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Clinical evaluation of a biphasic
calcium phosphate grafting
material in the treatment of human
periodontal intrabony defects

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사람 골연하 결손부의 치료에서 이상인산칼슘
이식 후의 임상적 평가

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이 논문을 치의학 석사학위신청 논문으로 제출함

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국문 초록

사람 골연하 결손부의 치료에서 이상인산칼슘 이식 후의 임상적 평가

이 민 재

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치의학과

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이 연구의 목적은 치주질환으로 인한 골연하 결손부의 치료에서 이상인산칼슘 이식 후의 임상적 및 방사선학적 결과를 평가하는 것이다.

2벽성 또는 3벽성 형태를 가지며 4mm 높이 이상을 갖는 치주 골연하 결손부를 가진 25명의 피실험자를 대상으로 하였다. 피실험자는 임의적으로 나뉘어 14명에게는 open flap debridement (OFD)와 함께 이상인산칼슘을 이식하였으며 다른 11명에게는 open flap debridement (OFD)만을 시행하였다. 임상적 지표는 수술 전과 수술 6개월 후로 나누어 측정하였으며 지표들은 Plaque index (PI), Gingival index (GI), Probing depth (PD), Clinical attachment level (CAL), Gingival recession (REC) 의 다섯가지 항목을 포함하였다. 또한 방사선학적 평가를 수술 전, 수술 6개월 후로 나누어 Intrabony defect depth (IBD)를 조사하였다. 피실험자들은 수술 후 6개월 동안 치태 조절 프로그램을 받게 하였다.

모든 그룹에서 실험기간동안 유의적인 PD의 감소와 CAL의 획득이 일어났다 ($P < 0.007$). 수술 후 6개월에 BCP를 적용한 그룹에서 $3.7 \pm 1.2\text{mm}$ 의 평균적인 PD의 감소와 $3.0 \pm 1.1\text{mm}$ 의 CAL의 획득이 일어났다. OFD를 한 그룹에서는 각각 $2.5 \pm 0.8\text{mm}$ 과 $1.4 \pm 1.0\text{mm}$ 의 임상적 변화가 있었다. OFD를 적용한 그룹과 비교하였을 때, 추가적인 CAL의 획득은 BCP를 적용한 그룹이 유의적으로 많았다 ($P = 0.028$). 또한 추가적인 PD의 감소도 BCP를 적용한 그룹에서 유의적으로 많았다 ($P = 0.048$).

치은 퇴축은 두 그룹 모두에서 유의적으로 증가하였으며 BCP를 적용한 그룹의 퇴축량이 유의적으로 적었다 ($P = 0.023$). 방사선학적 평가에서는 골충전의 높이가 BCP를 적

용한 그룹이 유의적으로 많았다 ($P= 0.045$).

BCP를 골연하 결손부에 적용한 것이 OFD를 단독으로 시행한 것 보다 임상적으로 이득이 있었으며 따라서 BCP는 치주 결손부에 있어서 사용가능한 적절한 이식재로 생각된다.

I . Introduction

Numerous studies¹⁻⁴⁾ have investigated the regenerative treatment of periodontal intrabony defects, and a variety of treatment approaches for the restoration of lost periodontal structures have been suggested. These comprise the use of guided tissue regeneration (GTR)⁵⁻⁷⁾ bone replacement grafts⁸⁻¹⁰⁾ and biologic factors, such as enamel matrix proteins¹¹⁻¹³⁾ and growth factors,¹⁴⁻¹⁶⁾ or a combination of these techniques.

Although traditional approaches use barrier membranes to allow periodontal ligament (PDL) progenitor cells to selectively repopulate on root surfaces, the efficacy of bioactive agents is mainly based on mitogenic and chemotactic effects on PDL and alveolar bone cells. Overall, the use of these techniques resulted in additional benefits in terms of clinical attachment level (CAL) gain and probing depth (PD) reduction compared to open flap debridement (OFD) alone. Nevertheless, the magnitude of CAL and PD changes differed between the studies.^{4,5)} In particular, the success of GTR is known to be technically sensitive and dependent on various confounders.^{17, 18)}

Regarding bone replacement grafts, from a biologic point of view, autogenous bone grafts have been considered the most predictable or gold-standard material,^{19,20)} but it is necessary to harvest the graft from a donor area, which might require a second surgical site. Alternatively, xenografts and allografts have been well documented to be suitable as bone replacement grafts.²¹⁻²³⁾ However, some studies²⁴⁻²⁶⁾ frequently state an incomplete resorption of these materials. Moreover, although statistically negligible, there is still a risk of transmitting diseases by the use of allografts and xenografts.

The use of alloplastic materials, which are synthetic, inorganic, biocompatible bone-graft substitutes, represents a possible alternative for the treatment of intrabony defects. Advantages are an easier accessibility, eliminating the need of a donor site as is necessary with autogenous grafts, and no risk for disease transmission, as may accompany the use of allografts and xenografts.

Hydroxyapatite (HA) and β -tricalcium phosphate (β -TCP) have shown significant clinical improvements in grafted sites compared to non-grafted sites in controlled clinical studies.²⁷⁻²⁹⁾ A new biomaterial was introduced recently for periodontal regenerative therapy. This fully synthetic bone graft substance, termed HA/ β -TCP, is a composite of medical purity biphasic calcium phosphate: a mixture of 60% HA, which is 100% crystalline, and 40% of the β form of tricalcium phosphate in particulate form. A previous study³⁰⁾ demonstrated the superiority of using a composite of these two materials over the use of either material alone. But Controlled clinical studies on the use of the HA/ β -TCP as a bone replacement graft in the treatment of periodontal defects are insufficient. Therefore, the aim of this clinical trial was to evaluate the clinical outcomes of this HA/ β -TCP in human periodontal intrabony defects compared to OFD alone.

II . MATERIALS AND METHODS

A. Study Design and Population

The present study was designed as a prospective controlled clinical trial. 25 subjects (13 males and 12 females; age range: 31 and 64 years; mean age: 46.3 \pm 8.5 years), who were referred for treatment of moderate or severe chronic periodontitis to the Department of Periodontology, Chosun University Dental Hospital, were included in the study.

These patients had received non-surgical periodontal therapy from the same periodontist without systemic or locally delivered antibiotics, 10 to 14 weeks before being enrolled in this prospective study.

All participants were informed about the risks and benefits of the procedure and signed an informed consent. Two different therapeutic modalities for the treatment of deep intraosseous periodontal defects were compared. One group were treated by a bone replacement graft with BCP biomaterial (GENESIS-BCP™, DIO corporation, Busan, Korea). In the another group, OFD without any bone replacement graft was performed.

Inclusion criteria were: no systemic diseases or pregnancy; no smoking habit; no regular medications for any reason; chronic generalized periodontitis; completion of the initial treatment (including subgingival scaling and root planing); compliance with the maintenance program; presence of a vertical intrabony defect (IC) in the interproximal area with a depth \geq 4 mm, defined as the distance in millimeters from the bottom of the defect to the most coronal extension of the alveolar bone crest after all granulation tissue had been removed; absence of furcation involvement or vertical defects extending into the furcation area; teeth had to be vital and free of radiographic signs of periapical abscesses; teeth free of carious lesions in the region of the defect.

This study protocol was approved by Chosun University Dental Hospital Instruction Review Board (CDMDIRB-1112-56).

B. Clinical Measurements

Complete oral and periodontal examinations of each subject were carried out at baseline (prior to the surgical procedure) and 6 months post-surgery. Clinical parameters included Plaque Index (PI),³¹⁾ Gingival Index (GI),³¹⁾ Probing Depth (PD), Clinical Attachment level (CAL), Gingival Recession (REC). For CAL and REC, the cemento-enamel junction (CEJ) was used as the reference point. All clinical measurements were made at six sites per tooth (mesio-facial, mid-facial, disto-facial, mesio-lingual, mid-lingual, and disto-lingual) using a pressure-sensitive probe (Hawe Click-Probe, Kerr Hawe, Bioggio, Switzerland) set to a probing force of 0.25 N. Measurements were rounded up to the nearest millimeter. All measurements were recorded by a calibrated examiner who was not aware of the surgical procedure to be performed. To ensure acceptable intraexaminer reliability, the examiner was calibrated to show >90% agreement within ± 1 mm by duplicate measurements of PD and CAL of 30 randomly selected teeth. Periodontal probing or recording of attachment levels should not be done prior to 6 months, since probing force may damage the healing site, thereby diminishing the regenerative outcome.

C. Surgical Procedure

At the time of the surgical procedure, subjects were randomly allocated to one of two experimental groups. All treatments were performed by the same surgeon.

Occlusal therapy consisting of adjustment or splinting of teeth should be accomplished prior to surgery to reduce or eliminate excessive mobility or fremitus patterns. The literature suggests that teeth with demonstrable mobility have a poorer long-term outlook after surgery.³³⁾

In all groups, defects were accessed using papilla preservation flaps. The simplified papilla preservation flap was used to gain access to the root surface and the marginal alveolar bone in areas where the interproximal space had a mesio-distal width ≤ 2 mm measured at the level of the interproximal soft

tissue.³⁴⁾ The modified papilla preservation technique³⁵⁾ was used in areas with a mesio-distal width of the interproximal space >2 mm. Flaps were extended horizontally (mesially and distally) to obtain complete access to the intrabony defect.

Alveolar bone was exposed about 3 mm beyond the defect's edge. Additional care should be taken to avoid either flap perforation or loss of the papilla due to granulomatous tissue from the lesion that adheres to the inner aspect of the flap.

The exposed root surfaces were scaled and planed with ultrasonic instruments and hand curettes. Following the defect debridement, a saturated solution of tetracycline may be applied to the root surface to biologically enhance regeneration through removal of the smear layer and residual colonies of bacteria, including possible exposure of collagen fibrils. Subsequently, the defects and adjacent mucoperiosteal flaps were rinsed thoroughly with sterile saline.

At this stage, the following intrasurgical measurements were performed: the distance from the CEJ to the bottom of the defect (CEJ-BD) and the distance from the CEJ to the most coronal extension of the interproximal bone crest (CEJ-BC). The intrabony component (INTRA) of the defects was defined as $(\text{CEJ-BD}) - (\text{CEJ-BC})$. Further, the defects were categorized as to the number of surrounding osseous walls.

Afterwards, random assignment to the respective treatment was performed. A sealed envelope, with a card indicating the surgical procedure to be applied, was opened by the surgeon immediately after debridement and defect measurements. In the BCP group, the BCP material was prepared according to the manufacturer's instructions and filled into the defects up to the level of the surrounding bony walls. In the OFD group, no filler was used.

A periosteal releasing incision was performed to ensure primary closure. Finally, the flaps were coronally advanced to obtain complete coverage of the defect. Care was taken to secure an adequate tension-free interproximal closure. Interdental closure was accomplished first with an interdental suture

positioned between the apical part of the buccal gingiva and an apical area of the lingual/palatal flap; in addition, a inverted vertical mattress suture was used (Fig. 1).

D. Radiographic evaluation

Pre- and postoperative standardized radiographs were taken for diagnostic purposes. Radiographs were obtained following the longcone parallel technique. Intrabony defect (IBD) was evaluated at baseline and after 6 months. The radiographic IBD depth (vertical distance from the crest of the alveolar bone to the base of the defect) was measured by means of the Infinit π -ViewStar calipers at Choson University Dental Hospital Radiology System, as seen in Fig. 2. This method had been introduced by Pradeep et al. previously.³²⁾

E. Medication and Maintenance

All subjects were instructed to rinse with 0.2% chlorhexidine gluconate mouthrinse twice a day until postoperative four weeks. No periodontal dressing was placed. Antiphlogistic medication (ibuprofen 400 mg, three times a day) was prescribed and used by subjects if necessary. No systemic antibiotics were prescribed. Sutures were removed 10 days after the surgery. Subjects were not allowed to brush or floss their teeth in the surgical area for 4 weeks. Within the first 2 months, oral hygiene control and professional supragingival tooth cleaning were conducted every 2 weeks. Thereafter, recall visits for postoperative hygiene were performed monthly. Postoperative visits include plaque removal (both mechanically and with topical chlorhexidine), selective stain removal and reinforcement of oral hygiene.

F. Statistical Analyses

For all treatment groups, primary values of continuous variables were recorded as the mean and standard deviation. In all calculations, the deepest site of the tooth was included. Comparison of age among the groups was done

using the independent t-test. For data of categoric variables (bone-wall characteristics), absolute and relative frequencies were calculated and compared among groups using the χ^2 test. Comparisons of all other variables (PI, GI, PD, CAL, REC) among the groups were performed using the Wilcoxon test. For differences of these parameters from baseline to 6 months in each treatment group, the Wilcoxon signed-rank test was used. And the radiographic IBD depths were performed using the same method. A P value of < 0.05 was considered significant. Data processing and all statistical analyses were performed using a statistical software package (SPSS ver. 12.0.0).

III . RESULTS

None of the patients enrolled in this study reported any unusual pain or discomfort, abscess formation, swelling, or allergic reactions during the course of treatment. Closure was achieved in all treated defects and maintained for the entire healing period. No radiographic signs of root resorption were observed at the final control.

No statistically significant differences were found among the two treatment groups for any of the subject characteristics at baseline. Also, there were no statistical differences between the locations of the defects: 15 defects were treated in the lower jaw, and 10 defects were treated in the upper jaw.

In two treatment groups the initial depth of the intrabony defects was similar. The distributions of wall-defect type (2- or 3-wall) were not significantly different between the two treatment groups (Table 1).

Hygiene indexes in two groups at baseline and 6 months are presented in Table 2. PI scores remained low from baseline throughout the study period. No statistically significant differences were found among the groups. And, 6 months after surgery, the GI scores is not a statistically significant result but somewhat improved result in all groups. All other comparisons of GI among groups did not show significant deviations.

All clinical parameter changes are summarized in Table 3. There were no significant differences in the initial PD, CAL, and REC measurements within the BCP and OFD groups. Compared to baseline data, all cohorts exhibited a significant reduction of PD values and CAL gain 6 months after surgery ($P < 0.007$). The groups treated with BCP produced a significantly higher gain of CAL than patients treated with OFD alone. Compared to OFD, the amount of additional CAL gain was 1.6 ± 0.4 mm in the BCP group ($P = 0.028$). Regarding changes of PDs compared to OFD, the BCP group yielded a significantly greater change of PD values (additional PD reduction: 1.2 ± 0.4 mm, $P = 0.048$). REC significantly increased in two groups 6 months after surgery. The change of REC values in the

BCP group (0.4 ± 0.5 mm) was lower than patients treated with OFD alone (1.2 ± 0.8 mm, $P = 0.023$).

Variations of clinical parameter based on wall defect have no statistical significant difference. Also variations of clinical parameter based on maxilla and mandible have no statistical significant difference (Table 4,5).

Variations of IBD score between BCP and OFD Group are summarized in Table 6. Initial IBD score has no significant difference. Compared to baseline data, decrement of IBD past 6 months after surgery has statistical significant difference in both group. Compared to OFD group, decrement of IBD is significantly larger in BCP group ($P = 0.045$).

IV. DISCUSSION

Bone replacement grafts are widely used to promote bone formation and periodontal regeneration. Conventional surgical approaches, such as open flap debridement, provide critical access to evaluate and detoxify root surfaces as well as establish improved periodontal form and architecture; however, these surgical techniques offer only limited potential in restoring or reconstituting component periodontal tissues.

Bone grafting materials function, in part, as structural scaffolds and matrices for attachment and proliferation of anchorage-dependent osteoblasts. A wide range of bone grafting materials, including bone grafts and bone graft substitutes, have been applied and evaluated clinically, including autografts, allografts, xenografts, and alloplasts. Although not all bone grafting materials support the formation of a new periodontal attachment apparatus, there is conclusive evidence that periodontal regeneration is achievable with bone replacement grafts in humans.⁹⁾

Among the graft materials, especially autogenous bone grafts have been considered to be the 'gold standard' among bone replacement grafts because they are osteoconductive and retain cell viability, including osteoblasts and osteoprogenitor stem cells, which facilitate osteogenesis.³⁶⁻³⁸⁾ The use of autografts in intrabony periodontal defects has been reported to result in an reduction of PD and increasement of CAL values compared to OFD alone.^{8,9)} Although there is no risk for cross-infection or immunogenic reaction with autogenous materials, their limited availability and the necessity of a donor site, and thus, often a second surgical site may limit their use.³⁶⁾ In addition, autogenous bone grafts also have the potential disadvantage of involving a higher degree of resorption of the graft material.

For these reasons, alloplastic materials are used. Alloplastic materials match the biologic function of autogenous bone grafts and have comparable clinical benefits without the need for a second surgical site. And the major advantage of

alloplasts over autogenous grafts is their easy availability. In addition, there is no risk for crossinfection.

The mixture of hydroxiapitite (HA) and beta-tricalcium phosphate (β -TCP) has been studied extensively as a new alloplastic material.³⁹⁾ Until now many kinds of biphasic calcium phosphate material have been produced. Among them, a new synthetic bone substitute, GENESIS-BCP™, was manufactured from DIO corporation (Busan, Korea). Until now, bone graft substitutes with biphasic calcium phosphate (BCP) composition have been simply made by a physical mixing. However, the GENESIS-BCP™ was made by a synthetic process. Other BCP materials mixed randomly and had properties independently owing to normally be composed to mixture form. GENESIS-BCP™, however, having the form of compound, whose molecule structure is regular. For this reason, its structure could be maintained even if existing early absorbable component.

It's particle size was 100~500 μ m. In prior study, David J et al. reported that particle size of 300~500 μ m seems to be preferred for use in periofintal defect.⁴⁰⁾

In contrast to most studies,^{12, 13, 41-46)} we tested the clinical effectiveness of a biphasic calcium phosphate graft in the treatment of intrabony defects in comparison to OFD.

To limit patient- and defect-based factors which might confound the outcome of periodontal surgery, the study was only conducted in non-smokers, in compliant patients with good oral hygiene, and with comparable subject and defect characteristics among cohorts (Table 1). Furthermore, during the study period, changes of PI did not differ among groups.

In this study, the depth of intrabony defects had to be ≥ 4 mm. Because the amount of bone fill, that evidently can be achieved by OFD alone, together with the crestal resorption and the residual defect total 3.5mm. Thus, to benefit from the extra cost and time related to adjunctive therapy such as bone graft and GTR, the depth of an intrabony defect should equal or exceed 4mm.⁴⁷⁾

In prior research, applying BCP, Gregory-George K reported that the combined use of autogenous bone with BCP led to significantly greater gain of clinical

attachment and hard tissue formation compared to the use of autogenous bone alone.⁴⁸⁾ In research applying novel biphasic calcium composite(BCC) grafting material comprised of a porous β -tricalcium phosphate and calcium sulfate phase at intrabony defects, clinical benefits of BCC has no difference from applying autogenous bone, but has shown improved result than OFD alone.⁴⁹⁾

The application of the BCP biomaterial provided significantly greater PD reductions and CAL gains than OFD alone. In the increment of recession, the treatment group with BCP was lower than the control group treated with OFD alone. The additional CAL gain in the BCP group compared to the OFD group was 1.6 ± 0.4 mm, which corresponds well with the findings of several studies^{42-44,46)} on alloplastic bonereplacement materials. It is also in accordance with the results of a meta-analysis, in which the additional CAL gain for alloplastic materials ranged from 1.0mm for bioactive glass to 1.4 mm for hydroxyapatites.⁸⁾ On the other hand, there are a few studies^{45,50,51)} that did not show a clinical benefit of synthetic graft materials compared to OFD. There might be several reasons for the discrepancies in the clinical outcomes. First, differences in defect characteristics and the surgical methods used might lead to different results. In the present study, papilla preservation techniques, which are known to improve primary closure and postoperative healing results in regenerative procedures, were applied in all treated sites. In the cited studies,^{45,50,51)} this approach has not been considered. Second, the overfilling of the defects with the biomaterial, as reported by Shirakata et al.⁵¹⁾ may impair primary wound closure and cause different results. Further, contrary to other studies,^{13,37,51)} the high frequency of maintenance and the level of plaque control in our study population, which are known to correlate with beneficial results in periodontal surgery,⁶⁾ may have additionally supported postoperative healing.

Ellegaard & L  e⁵²⁾ also reported finding greater defect resolution in sites characterized as three-wall defects as compared with two-wall or combination three-wall and two-wall defects. Schallhorn⁵³⁾ reported that the degree of bone fill was associated with the morphology of the intrabony defect (the number of remaining bony walls). In this study, the clinical results according to the

2-wall, 3-wall or mandible, maxilla did not show statistical significant difference. The sample size is insufficient to indicate statistical significance. But, it is considered that teeth did not developed because graft materials include unabsorbed HA, act as space remaining regardless of region.

In this study, the application of the BCP material was well tolerated and led to superior PD and CAL changes compared to OFD. Notwithstanding, it remains unclear to what extent the CAL gains obtained represent the regeneration of periodontal attachment.

Because histologic specimens were not obtained in this study, inferences about the quality of bone formation at any given time-point or the type of healing attachment gained cannot be made. Histologic examinations revealed that the attachment gain that occurs after debridement only is mainly due to the formation of a long junctional epithelium, rather than to the formation of new bone and attachment that is achieved with the other treatment modalities.⁵⁴⁾

Root conditioning may increase the amount of clinical attachment gain and enhance the possibility of true periodontal regeneration by demineralization of the outer layer of the cementum. S. Renvert et al. presented that an average gain of probing attachment level amounting to 2.0 mm was obtained following acid treatment as compared to 1.1-1.2 mm for the nonacid-treated controls. For exposing collagen fibers, tetracycline HCL is applied to root surface.⁵⁵⁾

In the standardized radiographs, 6 months after treatment with BCP, radiographic defect fill with bone-like radiopaque tissue, which was indistinguishable from native bone and, therefore, considered new bone, was observed. Nonetheless, the clinical findings of this study must be validated by reentry and/or by histologic analysis in future studies to examine the quality of the defect fill. Moreover, the results of the present study are only applicable to intrabony defects. For other types of defects, no results are available. Finally, it must be emphasized that sample size of this trial is limited. Further studies with a higher number of subjects and long-term observations should verify the findings presented here.

V . CONCLUSIONS

Within the limits of this randomized clinical trial, the application of a BCP grafting material for treatment of intrabony defects resulted in a significantly higher reduction of PD, clinical attachment gain and lower increment of gingival recession compared to OFD. The beneficial clinical results were indicating that the BCP material is a suitable bone replacement material for intrabony defects. In the future, higher number of subjects and long-term observations should verify the findings presented here. And further studies are necessary to evaluate the histologic nature of the newly formed tissue.

Table 1. Baseline subject and periodontal defect characteristics

| Variables | BCP(n=14) | OFD(n=11) | BCP Vs OFD |
|-----------|-----------------|-----------------|------------|
| | Mean(\pm SD) | Mean(\pm SD) | P-value |
| Age | 45.8(8.4) | 47.0(8.8) | 0.730 |
| PI | 0.6(0.5) | 0.7(0.5) | 1.000 |
| GI | 1.0(0.6) | 0.9(0.7) | 0.527 |
| PD | 7.8(2.0) | 7.5(1.7) | 0.959 |
| CAL | 8.9 (2.0) | 8.5(2.1) | 0.929 |
| REC | 1.1(0.9) | 0.9(0.9) | 0.726 |
| CEJ-BD | 9.0(2.8) | 8.8(1.8) | 0.964 |
| CEJ-BC | 4.4(1.5) | 4.1(1.4) | 0.321 |
| INTRA | 4.6(1.8) | 4.7(1.7) | 0.734 |
| 2-wall | 7(50%) | 6(54.5%) | 0.782 |
| 3-wall | 7(50%) | 5(45.5%) | 0.564 |
| Maxilla | 4(28.6%) | 6(54.5%) | 0.479 |
| Mandible | 10(71.4%) | 5(45.5%) | 0.368 |

Table 2. PI and GI scores at baseline and the 6-months after

| Variables | Baseline | 6 Months | Difference | P-value |
|-----------|----------|----------|------------|---------|
| PI | | | | |
| BCP | 0.6(0.5) | 0.8(0.6) | 0.2(0.8) | 0.480 |
| OFD | 0.7(0.5) | 0.6(0.5) | -0.1(0.7) | 0.655 |
| P-value | 1.000 | 1.000 | 1.000 | - |
| GI | | | | |
| BCP | 1.0(0.6) | 0.6(0.5) | -0.4(0.8) | 0.132 |
| OFD | 0.9(0.7) | 0.5(0.5) | -0.4(0.7) | 0.102 |
| P-value | 0.527 | 0.705 | 0.791 | - |

Table 3. Clinical parameters at baseline and the 6-months after

| Varilables | Baseline | 6 Months | Difference | P-value |
|------------|----------|----------|------------|---------|
| PD | | | | |
| BCP | 7.8(2.0) | 4.1(1.2) | -3.7(1.2) | 0.001 |
| OFD | 7.5(1.7) | 5.0(1.3) | -2.5(0.8) | 0.003 |
| P-value | 0.959 | 0.504 | 0.048 | - |
| CAL | | | | |
| BCP | 8.9(2.0) | 5.9(1.3) | -3.0(1.1) | 0.001 |
| OFD | 8.5(2.1) | 7.1(1.4) | -1.4(1.0) | 0.007 |
| P-value | 0.929 | 0.351 | 0.028 | - |
| REC | | | | |
| BCP | 1.1(0.9) | 1.5(1.1) | 0.4(0.5) | 0.002 |
| OFD | 0.9(0.9) | 2.1(1.0) | 1.2(0.8) | 0.006 |
| P-value | 0.726 | 0.230 | 0.023 | - |

Table 4. Changes in clinical parameters depending on wall defect

| Varilables | 2-wall | 3-wall | P-value |
|------------|-----------|-----------|---------|
| PD change | | | |
| BCP | -4.1(1.3) | -3.1(0.7) | 0.157 |
| OFD | -2.5(0.5) | -2.6(1.1) | 0.414 |
| P-value | 0.180 | 0.480 | |
| CAL change | | | |
| BCP | -3.6(1.1) | -2.6(1.0) | 0.157 |
| OFD | -1.2(0.8) | -1.8(1.3) | 1.000 |
| P-value | 0.180 | 0.461 | |
| REC change | | | |
| BCP | 0.6(0.5) | 0.1(0.4) | 0.157 |
| OFD | 1.5(0.5) | 0.8(0.8) | 0.157 |
| P-value | 0.317 | 0.180 | |

Table 5. Changes in clinical parameters between Mx. and Mn.

| Varilables | Mx. | Mn. | P-value |
|------------|-----------|-----------|---------|
| PD change | | | |
| BCP | -4.3(1.3) | -3.4(1.1) | 0.414 |
| OFD | -2.7(0.8) | -2.4(0.9) | 0.655 |
| P-value | 0.083 | 0.109 | |
| CAL change | | | |
| BCP | -3.8(1.0) | -2.8(1.1) | 0.655 |
| OFD | -1.5(1.0) | -1.4(1.1) | 0.655 |
| P-value | 0.180 | 0.197 | |
| REC change | | | |
| BCP | 0.5(0.6) | 0.3(0.5) | 0.157 |
| OFD | 1.2(0.8) | 1.2(0.8) | 0.655 |
| P-value | 0.655 | 0.257 | |

Table 6. IBD scores at baseline and the 6-months after

| Varilables | Baseline | 6 Months | Difference | P-value |
|------------|----------|-----------|------------|---------|
| IBD | | | | |
| BCP | 4.5(1.5) | 2.1(0.7) | 2.4(1.1) | 0.001 |
| OFD | 4.7(1.7) | 3.3(1.0)) | 1.4(0.9) | 0.003 |
| P-value | 0.646 | 0.037 | 0.045 | - |



Fig. 1. Treatment of an intrabony defect with BCP on the distal aspect of an lower left first molar. A) Preoperative clinical view. B) Intraoperative view of the debrided intrabony defect. C) Defect filled with the BCP biomaterial. D) Sutures immediately after flap closure. E) Clinical view of healing result after 6 months

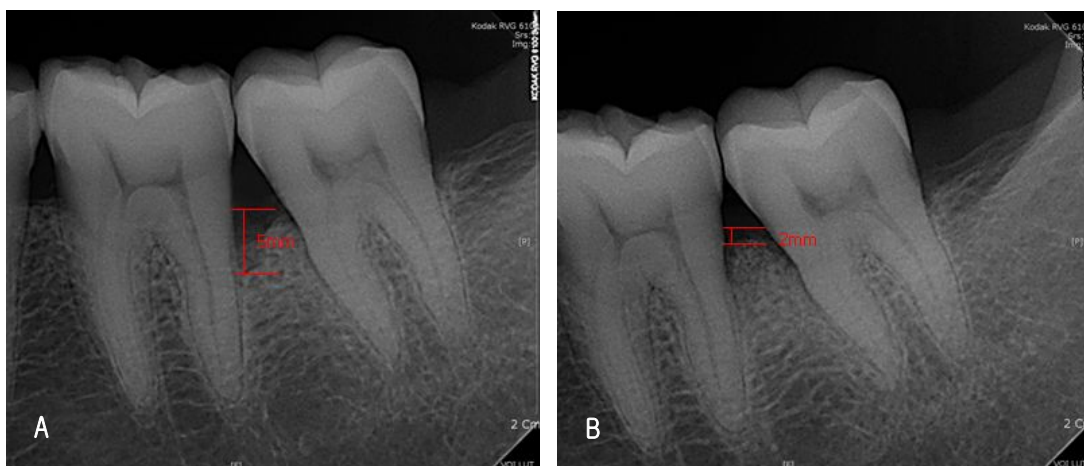


Fig. 2. Radiographic evaluation. A) Baseline radiograph showing IBD=5.0mm with linear measurement. B) Radiograph after 6 month showing IBD=2.0mm with linear measurement.

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