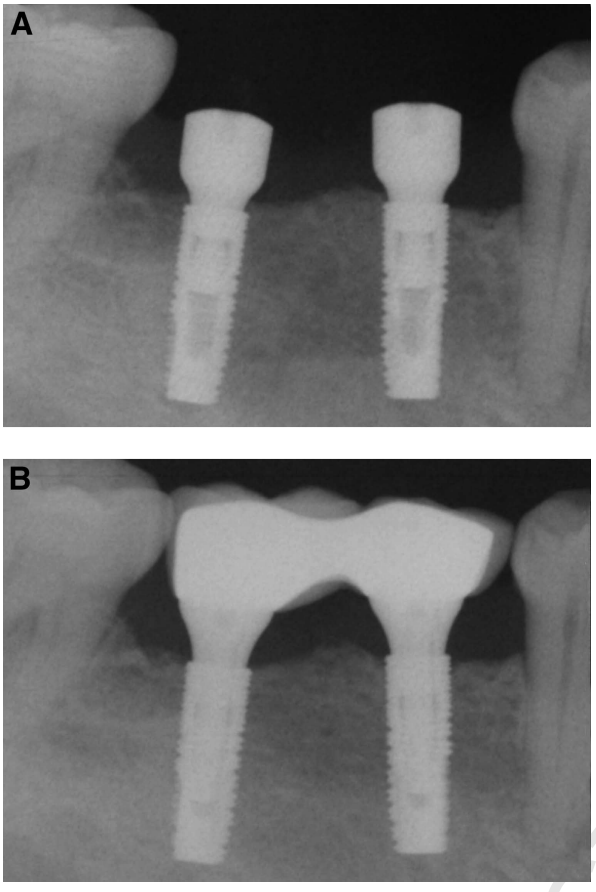

Fig. 3. Periapical radiograph taken immediately (**A**) and 1 year (**B**) after implant placement.

groups (<3 mm). A P value of <.05 was considered to be statistically significant.

RESULTS

Most patients (50.3%) received a single implant, and 31.2% received 2 implants, 13.9% received 3 implants, and 4.6% received ≥4 implants. Mandibular molar implants were most commonly performed (192), followed by maxillary molar implants (92), mandibular premolar implants (86), maxillary premolar implants (42), mandibular incisor implants (11), and maxillary incisor implants (9). The predominant implant site was the mandibular first molar position, where 42.2% of the implants were placed.

None of the 432 inserted fixtures were lost during follow-up, giving our study a success rate of 100%. Additionally, no implants were found to be mobile during the 20 N·cm torque testing performed 3-4 months after the implant was placed. Table I presents the overall clinical characteristics of the implant and the related mucosa 1 year after surgery. The mean pocket probing depth was 2.1 mm (SD 0.7), and the average BOP index was 0.1 (SD 0.3). The average GI score was 0.1 (SD 0.3), which was used to evaluate peri-implant mucosal health and inflammation. In 6 of the implants, keratinized mucosa was absent on the buccal side of the implant; however, this sample size was too small to allow us to conduct a comparative analysis on the role of keratinized mucosa in implant surgery outcomes.

Table I. Probing depth, gingival index, bleeding on probing index, and crestal bone loss when implants were placed without a flap

	1 year
Probing depth (mm)	2.1 ± 0.7
Bleeding on probing index	0.1 ± 0.3
Gingival index	0.1 ± 0.3
Crestal bone loss	0.3 ± 0.4

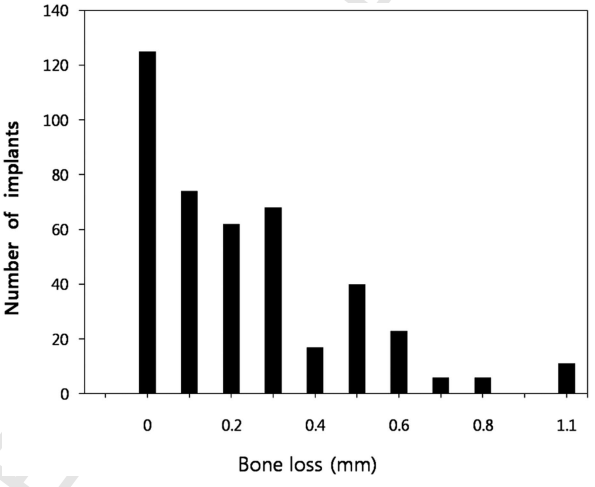

Fig. 4. Number of implants that exhibited varying amounts of bone loss during the healing period from the time of implant placement to the 1-year follow-up.

The mean marginal bone loss was 0.3 mm (SD 0.4 mm, range 0.0-1.1 mm). The bar charts in Fig. 4 illustrate the frequencies of bone loss among the implants. No implants exhibited bone loss >1.2 mm, 10 implants experienced bone loss >1.0 mm, and 125 implants exhibited no bone loss. The relationship of the soft tissue thickness to the marginal bone loss was also analyzed (Table II). The mean bone loss for the thick (ε3 mm) and thin groups (<3 mm) at 12 months were 0.3 ± 0.6 mm and 0.3 ± 0.2 mm, respectively. No significant difference was found between the 2 groups.

DISCUSSION

According to Albrektsson's success criteria,[17] the average marginal bone loss should be <1.5 mm during

Table II. Soft tissue thickness and crestal bone loss

Soft tissue thickness	*No. of implants*	*Crestal bone loss (mm)*
<3.0 mm	318	0.3 ± 0.2
≥3.0 mm	114	0.3 ± 0.6

the first year of functional use of an implant. The marginal bone loss is reported to range from 0.4 to 1.2 mm 1 year after flap implant surgery.[19-25] The findings of the present study demonstrate that the mean bone loss was 0.3 mm 1 year after flapless implant surgery; no implants failed to osseointegrate, and no implants exhibited bone loss >1.2 mm. These low frequencies of both implant failures and progressive bone loss agree with findings from earlier studies[9,10] which found that flapless implant surgery is a predictable procedure with a high success rate. One explanation for the high success rate may be that when flaps are not reflected, the periosteum is preserved, which may help to optimize the healing of the peri-implant tissue.

The amount of bone loss in the present study is encouraging, even compared with the results of earlier studies that measured bone loss after flapless implant surgery.[26-29] The lower rate of crestal bone loss in the present study may be due to our use of a tissue punch narrower than the implant itself. Some earlier studies[9,26-29] used a tissue punch wider than the selected implant. The gap between the implants and the peri-implant mucosa was determined based on the size of the soft tissue punch and the size of the implant. In patients in whom a wider tissue punch was used, a wide gap was created between the implants and the surrounding mucosa. However, when the mucosa is punched with a narrow tissue punch, the peri-implant mucosa is in direct contact with the implants, and no gap is produced. Small, clean, closed wounds are known to heal quickly and with little scar formation. In contrast, large open wounds heal slowly and with significant scarring.[30-32] This principle can also be applied to wounds around flapless implants. The flapless procedure, which uses a narrower tissue punch, produces a surrounding mucosa that has smaller, cleaner, and more closed wounds compared with those of procedures using a wider tissue punch. The smaller wounds may improve the ability of the peri-implant mucosa to quickly attach to the surface of the implant after the procedure, which could lead to a lower rate of crestal bone loss.

Effective plaque control after flapless implant surgery could be another factor involved in the lower rate of crestal bone loss in the present study. Implants can easily be cleaned immediately after the flapless implant procedure, because the implant surface is in close contact with the surrounding mucosa. Early plaque control plays an important role in promoting the health of the peri-implant mucosa and in preventing peri-implant bone loss.[33,34] We observed excellent peri-implant mucosal health in the present sample after flapless implant surgery, as confirmed by low GI and BOP index scores. The maintenance of healthy soft tissue adjacent to flapless implants may also contribute to the minimal bone loss in this study.

There have been conflicting results regarding the necessity of having keratinized mucosa around implants.[35-39] Krekeler et al.[35] suggested that implants placed in the keratinized gingiva have a more stable soft tissue–implant interface, whereas implants in the movable soft gingiva have a less stable soft tissue–implant interface and were more likely to cause soft tissue problems, such as infection. However, several other reports demonstrate long-term implant survival in the absence of keratinized tissue,[38-40] showing that keratinized tissue is not essential for the success of an implant. The necessity of keratinized tissue around flapless implants should be reevaluated after flapless implant surgery in cases in which the peri-implant mucosa heals with little scar formation, with an increase in blood vessels, or with a decrease in peri-implant bone loss. In the present study, 6 implants showed that keratinized mucosa was absent in the buccal side of the implant. However, these data were too few to allow for comparative analysis on the role of keratinized mucosa in implant surgery outcomes.

Resulting from the small access punch technique used in this study, the implant surface may be contaminated by soft tissue contact during the flapless implant procedure. Some authors have argued that it is important to avoid contamination of the implant surface by bacteria and biologic molecules (including saliva and foreign bodies) during the surgical insertion of implants into the jaw.[41] In contrast, Ivanoff et al.[42] reported that preoperative soft tissue contamination of titanium implants did not prevent osseointegration, after examining the differences in bony contact between biologically contaminated implants and standard control implants. There were no major morphologic differences between the control and test sites regarding their bone or marrow structures and bone-to-implant contacts. Esposito et al.[40] reported that clinical observations and experimental evidence failed to indicate any soft tissue contact–related causes for implant failures. Our study produced similar results to those of Ivanoff et al.[42] and Esposito et al.,[40] in that osseointegration occurred in all of the present cases despite potential contamination caused by the small puncture. Nevertheless, we recommend that flapless implant surgeries include meticulous preoper-

ative disinfection, particularly in the area of the mucosa through which the implants pass.

In conclusion, the present results indicate that the flapless procedure is advantageous for preserving crestal bone and mucosal health surrounding dental implants. Our findings support the clinical use of flapless implant surgery to increase the success rate of the implant procedure.

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