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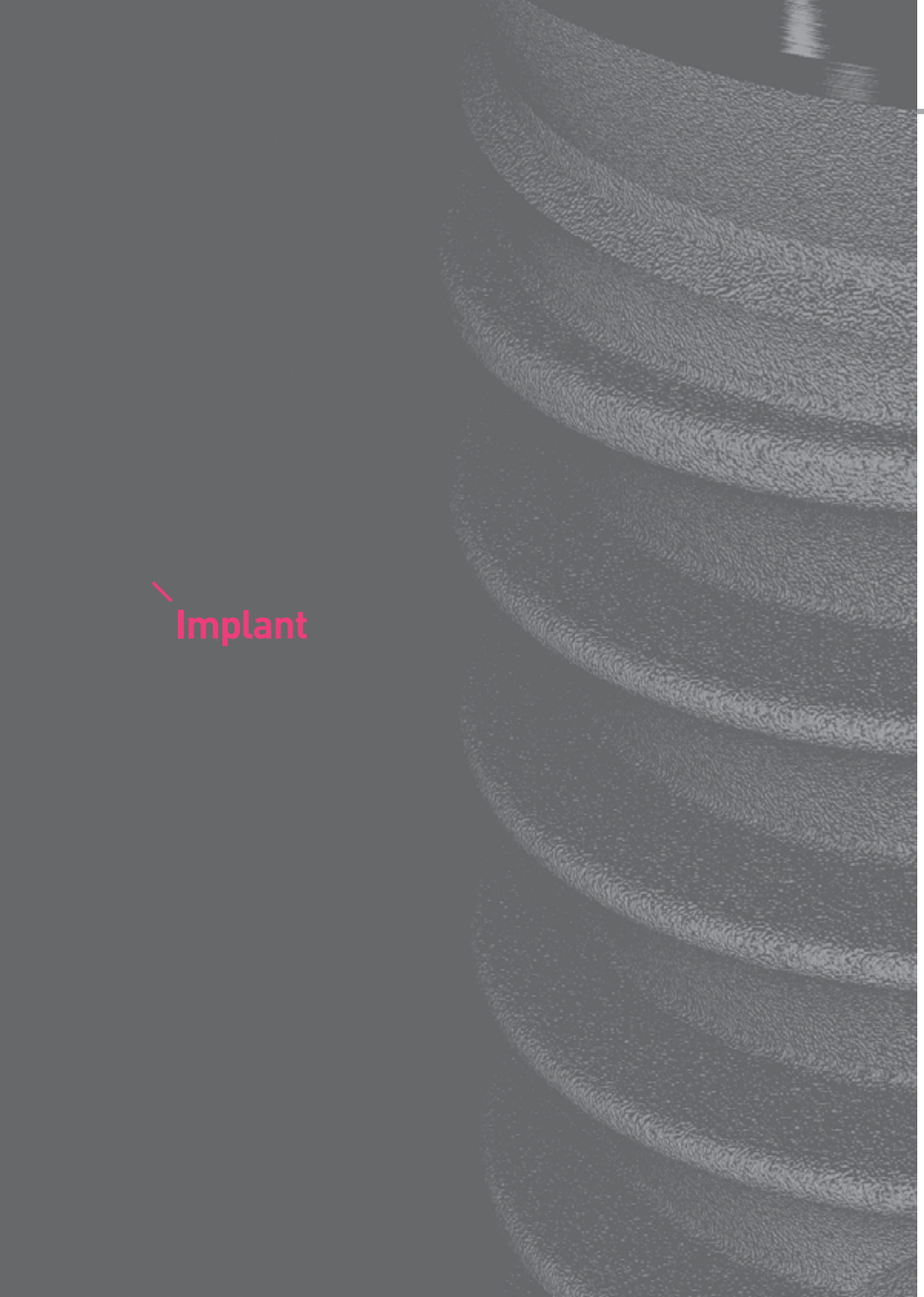

Implant

Results of immediate loading for implant restoration in partially edentulous patients: a 6-month preliminary prospective study using SinusQuick™ EB implant system

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ABSTRACT

STATEMENT OF PROBLEM. Many dental clinicians are concerned about immediate loading of inserted implants. However, there have been few clinical studies surveying the success rates of immediate loading, based on Korean implant systems. PURPOSE. The aim of this study was to evaluate the outcome of immediate functional loading of the implant (SinusQuick™ EB, Neobiotech Co., Seoul, Korea) in partially edentulous maxilla or mandible. MATERIAL AND METHODS. Total 15 implants were placed. Within 2 weeks after implant insertion, provisional implant-supported fixed partial dentures were delivered to the patients. Quantitatively, marginal bone loss was measured at the time of immediate loading, after 3-months of continued loading and at the last follow-up. The mean follow-up period was 4.8 months. RESULTS. Mean marginal bone loss from implant surgery to early loading, 3-months follow-up and last follow-up was 0.03 ± 0.07 mm, 0.16 ± 0.17 mm and 0.29 ± 0.19 mm. No implant failed up to 6 months after insertion, resulting in a 100% survival rate. CONCLUSION. Immediate loading exhibited high success rate in partial edentulism for up to 6 months. Well-controlled long term clinical studies with large sample size are necessary to confirm this finding.
KEY WORDS. Immediate loading, Partially edentulous, Dental implant, Prospective clinical study, Marginal bone loss

INTRODUCTION

Traditionally, implant treatment is based on a 2-stage protocol with a healing period of 3-6 months during which the implants are submerged to achieve osseointegration.[1] Recently, this clinical suggestion has been challenged. Numerous practitioners now advocate immediate or early loading of implants.[2] The advantages of immediately loaded implants are clear: they require shorter treatment periods and allow immediate recovery of function and esthetics.[3]

High success rate of immediately loaded implants in humans was first documented in the middle 1980s. The 88% cumulative success rate on 1739 immediately loading implants was suggested.[4] The clinical performance and prognosis of the singlestage surgical protocol are known to be comparable to the traditional 2-stage method.[5] There are some articles reporting a cumulative survival rate of 95%, which investigated immediately loaded single implants.[6,7] Results from these studies suggest that immediate loading could achieve equal success rates as those found in delayed loading.

It is also known as a common claim that treatment with immediate loading improved patient satisfaction and was cost effective although no scientific evidence was presented to support.[8] However, advantages of early or immediate loading as mentioned may be offset by an increased risk of implant failure. It was reported that immediately loaded implants were approximately 3 times more likely to fail within 1 year of placement.3 Furthermore, there have been few clinical studies investigating the success or failure rates of immediate loading based on Korean implant systems.

The aim of this preliminary prospective study was to evaluate the outcome of immediate functional loading in partial edentulism, using SinusQuick™ EB (Neobiotech Co., Seoul, Korea) implant system.

MATERIAL AND METHODS

Four subjects (2 smokers and 2 non-smokers) recruited from a population of patients under routine care at Seoul National Bundang Hospital were enrolled in the study. The patients were selected according to the following inclusion criteria: they were in normal general health with sufficient bone to allow the placement of implants at least 7 mm length. Patients with high masticatory or parafunctional forces were excluded. The mean age of the subjects was 50.3 years (range from 39 to 65 years), with a gender distribution of 100% men. Informed written consent was obtained from all subjects following approved institutional review board guidelines for clinical research.

Surgery was performed under local anesthesia (1 : 100,000 Epinephrine) or conscious intravenous sedation with 1% Propofol solution and Midazolam. After a crestal incision, a mucoperiosteal flap was elevated. Implants were inserted according to the procedures recommended by manufacturers. During the period from April to October 2009 (range from 2 to 6 months), 15 SinusQuick™ EB implants were installed in patients'jaws. Immediate loading was applied to the implants showing implant stability quotient (ISQ) and insertion torque values that were more than 60 and 35 Ncm, respectively. Immediate loading is defined as provisional or final implantsupported restoration delivered within 2 weeks.[9] Therefore, provisional implant-supported fixed partial dentures were delivered within 2 weeks (Fig. 1). The patients were instructed in soft diet and thorough oral hygiene care. The definite restoration was performed approximately 12 weeks after implant insertion.

Periapical radiographs were taken using commercially available film holders and a paralleling imaging technique during the investigating period. In each patient, peri-implant marginal bone level was evaluated by IMPAX® (Agfa Co., Mortsel, Belgium) system of periapical radiographs. Measurements were recorded at the time of surgery, immediate loading, after 3-months of continued loading, and at the last follow-up (Fig. 2). Marginal bone height was determined on these images by measuring the distance from a reference point, defined as the platform of the implant (Fig. 2), to the most coronal point of bone-to-implant contact on both the mesial and distal sides of the implant. A single value for marginal bone height was then calculated by obtaining the mean of these two measurements for each implant.

The definition of implant success was based on the following clinical and radiologic criteria: 1) absence of clinically detectable implant mobility, 2) absence of pain or any subjective sensation, 3) absence of recurrent peri-implant infection, and 4) absence of continuous radiolucency around the implant.[10]

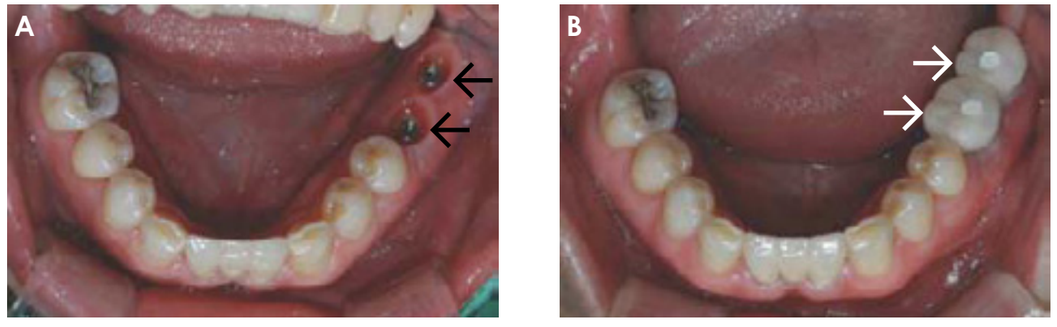

Fig. 1. (A) Two implants (SinusQuick™ EB, Neobiotech Co., Seoul, Korea) were inserted at #36 and #37 area (black arrows). (B) Provsional restoration (white arrows) was delivered 14 days after implant placement.

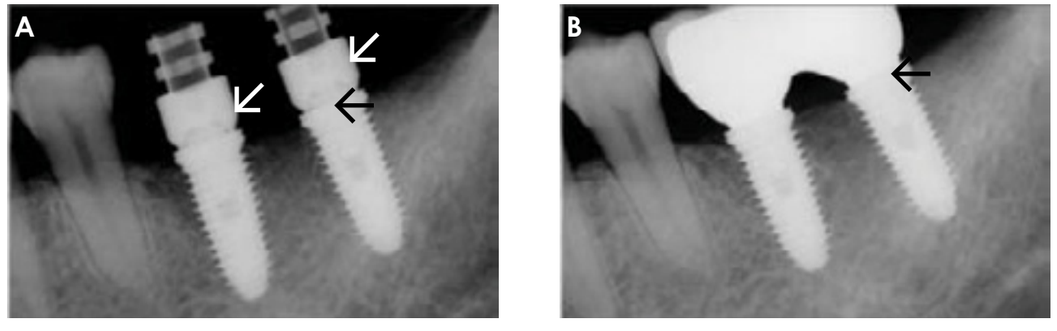

Fig. 2. Periapical radiograph was taken at the time of (A) immediate loading and (B) 3-months after continued loading. The platform (black arrows) was a reference point to measure marginal bone loss. Provsional resin restoration was made by polymethylmethacrylate that is radiolucent. Therefore, only temporary cylinders are seen (white arrows).

RESULTS

Total 15 implants were placed and were loaded immediately. Table I shows the details of distribution of inserted implants. Marked variability was noted in the implant sizes selected for placement, although implants 11.5 mm length and 5.0 mm diameter were most commonly used. The mean follow-up period was 4.8 months (range, 2 to 6 months). Mean marginal bone loss from implant surgery to immediate loading, 3-months followup and last follow-up was found to be 0.03 mm, 0.16 mm and 0.29 mm respectively (Table II). No implant failed up to 6 months after insertion, resulting in a 100% survival rate.

Table I. Distribution of implant dimensions

Diameter (mm)	Length (mm)					No. of Implants
	7	8.5	10.0	11.5	13	
3.5	0	0	1	3	0	4
4.0	1	0	0	0	0	1
5.0	3	1	0	2	4	10
No. of implants	4	1	1	5	4	15

Table II. Marginal bone loss at early loading, 3-months follow-up and last follow-up

Time	No. of implants	Marginal bone loss (Mean ± SD) (mm)
Early loading	15	0.03 ± 0.07
3-months follow-up	15	0.16 ± 0.17
Last follow-up	15	0.29 ± 0.19

DISCUSSION

All the inserted implants showed successful integration and stable peri-implant condition up to six months. Primary stability was reported to be the most important determining factor on immediate implant loading.[6] Micromovements of more than 100 µm were sufficient to jeopardize healing with direct bone-to-implant contact.[6] Szmukler-Moncler et al. indicated that micromotions at the bone-implant interface beyond 150 µm resulted in fibrous encapsulation instead of osseointegration.[11] If the primary implant stability could not be achieved or was questionable, it was strongly recommended to follow a conventional treatment protocol.[6] Most agreed that an insertion torque of at least 32 Nm and a resonance frequency analysis of at least 60 ISQ was required to achieve a high level of stability.[12] In this study, mean ISQ of 15 early loaded implants was 64.9 ± 4.9.

Generally, clinicians agreed that the quality of bone was significant for success in immediate loading. The initial stability of the implant reduces in the first 3-6 weeks after placement due to remodeling and an increased ratio of woven to lamellar bone.[12] Barewal et al. indicated that implants placed in areas of high bone quality are relatively stable over the early healing periods.[13] However, we reported that both maxillary and mandibular arches showed no failure of implants although the sample size was too small to analyze the data. Horiuchi etal. also reported about no difference in the success rate between arches in immediate loading.[14] Further studies are required about the relationship between bone quality and the success rate of immediate loading.

It has been established that there are no absolute contraindications to implant placement although a number of conditions exist, which are associated with an increased risk of failure.[12] Tobacco was reported to be only a risk factor for the implant failure.[3] However, the results of this investigation showed there was no implant failure in the participating patients who were smokers. Long-term studies about relevance of smoking to early loading are necessary.

There were some limitations associated with this study. The number of investigated implants was insufficient to analyze the data using proper statistics. The follow-up period was also short. Therefore, we could not assess the long-term outcome of immediate loading. Further controlled clinical studies are needed to evaluate the long-term success of early loaded implants.

CONCLUSION

Within the limitation of this clinical study the preliminary results indicate that immediate loading of the implants in partial edentulism, based on SinusQuick™ EB implant system, may be successful for short period up to six months. Well-controlled long term clinical studies with large sample size are necessary.

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임플란트의 collar design이 변연골과 연조직에 미치는 영향

대한치과보철학회지 2012년 50권 1호

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연구 목적 :

임플란트 경부가 잘 설계된 경우 양호한 연조직 반응을 통해 변연골을 보존하는데 도움이 된다. 본 실험에서는 연, 경조직 경계부에 가장 가까이 위치하는 임플란트의 collar design이 변연골 변화와 연조직 반응에 미치는 영향을 동물실험을 통해 알아보고자 하였다.

연구 재료 및 방법 :

2마리의 건강한 Beagle dog에 임플란트 collar design만 다른 두 종류의 임플란트(Neobiotech Co. Seoul, Korea)를 식립하였다. Collar에 bevel 을 부여한 군(Bevel 군)과 "S"자 형태를 부여한 군(Bioseal 군)으로 나누어 마리 당 7개, 군당 7개, 총 14개의 임플란트를 무작위로 식립한 후 Healing abutment를 즉시 체결하였다. 디지털 표준구내 방사선사진을 이용해 4주 간격으로 총 12주간 근원심 변연골 변화를 관찰하였고, 12주에 희생하여 조직학적 분석을 통해 협설 변연골 흡수 및 임플란트 주변 연조직 반응을 평가하였다. Mann-Whitney test를 통해 동일한 방사선 사진 촬영 시점에서 근원심 변연골 변화량 및 조직계측치를 군 간 비교하였고, Kruskal-Wallis test를 통해 방사선 사진상 근원심 변연골 변화량이 시간에 따른 차이가 있는지 군 내 분석 한 후 Duncan test를 통해 사후 검증하였다(α=.05).

결과 :

방사선학적 분석 결과 각 촬영 시점에서 두 군간 근원심 변연골 변화량의 차이를 보이지 않았다(P>.05). 군 내에서 시간에 따른 근원심 변연골의 흡수량을 분석한 결과 Bevel 군에서는 시간에 따른 차이를 보이지 않았으나 (P>.05), Bioseal 군에서는 시간에 따른 차이를 보였으며, 4주및8주와 비교했을 때 12주에서 변연골의 증가를 보였다(P<.05). 조직학적 분석 결과 협설측 변연골 흡수량에서 두 군간 차이를 보이지 않았으나 (P>.05), Bevel 군에 비해 Bioseal 군에서 더 견고한 결합조직부착을 관찰할 수 있었으며, 생물학적 폭경의 값은 두 집단 간 차이를 보이지 않은 반면에 (P>.05), 접합상피부착은 Bevel 군에서 유의하게 길었고, 결합조직부착은 Bioseal 군에서 더 길게 나타났다 (P<.05).

결론 :

Bevel 군에 비해 Bioseal 군에서 결합조직부착은 길게 형성된 반면에 접합상피부착은 더 짧게 나타났으며, 생물학적 폭경과 초기 변연골 흡수에는 차이가 없음을 알 수 있었다. 연조직 반응의 차이가 실제 기능하중 하에서 변연골 변화에 미치는 영향에 대해서 향후 연구가 필요할 것으로 생각된다. (대한치과보철학회지 2012;50:21-8)

주요단어 :

Collar design; 변연골흡수; 생물학적 폭경; 결합조직부착; 접합상피부착; Bioseal

Effects of implant collar design on marginal bone and soft tissue

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Purpose :

The purpose of this study was to investigate the effects of implant collar design on marginal bone change and soft tissue response by an animal test.

Materials and Methods :

Two types of Implant (Neobiotech Co. Seoul, Korea) that only differs in collar design were planted on two healthy Beagle dogs. The implants were divided into two groups, the first group with a beveled collar (Bevel Group) and the second group with "S" shaped collar (Bioseal group). Standardized intraoral radiographs were used to investigate the mesio-distal change of the marginal bone. Histological analysis was done to evaluate the bucco-lingual marginal bone resorption and the soft tissue response adjacent to the implant. Mann-Whitney test was done to compare the mesio-distal marginal bone change at equivalent time for taking the radiographs and the tissue measurements between the groups

Results :

Radiographic and histological analysis showed that there was no difference in marginal bone change between the two groups (P>.05). Histological analysis showed Bioseal group had more rigid connective tissue attachment than the Bevel group. There was no difference in biological width (P>.05). Bevel group showed significantly longer junctional epithelium attachment and Bioseal group showed longer connective tissue attachment (P<.05).

Conclusion :

For three months there were no differences in marginal bone change between the Bevel group and the Bioseal group. As for the soft tissue adjacent to the implant, Bioseal group showed longer connective tissue attachment while showing shorter junctional epithelium attachment. There were no differences in biologic width. (J Korean Acad Prosthodont 2012;50:21-8)

Key words :

Collar design; Marginal bone resorption; Biologic width; Cnnective tissue attachment; Junctional epithelium attachment; Bioseal

서론

치과용 골내 임플란트를 이용한 치료는 부분 또는 완전무치악 환자의 구강기능 회복을 위한 예지성 높은 치료방법으로 인정받고 있다.[1,2] 기능적이며 심미적으로 장기간 임플란트 치료의 성공을 위해서는 여러 가지 요소가 관여하는데,[3] 그 중에서도 특히 임플란트 변연골을 보존하고 주변 연조직을 건강하게 유지하는 것이 중요하다.[4]

초기 변연골 흡수의 원인으로 임플란트 수술 시 골막거상, 골삭제, 과도한 응력, 세균 침입 및 생물학적 폭경의 침범 등을 들 수 있다.[5] 수술 시 시행하는 골막거상은 혈액공급에 영향을 줄 수 있지만, 망상골이 풍부한 경우에는 피질골 흡수에 미치는 영향은 크지 않다.[5] 임플란트 식립 드릴링으로 인한 외상이 초기 변연골 상실의 원인이라고 주장하기도 하지만,[6] 2차 수술시 이전보다 골이 증가한 경우를 종종 확인할 수 있다.[5] 임플란트 주위골에 과하중이 전달될 경우 변연골 흡수가 야기되지만,[7,8] 비교적 약한 하중 또는 점진적인 하중은 오히려 골흡수를 막는다고 보고되고 있다.[9-12] 세균은 자연치에서는 주변골상실의 근본적인 원인이지만, 임플란트의 경우에서는 보조적인 인자에 국한되며 초기 변연골 흡수의 원인으로 보기는 어렵다.[13-15]

임플란트에서도 골유착을 보호하기 위한 최소한의 연조직 즉, 생물학적 폭경이 형성될 때까지 변연골 흡수가 일어난다고 밝혀진바 있으며,[16] 임플란트에서 생물학적 폭경이 주변조직에 미치는 영향에 대한 많은 연구가 있어 왔다.[16-20] 임플란트의 생물학적 폭경은 전체적으로는 안정적으로 존재하지만 시간의 경과에 따라 접합상피 부착은 증가하고 결합조직 부착은 감소하는 특징을 보인다.[19,20] 생물학적 폭경은 수직적 길이 외에도 수평적 공간을 포함하여 인접한 임플란트 사이 거리가 3mm 이하일 때는 생물학적 폭경을 확보하기 위해 골흡수가 발생한다고 보고된 바 있다.[21] 특히 변연골의 보존을 위해서는 생물학적 폭경을 이루는 구성요소 중 접합상피보다는 결합조직 부착이 더욱 중요하다.[22]

연조직과 경조직의 경계에 위치하는 임플란트 경부의 디자인은 연조직 반응과 변연골 보존에 영향을 미친다.[17,18,22] 플랫폼 스위칭은 식립된 임플란트의 플랫폼보다 작은 직경의 지대주를 연결하는 술식으로서,[23,24] 염증세포 침윤대를 내측으로 이동시킬 뿐만 아니라 변연골에 가해지는 응력을 감소시켜 변연골 흡수를 감소시킬 수 있는 장점이 있다.[25-27] 또한 임플란트 연조직 관통부위의 오목한 디자인이 결합조직의 두께 증가와 견고한 부착을 가능하게 하며,[22] 임플란트 경부의 표면 roughness나 microthread 설계가 변연골 흡수를 감소시킨다는 보고가 있다.[28,29] 근자에는 이러한 보고들을 근거로 임플란트 경부가 디자인된 제품들이 임상에 많이 사용되고 있다.[28-30]

하지만 임플란트 경부 디자인에 관한 기존 연구들은 비교한 임플란트의 제조사가 다르거나, 크기뿐만 아니라 경부 이외에 다른 부분의 디자인에서도 어느 정도 차이가 존재하기 때문에 경부 디자인만의 영향을 파악하는 데는 다소의 제한점이 있다.[17,22,28-31] 또한 임플란트 경부 디자인 측면에 대한 연구에서도[28,29] 연, 경조직 경계부에 가장 가까운 임플란트 collar design에 관한 연구는 미흡한 편이다.

이에 본 연구에서는 임플란트 제조사, 크기 및 전체적인 디자인이 동일하지만 collar 부위에 단순한 bevel 형태 또는 결합조직 부착길이의 증가를 위한"S"자 형태를 갖는 임플란트를 제작, 이용하여, 임플란트의 collar design이 변연골 변화와 연조직 반응에 미치는 영향을 동물실험을 통해 알아보고자 하였다.

연구 재료 및 방법

1. 연구 재료

실험용 임플란트(Neobiotech Co., Seoul, Korea)는 두 가지의 collar 디자인을 가지고 있으며, collar 부위에 bevel만을 가지고 있는 집단을 Bevel 군", S"자 형태를 가지고 있는 집단을 Bioseal 군으로 나누었다(Table 1). 나머지 부위는 internal cone 연결부를 가지는 tapered-screw 형태로 동일하고 두 군 모두에서 collar 부위는 machined 표면이나 나머지 부위는 resorbable blasting media (RBM) 표면처리(Ra = 1.2 – 1.5) 되었으며 자세한 수치 및 형태는 Fig. 1과 같다.

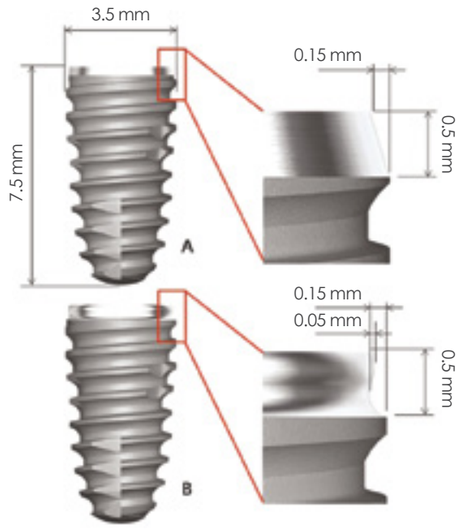

Figure 1. Design of implant fixtures used in this study: A, Bevel group; B, Bioseal group.

Table 1. Implant fixtures used in this study.

Group	N	Description	Length (mm)	Diameter (mm)
Bevel	7	bevel and machined surface	7.5	3.5
Bioseal	7	"S"-shaped and machined surface	7.5	3.5

2. 연구 방법

1) 실험 동물의 발치

본 연구에서는 2마리의 건강한 비글견(평균 2세, 평균 15 kg)이 사용되었으며, 전남대학교 수의과대학 동물실험 윤리위원회의 승인 하에 진행했다. 수술실은 소독상태를 유지하였으며 실험동물의 발치는 2% isoflurane (Isoflurane®, Choongwae Co. Seoul, Korea)과 oxygen으로 흡입진정마취 하에 시행했으며 Lactated Ringer's solution을 발치 종료 시까지 5 ml/kg/h 속도로 투여하였고 1:100,000 epinephrine이 포함된 2% lidocaine HCL (Yu-Han Co., Gunpo, Korea)을 이용하여 하악 편측에 1.8 ml씩 점막에 추가적인 국소침윤마취를 하였다. 양측의 하악 소구치 및 제 1 대구치를 발거한 후, 4-0 흡수성 봉합사(Vicryl®, Ethicon, Somerville, NJ, USA)로 봉합하였다.

2) 임플란트 식립(Fig. 2)

약 4주간 치유 후 발치와 동일한 방법으로 실험동물을 진정마취 후 국소마취 하였다. 무치악 치조정 절개로 협설측 전층 판막을 박리하고 치조정을 평탄하게 하여 임플란트를 식립하기 위한 골폭을 확보한 후, 3 mm 이상의 임플란트 사이 간격을 두어 마리 당 7개씩 무작위 배정 식립으로 총 14개의 임플란트를 식립하였다. 임플란트 수술용 엔진(NSK Surgic XT, NSK, Tochigi-ken, Japan)의 출력토크를 30 Ncm로 설정하였으며, 엔진으로 식립이 완료되지 않은 임플란트는 수동토크렌치(Neobiotech Co., Seoul, Korea)를 이용하여 collar-thread간의 경계부위가 치조정과 일치되도록 육안으로 확인하면서 식립하였다. Healing abutment (ISH404, Neobiotech Co., Seoul, Korea)를 즉시 체결하고 4-0 흡수성 봉합사(Vicryl®, Ethicon, Somerville, NJ, USA)로 봉합하였다.

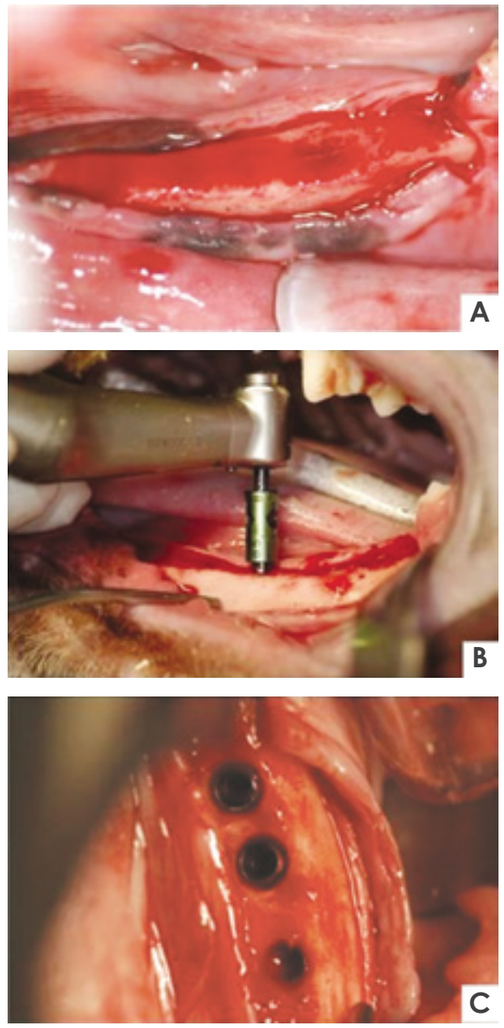

Figure 2. Surgical procedures. A: Flattening edentulous ridge, B: Drilling, C: After fixation.

3) 수술후관리

실험 동물의 발치 및 임플란트 식립 직후와 48시간 후 penicillin G procaine과 penicillin G benzathine (Dea-sung microbiological labs. co., Seoul, Korea)을 근육내 주사하였다(1 ml/5 kg). 술후1주간2% chlorhexidine을 10 cc 시린지에 넣어 하루에 2회 구강 내 소독을 하고 4주 간격으로 스케일링을 하였으며 유동식 사료를 공급하였다.

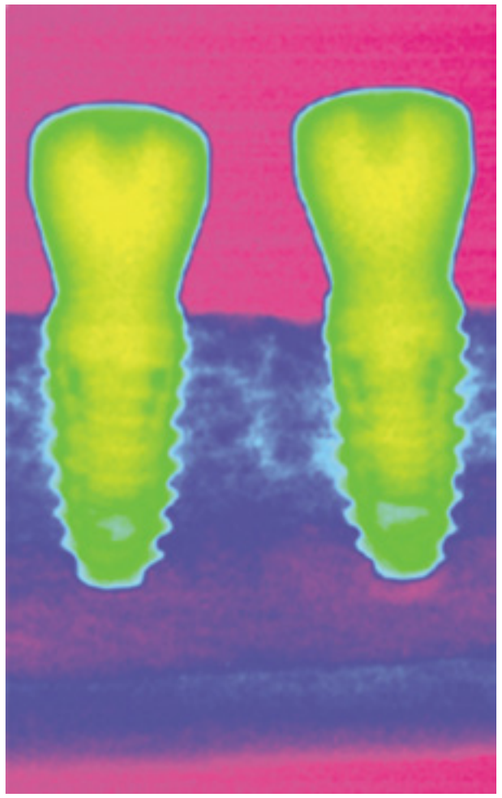

Figure 3. Gray scale color coding for radiographic analysis.

4) 방사선 계측

임플란트 식립 직후, 4주, 8주 그리고 12주에 진정마취하에서 portable X-ray (Port II, Genoray Co., Sungnam, Korea)를 이용해 평행 촬영법으로 총 4회 방사선 사진을 촬영하였다. Digital X-ray software (CDX-View, PointNix, Seoul, Korea)를 이용하여 gray scale image를 color coding 한 후(Fig. 3), 임플란트 장경과 변연골 수준 (임플란트 플랫폼에서 변연골 최상방까지의 거리)을 근원심측에서 각각 측정한 후, 실제 임플란트의 장경(7.5 mm)과 비교하여 다음과 같이 변연골 흡수량을 계산하였다.

$$\text{변연골 수준 (mm)} = \frac{\text{방사선 사진 상 변연골 수준 (mm)}}{\text{방사선 사진 상 임플란트 장경 (mm)}} \times 7.5\ (\text{mm})$$

변연골 흡수량 (mm) =
촬영 시 변연골 수준 (mm) − 수술시변연골수준(mm)

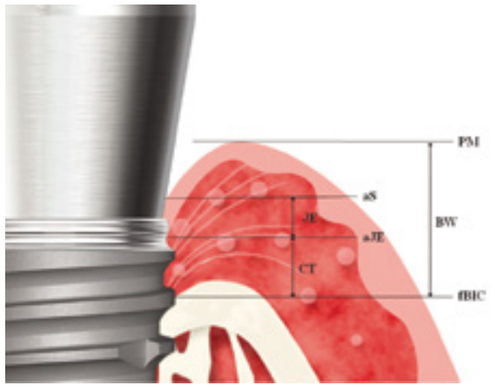

Figure 4. Histometric measurement. PM, marginal portion of mucosa; aS, apical extension of sulcus; aJE, apical portion of junctional epithelium, fBIC, first bone-implant contact; JE, length of junctional epithelium (aS/aJE); CT, length of connective tissue (aJE/fBIC); BW, biologic width (PM/fBIC).

5) 조직시편 제작 및 계측

임플란트 식립 후 12주에 pentobarbital sodium (Entobar, Hanlim Pharm., Seoul, Korea)을 과량 주사하여 희생시키고 하악골을 절단하여 블록을 채취하였다. 채취된 블록은 중성완충포르말린 (Sigma Aldrich, St. Louis, MO, USA)에 2주 동안 고정하고 알코올의 농도를 순차적으로 높여 탈수한 후 Technovit 7200 레진 (Heraeus KULZER, South bend, IN, USA)에 포매하였다. 포매된 시편은 임플란트의 중심부의 장축을 따라 EXAKT diamond cutter (KULZER EXAKT 300, EXAKT, Norderstedt, Germany)로협설방향으로 약 400 μm 두께로 절단한 후 EXAKT grinding machine (KULZER EXAKT 400CS, EXAKT, Norderstedt, Germany)으로 연마하여 30 μm 두께의 시편을 제작하였다. 시편은 hematoxylin & eosin 염색 후 CCD camera (Polaroid DMC2, Polaroid Co., MA, USA) 가 부착된 광학현미경(Olympus BX, Olympus Optical Co., Tokyo, Japan)으로 ×12.5, ×50의 디지털영상을 얻어 저장한 후 SPOT Software V4.0 (Diagnostic Instrument Inc., Sterling Heights, MI, USA) 을 이용하여 협설측에 다음과 같은 계측점을 선정하였다(Fig. 4).

PM: marginal portion of mucosa

aS: apical extension of sulcus

aJE: apical portion of junctional epithelium

fBIC: first bone-implant contact

계측점을 이용하여 다음을 구하였다(Fig. 4).

JE: length of junctional epithelium (aS−aJE, mm)

CT: length of connective tissue (aJE−fBIC, mm)

BW: biologic width (PM−fBIC, mm)

임플란트 collar-thread간의 경계부위에서 fBIC (first bone-implant contact)까지의 길이를 협설측에서 측정하여 변연골 흡수량을 구하였다.

6) 통계 분석

본 연구는 SPSS (Ver. 17.0, SPSS, Chicago, IL, USA)를 사용하여 통계 처리하였다. 실험 결과에 대한 정규성 검정을 실시한 결과 정규성을 만족하지 않아 비모수적 방법으로 분석하였다. Mann-Whitney test를 통해 동일한 방사선 사진 촬영 시점에서 근원심 변연골 변화량 및 조직계측치를 군 간 비교하였고, Kruskal-Wallis test를 통해 방사선 사진 상 근원심 변연골 변화량이 시간에 따른 차이가 있는지 군 내 분석 한 후 Duncan test를 통해 사후 검증하였다. 유의 수준5%에서 검정하였다.

결과

1. 임플란트 주위 변연골 변화

방사선 촬영을 통해 근원심 변연골 흡수량을 계산한 결과는 Table 2와 같으며, 각 촬영 시점에서 두 군간 차이를 보이지 않았다(P〉.05). 각군의대표적인방사선사진을Figs. 5, 6에나타내었다.

군 내에서 시간에 따른 근원심 변연골의 흡수량을 분석한 결과 Bevel 군에서는 시간에 따른 차이를 보이지 않았으나(P〉.05), Bioseal 군에서는 시간에 따른 차이를 보였으며, 4주및8주와 비교했을 때 12주에서 변연골 증가를 보였다(P〈.05) (Table 2).

조직학적 분석을 통해 희생 시의 협설측 변연골 흡수량을 비교한 결과를Table 3에 나타내었으며, 두 군간 차이를 보이지 않았다(P〉.05).

2. 임플란트 주위 연조직 반응

조직시편을 관찰한 결과 Bevel 군에 비해 Bioseal 군에서 더 견고한 결합조직부착을 관찰할 수 있었으며(Fig. 7), Bevel 군에서는 2개의 시편에서 연조직이 임플란트에서 탈락되었으나, Bioseal 군에서는 연조직 부착이 탈락된 시편은 없었다(Fig. 8).

Table 2. Mesiodistal marginal bone resorption in radiographic analysis

Group	Marginal bone resorption (mm)		
	Week 4	Week 8	Week 12
Bevel	0.26 ± 0.29^{aA}	0.34 ± 0.33^{aA}	0.14 ± 0.31^{aA}
Bioseal	0.45 ± 0.30^{aA}	0.36 ± 0.30^{aA}	0.07 ± 0.26^{aB}

Different lowercase letters in the same column indicate significant differences between Bevel and Bioseal at the same time using Mann-Whitney test (P<.05). Different uppercase letters in the same row indicate significant differences according to time using Kruskal-Wallis test and Duncan post-hoc test (P<.05).

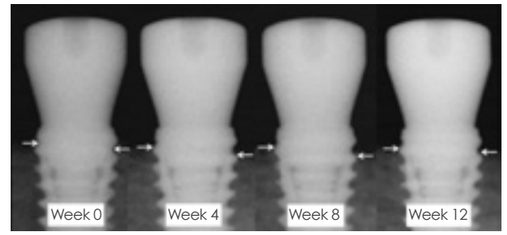

Figure 5. Radiographic analysis on Bevel group. The white arrows indicate mesiodistal marginal bone level.

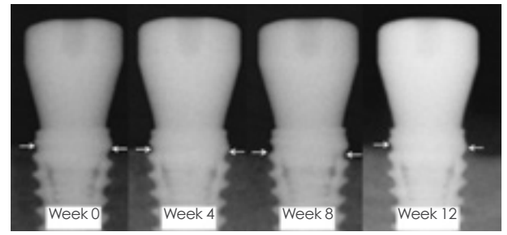

Figure 6. Radiographic analysis on Bioseal group. The white arrows indicate mesiodistal marginal bone level.

Table 3. Buccolingual marginal bone resorption in histometric analysis

Group	Marginal bone resorption (mm)	
	Buccal	Lingual
Bevel	0.91 ± 0.17	0.25 ± 0.23
Bioseal	0.77 ± 0.20	0.23 ± 0.16
P	0.132	0.937

Mann-Whitney test was used to assess differences between Bevel and Bioseal.

Table 4. Result of histometric analysis for soft tissue

Group	Histometric measurement (mm)		
	JE	CT	BW
Bevel	1.25 ± 0.19	1.09 ± 0.31	3.33 ± 0.34
Bioseal	0.84 ± 0.27	1.54 ± 0.20	2.83 ± 0.23
P	0.015	0.004	0.065

Mann-Whitney test was used to assess differences between Bevel and Bioseal. JE, length of junctional epithelium ; CT, length of connective tissue; BW, biologic width.

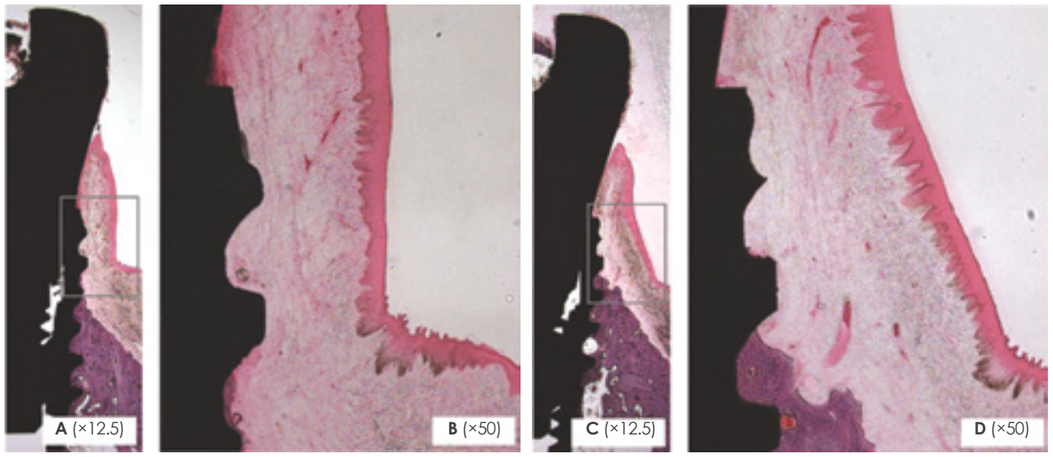

Figure 7. Histological analysis of two groups. A: Bevel group. Hematoxylin & eosin staining, B: Detail of (A), C: Bioseal group. Hematoxilin & eosin staining, D: Detail of (C). The connective tissue of Bioseal group was more firm and dense. In addition, Bioseal group had more connective volume.

조직계측학적 분석 결과를 Table 4에 나타내었다. 접합상피부착 (JE)과 결합조직부착(CT)에서 두 집단 간 통계적으로 차이를 보였으나(P<.05), 생물학적 폭경(BW)의 값은 두 집단간 차이를 보이지 않았다(P>.05). 접합상피부착은 Bevel 군에서 유의하게 길었고, 결합조직부착은 Bioseal 군에서 더 길게 나타났다.

고찰

본 연구에서는 임플란트 변연골의 변화 및 연조직 반응을 관찰하기 위하여 방사선학적 분석 및 조직학적 분석을 시행하였다. 본 연구에서 이용한 표준구내방사선사진의 경우 경조직 관찰은 용이한 반면 연조직은 관찰이 어려우며, 주기적인 촬영을 통해 시간에 따른 변연골 변화를 관찰하는데 용이한 장점을 가지지만 관찰 부위가 임플란트 근원심부위에 한정되어 실제 골흡수가 많은 협측피질골 부위를 평가할 수 없는 한계를 지니고 있다.32 이를 보완하기 위해 임플란트 식립 후 12주에 실험 동물을 희생시켜 협설방향으로 절단된 조직시편을 제작 한 후 광학현미경을 통해 협설측 변연골 및 주변 연조직을 관찰하여 계측, 분석하였다.

임플란트의 식립 깊이는 임플란트 collar에서 연조직 부착을 유도하기 위해 collar-thread 경계부위가 치조정과 일치되도록 하였다. 그러나 collar-thread 경계부위가 치조정에 일치되도록 식립하더라도 육안으로 확인하기 어려운 오차가 존재할 수 있으므로, 식립 직후 방사선사진을 촬영하여 변연골 수준을 구하였고, 4주마다 측정한 변연골 수준과 비교하여 골변화량을 계산하였다.

Figure 8. Soft tissue detachment observed in Bevel group only. In Bioseal group, all specimens had tight soft tissue attachment.

방사선학적 분석을 통해 각 촬영시점에서 두 군의 근원심변 연골 변화량을 비교한 결과 통계적으로 유의한 차이를 보이지 않았다. 조직계측학적 분석을 통해 협측과 설측의 변연골 흡수량을 비교한 결과 Bevel 군에서 변연골 흡수량이 다소 많았지만 두 군간 통계적으로 유의한 차이를 보이지 않았으며 이는 실험 동물을 희생시킨 시기에 해당하는 12주의 방사선학적 분석 결과와 상응한다. 근원심 변연골 변화량을 군내 분석한 결과 Bevel 군에서는 4주에서 변연골 흡수가 관찰된 이후 변연골 변화량이 시간에 따른 차이를 보이지 않은 반면에, Bioseal 군에서는 4주에서 변연골 흡수가 관찰된 이후 12주에 변연골이 회복되어 처음 식립시와 비교하였을 때 단지 0.07 mm 의 변연골 흡수를 보였다. 따라서 임플란트 collar의"S"자 형태가 변연골이 조기에 회복이 되는데 영향을 주는 것으로 보여진다. 다만 통계적으로 유의하지 않지만 4주의 변연골 흡수량이 Bevel 군에비해Bioseal 군에서 다소 많았으며 향후 그 원인에 대한 추가적인 연구가 필요하다고 생각된다.

각 군의 조직시편을 관찰하여 연조직을 비교한 결과 Bioseal 군에서 더욱 긴밀한 결합조직부착을 보였으며, 일부 Bevel 군시편에서는 접합상피 및 결합조직이 임플란트 표면에서 탈락되어 있었다. 조직시편 제작과정에서 연조직이 탈락할 수도 있지만, Bioseal 군에서는 탈락된 시편이 발견되지 않은 점을 고려하였을 때 Bioseal 군에서 좀 더 긴밀한 접합상피 및 결합조직부착을 보였다고 생각된다.

연조직에 대한 조직계측학적 분석 결과 Bioseal 군에서 결합 조직부착은 길게 형성된 반면에 접합상피부착은 짧았다. 비글견의 경우 임플란트에 부착하는 결합조직의 길이는 1 – 2 mm로 알려져 있는데,22 Bioseal 군에서는 약 1.5 mm의 결합조직부착을 보였고, 이는 1 mm의값을보인Bevel 군에 비해 길었다. 따라서 임플란트 collar에"S"자 형태를 부여하는 것이 더 긴 결합조직부착을 유도한다고 생각되며, 곡면의 입체적인 외형을 고려하였을 때 결합조직의 체적이 증가하는 효과도 함께 가진다고 여겨진다. 생물학적 폭경의 값은 Bevel 군에서 다소 길게 나타났으나 통계적 유의성은 보이지 않았으며, 이는 임플란트 디자인이 생물학적 폭경에 영향을 주지 않는다는 이전의 연구들과 같은 경향을 보인다.22,33 비록 통계학적으로 유의하지는 않지만 Bioseal 군에서 생물학적 폭경의 값이 약 0.5 mm 짧은 것은 임플란트 collar에"S"자 형태를 부여한 것이 플랫폼 스위칭 효과를 보이기 때문이라고 생각된다. 임플란트에서의 생물학적 폭경은 수직, 수평적인 공간을 모두 포함하는데,21"S"자 형태의 함요부가 0.15 mm 깊이로 환형으로 부여되어 있는 것을 고려한다면 약 0.3 mm 정도의 플랫폼 스위칭 효과를 보인다고 볼 수 있어 이를 고려할 경우 두 군 사이의 생물학적 폭경의 값의 차이는 더욱 줄어든다.

Bioseal 군에서 접합상피부착이 Bevel 군에 비해 짧은 것은 수술후 tissue remodeling 과정 동안 결합조직이 조기에 안정화 되어 상피조직의 하방이동을 막았기 때문이라고 생각된다. 상피조직이 하방으로 이동할 경우 변연골 흡수를 일으킬 가능성이 커지므로 이를 막는 것은 변연골 보존에 중요하다.18,34 방사선학적 분석 결과 Bioseal 군에서 4주 까지 초기 변연골 흡수를 보인 후 지속적으로 변연골이 회복된다는 점을 비추어 보았을 때 결합조직의 조기 안정과 견고한 부착이 접합상피의 하방이동과 변연골 흡수를 막는다고 미루어 볼 수 있다.

이번 연구를 통해 임플란트 collar에"S"자 형태를 부여하는 것이 bevel 만 부여한 것에 비해 양호한 연조직 반응을 보였음을 알 수 있었다. 반면 실제 골흡수 양상에서는 차이를 보이지 않았으므로 연조직 반응의 차이가 실제 변연골 변화에 있어 차이를 보이는지 알아보기에는 다소 한계가 있었다. 임플란트의 collar design에 따른 연조직 반응의 차이가 실제 기능하중 하에서 변연골 변화에 미치는 영향에 대해서 향후 연구가 필요할 것으로 생각된다.

결론

본 연구를 통하여 Bevel 군에 비해 Bioseal 군에서 결합조직부착은 길게 형성된 반면에 접합상피부착은 더 짧게 나타났으며, 생물학적 폭경과 초기 변연골 흡수에는 차이가 없음을 알 수 있었다.

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Differences in implant stability associated with various methods of preparation of the implant bed: An in vitro study

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Abstract

Statement of problem. It is difficult to achieve the primary stability necessary for immediate loading in the posterior maxilla because of thin cortical bone, low density trabecular bone, and inadequate bone height due to the presence of the maxillary sinus.

Material and methods.

Sixty screw-shaped implants (4.0 × 10 mm) were inserted into solid rigid polyurethane blocks. The implants were divided into 6 groups (n=10) to test 2 variables: 1) location (monocortical or bicortical block) and 2) preparation method (standard preparation, underpreparation, or the osteotome technique). The insertion and removal torques were measured and resonance frequency analysis (RFA) was performed to determine the primary stability of each implant. Insertion and removal torque data were analyzed by 2-way ANOVA, followed by the post hoc Tukey HSD multiple comparison test. RFA data were analyzed by 2-way and 1-way ANOVAs and the Tukey HSD multiple comparison test (α=.05). The Pearson correlation analysis was also performed to examine correlations among the values.

Results.

The preparation method had a significant effect on insertion torque, RFA value, and removal torque; however location had a significant effect only on the removal torque (P<.001). There was a significant interaction between location and preparation method for RFA values (P=.045) and a significant difference in standard preparation method according to the location (P=.039); however, there was no significant difference in underpreparation (P=1.00) and osteotome technique (P=1.00). Statistically significant correlations were found between insertion torque and RFA values (r=0.529, P< .001), insertion torque and removal torque values (r=0.517, P< .001), and removal torque and RFA values (r=0.481, P<.001).

Conclusions.

Underpreparation and bicortical fixation significantly increased implant stability and the osteotome technique decreased implant stability in synthetic bone models that mimicked the posterior maxillary region. The primary stability values had statistically significant correlations to each other. (J Prosthet Dent 2012;107:366-372)

Clinical Implications

Based on the results of this in vitro study, standard preparation and the bicortical fixation method produce greater primary stability than the various other surgical methods evaluated.

Several critical factors are necessary for successful osseointegration of dental implants, including the primary stability and surface characteristics of the implant, anatomical conditions, bone metabolism, design of the interim prosthesis, and the occlusion pattern during the healing phase.[1] The primary stability of the implant, which results from the initial interlocking between alveolar bone and the body of the implant, affects the secondary stability of the implant because the latter results from subsequent contact osteogenesis and bone remodeling.[2,3] As a consequence, a high degree of primary implant stability is a key prerequisite for immediate or early loading.[4,5] The primary determinants of the primary stability of an implant are the surgical technique used, the design of the implant, and the mechanical properties of the bone tissue.[6]

The posterior region of the maxilla is characterized by thin cortical bone and trabecular bone of low density. In addition, in many instances the height of the bone in this region is insufficient to achieve high primary stability because of the presence of the maxillary sinus. Therefore, dental implants in this region show the highest rate of failure, and surgical techniques have been proposed to increase their primary stability.[7-10] The most widely used methods include preparation of the site with tools one size smaller than the diameter of the implant,[11] bone condensation using an osteotome,[12-14] and the use of bicortical fixation.[15] Among these methods, the osteotome technique was introduced to increase the primary stability and success rate of implants in areas of poor bone density, such as the posterior maxillary region.[16] Theoretically, the osteotome condenses the bone to increase primary stability by lateral osseocompression. However, according to Blanco et al,[17] who studied the placement of implants using the osteotome in the maxillary tuberosities of human cadavers and performed histomorphometric assessment around the implants, the increase in bone density is actually limited to the periapical area of the entire periimplant area, and in the pericylinder area there was no increase in bone density with the osteotome technique. In addition, many studies have suggested that the use of the osteotome decreases or does not affect primary stability.[18-20] According to Nkenke et

al,[21] use of the osteotome to condense the bone results in longitudinal cracks and gaps in the region of the bone collar, increasing the rate of implant failure. To date there is insufficient scientific and clinical evidence to support immediate loading in the posterior maxillary region.[22]

Several methods can be used to measure primary implant stability; these include biomechanical tests, which are represented by measurement of the insertion and removal torque and nondestructive measurements such as resonance frequency analysis (RFA). Biomechanical testing, such as measurement of the insertion and removal torque, is more accurate than nondestructive measurements such as RFA and the Periotest.[23] However since biomechanical testing is destructive and can be applied only once, its clinical utility is limited. Therefore, nondestructive measurements such as RFA are commonly used in clinical practice.[24] The use of RFA and the Periotest is also limited because of the low resolution and high variability of these instruments during examination.[25] Currently, there is no gold standard for the accurate measurement of implant stability, and studies have cast doubt upon the correlation between the values of insertion and removal torques and RFA.[21,26-29]

This study had 2 objectives: to compare the primary implant stability associated with different preparation methods in both monocortical and bicortical models of the posterior maxilla and to examine the correlation between biomechanical testing (insertion and removal torque) and RFA. The null hypotheses were that location (monocortical block or bicortical block) and preparation method (standard preparation, underpreparation, or osteotome technique) would not affect the primary stability of implants and that there would be no correlation between the values of insertion and removal torques and RFA.

MATERIAL AND METHODS

Polyurethane specimens

Solid rigid polyurethane blocks (Sawbones; Pacific Research Laboratories Inc, Vashon, Washington) were used to simulate monocortical and bicortical conditions in the posterior maxillary region (Fig. 1). To model cancellous bone, a density of 0.32 g/cm^3 was selected because the mean bone mineral density of the cancellous bone in the posterior maxillary region is 0.31 g/cm^3.[30] To mimic the cortical layer, epoxy sheets (Sawbones; Pacific Research Laboratories Inc) filled with short fibers were used to laminate the material that represented the cancellous bone. Given that the mean thickness of cortical bone in the maxillary region is 1.49 ±0.34 mm[31] and the maxillary sinus inferior border thickness is 0.86 ±0.21 mm,[32] a thickness of 1 mm was selected for the cortical layer in the model. For the monocortical block, one side of a 15 mm section that represented cancellous bone was laminated with 1 mm of cortex (to produce a bone block that was 16 mm thick in total). For the bicortical block, both sides of a 6 mm section that represented cancellous bone were laminated to provide a bone block that was 8 mm thick.

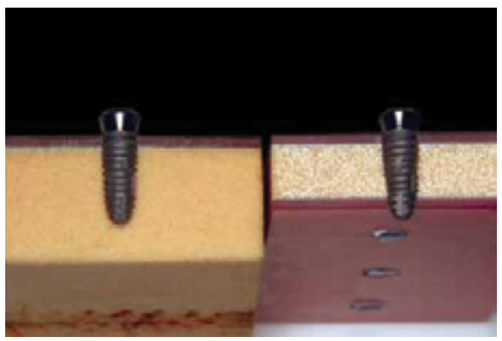

Figure 1. Polyurethane synthetic bone blocks and implant specimens. Left: bone blocks with monocortical layer. Right: bone blocks with bicortical layer.

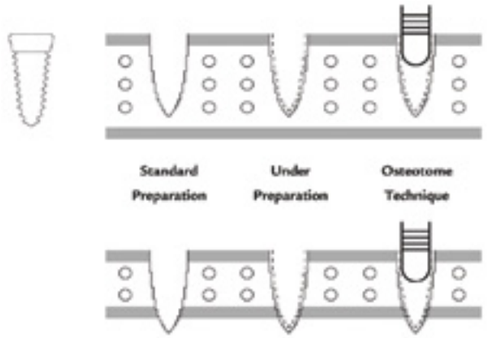

Figure 2. Schematic representation of different preparation methods for monocortical and bicortical blocks.

Implants

Sixty screw-shaped implants (SinusQuick; Neobiotech Co Ltd, Seoul, Korea) were used. All implants measured 4.0 mm in diameter and 10 mm in length. These implants were tapered, screwshaped implants of the self-tapping type. Their surfaces were treated with resorbable blast media (RBM), whose stability has been demonstrated.[33-35]

Preparation of the implant bed

Implant sites were prepared on the polyurethane blocks with a handpiece (INTRAsurg 300; KaVo Dental, Biberach, Germany). The procedure was performed at 1200 rpm with external cooling. The implants were divided into 6 groups with a combination of location and preparation method. Different surgical protocols were used for each of the 6 groups: the SM group (Standard preparation + Monocortical fixation); UM group (Underpreparation + Monocortical fixation); OM group (Osteotome technique + Monocortical fixation); SB group (Standard preparation + Bicortical fixation); UB group (Underpreparation + Bicortical fixation); and OB group (Osteotome technique + Bicortical fixation) (Fig. 2). Each group consisted of 10 implants, for a total of 60 implants.

For the SM, UM and OM groups, the implants were inserted into monocortical blocks. For the SM group, the procedure began with a round bur (Neobiotech Co Ltd), followed by a 2 mm-diameter twist drill; then, 2.8 mm, 3.2 mm, and 3.4 mm-diameter drills were used in accordance with the manufacturer's instructions (Neobiotech Co Ltd). The implants were then placed in the block. For the UM group, the 3.4 mm-diameter drill was not used before the implants were inserted. In the OM group, a round bur and the 2 mm-diameter twist drill were used, and the area was expanded by using 2.2 mm, 2.8 mm, and 3.5 mm-diameter osteotomes (Straumann AG, Basel, Switzerland) before placement of the implants in the block. For the SB, UB, and OB groups the implants were inserted in bicortical blocks with the same surgical protocols as those described for the SM, UM, and OM groups.

Measurement of insertion torque

When all implant specimens had been inserted, peak insertion torques were measured with a digital torque gauge instrument (MG series; Mark-10 Corporation, New York, NY) with a measuring range of 0 to 135 Ncm.

Resonance Frequency Analysis

RFA was performed by using the latest version of the Osstell Mentor (Osstell AB, Göteborg, Sweden). This device uses a wireless measurement with a magnetic post (Smartpeg; Osstell AB) connected to the implant. The manufacturer states that vibration of the magnetic post, which is excited by magnetic pulses from a handheld computer, generates resonance fre-

quencies, and the resulting RF value, in hertz, is converted automatically into implant stability quotient (ISQ). Values range from 1 to 100, and a high value indicates high implant stability.

Measurement of removal torque

The bone block was placed in a locking vice and fixed to transmit the removal torque longitudinally. The torque was increased gradually (displacement; 0.5 mm/min), and the point at which the specimen became unfastened was recorded. The removal torque was measured with the same torque gauge instrument (MG series; MARK-IO Corporation) that was used to measure the insertion torque.

Insertion and removal torque data were analyzed by 2-way analysis of variance (ANOVA) with location and preparation method, followed by multiple comparisons using the Tukey Honestly Significant Difference (HSD) multiple comparison test. RFA data were analyzed by 2-way ANOVA to examine the effect of location and preparation method and the 1-way ANOVA, followed by the post hoc Tukey HSD multiple comparison test to evaluate differences among the testing groups. The Pearson correlation analysis was also performed to examine correlations between insertion torque, RFA value, and removal torque. An alpha value of .05 was used for statistical analysis. All calculations were performed with statistical software (SAS version 9.1 for Windows; SAS Institute Inc, Cary, NC). Data are presented as mean (SD).

RESULTS

The mean insertion torques (SD) of each group are presented in Table I. Among the preparation methods, underpreparation had significantly higher mean (SD) insertion torque values (monocortical block, 104.57 (18.16): bicortical block, 104.62 (18.58)) than the other methods evaluated (P<.05). The osteotome technique had the lowest mean (SD) values (monocortical block, 58.92 (9.53); bicortical block, 60.58 (15.49)). Two-way ANOVA revealed that the preparation method had a significant effect on the insertion torque (Table II) (P<.001). However, there was no significant effect for the location (P=.361). The interaction between preparation method and location was not significantly different (P=.277). The Tukey HSD multiple comparison test showed significant differences among standard preparation, underpreparation, and osteotome techniques (P<.05).

The mean RFA values (SD) of each group are presented in Table III. Among the preparation methods, the under-preparation method had significantly higher mean (SD) RFA values in the monocortical block (66.50 (2.59) and the standard preparation method had significantly higher RFA values in the bicortical block (68.40 (5.87)) than other methods evaluated (P<.05). Similar to the insertion torque values, the osteotome technique had the lowest mean (SD) RFA values (monocortical block 58.90 (3.63), bicortical block 58.80 (4.08)) (Table III). Based on the 2-way ANOVA, the preparation method had a significant effect on the RFA values (Table IV) (P<.001); however, there was no significant effect on the location (P=.103). The Tukey HSD multiple comparison test showed there were significant differences among standard preparation, underpreparation, and the osteotome technique (P<.05). There was significant interaction between the location and preparation methods for the RFA values (P=.045). Therefore, based on the preparation method and location, modified 1-way ANOVA analysis and the Tukey HSD multiple comparison test were conducted. These revealed that there was a significant difference in standard preparation according to the location (P=.039), but there was no significant difference in underpreparation (P=1.00) and osteotome technique (P=1.00).

The mean removal torque values (SD) of each group are presented in Table V. Two-way ANOVA revealed that location and preparation method had a significant effect on the removal torque (Table VI) (P<.001). There was no significant interaction between preparation method and location on removal torque (P=.641). Among the preparation methods, there was no significant difference between standard preparation and underpreparation (P=.897); however, there was a significant difference between standard preparation and osteotome technique and between underpreparation and osteotome technique (P<.05). As for the difference of the location, bicortical fixation method had significantly higher removal torque values than the monocortical fixation method (P<.05) (Table V).

Statistically significant correlations were found between insertion torque and RFA values (r=0.529, P<.001), insertion torque and removal torque values (r=0.517, P<.001) and removal torque and RFA values (r=0.481, P<.001).

Table I. Mean values (SD) of insertion torque (Ncm)

	Standard Preparation	Under Preparation	Osteotome Technique
Monocortical fixation	89.45 (10.03)[a]	104.57 (18.16)[b]	58.92 (9.53)[c]
Bicortical fixation	76.98 (15.84)[a]	104.62 (18.58)[b]	60.58 (15.49)[c]

Different lower case letters in same column indicate significant differences (P<.05)

Table II. Two-way ANOVA for insertion torque

Source	Sum of Squares	df	Mean Squares	F	P
Corrected model	20917	5	4183	18.41	001
Location (A)	193	1	193	0.85	.3601
Preparation method (B)	20125	2	10063	44.28	<.001
A × B	598	2	299	1.32	.277
Error	12271	54	227		

Table III. Mean values (SD) of RFA values (ISQ)

	Standard Preparation	Under Preparation	Osteotome Technique
Monocortical fixation	63.30 (2.5)[a]	66.50 (2.59)[b]	58.90 (3.63)[d]
Bicortical fixation	68.40 (5.87)[c]	66.30 (2.54)[b]	58.8 (4.08)[d]

Different lower case letters in same column indicate significant differences (P<.05)

Table IV. Two-way ANOVA for RFA values

Source	Sum of Squares	df	Mean Squares	F	P
Corrected model	839	5	168	12.02	<.001
Location (A)	38	1	38	25.39	.103
Preparation method (B)	709	2	354	2.75	<.001
A × B	92	2	46	3.29	.045
Error	754	54	14		

Table V. Mean values (SD) of removal torque (Ncm)

	Standard Preparation	Under Preparation	Osteotome Technique
Monocortical fixation	40.53 (12.17)[aa]	38.32 (7.60)[aa]	17.02 (7.48)[ba]
Bicortical fixation	54.64 (12.04)[ab]	53.28 (11.86)[ab]	26.23 (9.88)[bb]

Different lower case letters in same column indicate significant differences (P<.05)

Table VI. Two-way ANOVA for removal torque

Source	Sum of Squares	df	Mean Squares	F	P
Corrected model	10949	5	2190	20.37	<.001
Location (A)	2442	1	2442	22.72	<.001
Preparation method (B)	8410	2	4205	39.13	<.001
A × B	96	2	48	0.45	.641
Error	5804	54	107		

DISCUSSION

This study demonstrated that 2 variables affect the primary stability of implants: location (monocortical block or bicortical block) and preparation method (standard preparation, and underpreparation or the osteotome technique). The correlation between biomechanical testing (insertion and removal torque) and RFA were also evaluated. The results lead to a rejection of the first null hypothesis that location and preparation method do not affect the primary stability of implants; the second hypothesis that there was no correlation between the values of insertion and removal torque and RFA was also rejected.

Primary stability is the result of mechanical engagement with the surrounding bone tissue and can be distinguished from secondary or biological stability by the presence of bone regeneration and remodeling in the latter. In addition, primary stability, rather than secondary stability, is a critical factor when immediate loading is considered because it develops within 1 week of implantation. For immediate loading, single implants must be inserted with a torque greater than or equal to 30 Ncm, and splinted implants with a torque greater than or equal to 20 Ncm.[5] In the present study, the insertion torque exceeded 30 Ncm in all groups. These values are higher than those reported by Nkenke et al,[26] who measured insertion torque in the posterior maxillary region of human cadavers. These findings suggest that measured insertion torque in polyurethane specimens is higher than that in the posterior maxillary region in humans, even though the mean density was similar. In addition, for all the groups in this study, the mean values of removal torque were lower than the mean values of insertion torque. This can be explained by the restricted viscoelastic properties of the surrounding artificial bone, resulting in less resistance during removal. These findings are in agreement with other recently published data using polyurethane foam blocks in which removal torques were lower than insertion torques;[36] similar observations have been made in animal studies.[37,38]

The preparation method had a significant effect on insertion torque, RFA values, and removal torque. The underpreparation method had a significant effect on insertion torque compared to standard preparation and the osteotome technique in either monocortical or bicortical blocks. However, the standard preparation method had a more significant effect on RFA values than the underpreparation method in bicortical blocks, and for removal torque values, there was no difference between the standard preparation and underpreparation method. These findings are somewhat different from those of another recent study on the influence of surgical technique and surface roughness on the primary stability of implants in artificial bone with a density equivalent to maxillary bone.[23] The authors found that both the insertion and removal torque values obtained with the undersized technique were higher than with the press-fit technique. Perhaps these differences were due to the presence of the cortical portion of the synthetic bone models of the present study. Tabassum et al,[36] showed that for implant sites with a cortical thickness of 2 mm or more, undersized drilling had no significant effect on insertion and removal torque. Over tightening of the implant may result in micro fractures of the cortical parts around the implants. The osteotome technique had significantly low values for insertion torque, RFA, and removal torque, which demonstrates that the use of the osteotome decreases implant stability in polyurethane blocks.

In addition, the outcomes of the present study also revealed that the use of a bicortical block significantly increased removal torque when compared with the use of a monocortical block. However there were no significant effects of the bicortical block on insertion torque or RFA values. The insertion torque and RFA values were affected by the preparation method and RFA values interacted significantly between preparation method and location. Among the preparation methods, the standard preparation caused a significant difference between bicortical and monocortical blocks, which means that with bicortical blocks, the standard preparation method is more effective in increasing RFA values than with monocortical blocks.

Primary stability can be measured during the placement of an implant by means of various parameters such as insertion and removal torque or by using RFA or the Periotest. Although individual parameters have been investigated, few studies of the correlations between parameters have been done. In this study, statistically significant correlations were found between insertion torque, RFA value, and removal torque, even though the correlation coefficient value was lower than another study with a smaller number of specimens.[29] Nevertheless, a similar study with a larger number of specimens showed low coefficient values with statistically significant differences.[39] In the present study, insertion torque, RFA value. and removal torque were correlated but only with a poor linear relationship for strength.

A limitation of the present study is that only the mechanical characteristics of the primary stability of an implant were considered. Furthermore, the model only simulated the oral environment, which is more complex. In vivo studies are required to understand the actual clinical situation in which many biological factors influence the primary stability of implants.

CONCLUSIONS

Within the limitations of this in vitro study, the following conclusions were drawn:

1. Preparation method and location had a significant effect on implant stability in synthetic bone models that mimicked the posterior maxillary region.

2. The underpreparation and bicortical fixation method significantly increased implant stability compared to standard preparation and monocortical fixation.

3. Low values of insertion torque, RFA, and removal torque were found in groups in which the osteotome was used, which demonstrates that use of the osteotome decreases implant stability in polyurethane blocks.

4. There were significant correlations between insertion torque, RFA value, and removal torque.

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임플란트의 초기안정성에 관한 고찰: 성견에서의 실험적 연구

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Study of initial stability change of implant: an experimental study in the dog

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PURPOSE :

The purpose of study was to analyze the initial stability change of N company A implant.

MATERIALS AND METHODS :

A total of 32 implant were placed in 4 mongrel dogs. Implant were divided into 2 groups following to manufacturer. Group 1 is consisted of 16 of A implant (N co., Seoul, Korea), and Group 2 is consisted of 16 of B implant (C co., Seoul, Korea). After implant placement, ITV (insertion torque value), ISQ (implant stability quotient), PTV (periotest value) were measured immediately, 2 weeks, 4 weeks and 16 weeks of healing period. With the animal's sacrifice 12 weeks after implant installation and histomorphometric analyses were performed. Statistical analyses were performed using SPSS for window (ver.20.0 SPSS Inc.). Statistical differences were considered significant at $p<0.05$.

RESULTS :

There was significant difference of ITV, ISQ, PTV between A implant and B implant at all of period ($p<0.05$). There was no significant difference of initial stability change of A implant ($p<0.05$). The percentage of direct bone-to-implant contact (BIC) and bone area ratio (BA) showed statistical significant between group 1 and 2 at 12 weeks ($p<0.05$).

CONCLUSION :

These result indicate that A implant does not have stability dip. In conclusion, A implant allows immediate or early loading implant protocol. (JOURNAL OF DENTAL IMPLANT RESEARCH 2013;32(2):33-39)

Key words :

Implant, Initial stability, Stability dip, Immediate loading

서론

최근 임플란트가 대중적으로 많이 적용됨으로써 환자들의 요구 및 시술자의 필요성에 의해 전통적인 치료시기를 줄이고자 하는 많은 노력이 요구되며, 그에 따라 임플란트의 치유기간에 대해 연구가 많이 진행되어 왔다. 2002년 스페인 World Congress에서는, 즉시 및 조기 하중부여가 많은 임상케이스에서 성공적으로 적용될 수 있음을 보고하였다[1]. 1990년 Schnitman 등에 의하면 즉시 로딩 임플란트의 성공률은 85.7%로 보고되었으며[2], 최근 Kan과 Rungcharassaeng에 의하면 단일 치아 임플란트에서는 100%까지도 보고되고 있다[3]. 2006년 Lioubavina-Hack, Natalia 등에 의하면 즉시 및 조기 하중부여의 가장 중요한 요소 중의 하나는 초기안정성이라고 연구한 바 있다[4]. 하지만, Simunek 등의 연구에 의하면 초기 안정도에서 즉시 및 조기 하중부여에 제한을 가하게 만드는 요인 중 하나는 'Stability dip'이다[5]. 임플란트는 식립 후 약 4주~6주 사이에 일차적 안정도가 떨어지면서 그 떨어진 만큼을 아직 올라가는 이차적 안정도가 충분히 상쇄하지 못하여 안정도 저하 현상이 나타나게 된다[6]. 이 시기에 하중을 부여하게 되면 골유착에 실패하게 된다[7]. 이러한 Stability dip을 줄여 안정도의 일정한 유 지가 가능하게 할 수 있다면 즉시 및 조기 하중부여에 유리한 조건을 만들어 줄 수 있다. 안정도의 저하를 극복하기 위한 노력으로는 일차적으로 기계적 안정도를 높이기 위해 임플란트의 전반적인 모양을 taper 형태로 제작하는 방법, 임플란트의 thread 디자인을 변경하는 방법, 임플란트 식립 시 under-drilling을 이용하는 방법, 임플란트의 상부 표면에 미세 나사산을 형성하는 방법 등을 통해 ITV (insertion torque value)를 물리적으로 높여 주어 초기 안정도에 기여하는 여러 가지 테크닉들이 소개되었다. 다음으로 생물학적 안정도를 높이기 위한 방법들로는 주로 임플란트의 표면처리를 개선하는 형태로 소개되고 있다. HA 코팅 임플란트나 SLA 표면처리 임플란트 등을 필두로 표면에 친수성을 부여한 임플란트까지 출시되어 각광을 받고 있다[8]. 본 연구에서는 표면처리된 임플란트의 연구와 즉시 및 조기 하중부여의 연구 사이에 상관관계를 찾기 위해, 최근 출시된 N사의 SLA 표면처리된 임플란트인 A implant를 이용하여 stability dip의 형성 유무와 즉시 및 조기하중 부여의 가능성에 대해 살펴보았다[9].

대상 및 방법

1. 실험동물

영구치가 완전히 맹출되고 체중이 20 kg 내외인 생후 1년 전후의 수컷 성견 총 4마리를 동일한 조건 하에서 약 2주간 사육한 후 실험하였다.

2. 실험재료

실험에 사용한 임플란트는 N사의 A 임플란트 16개와 C사의 B 임플란트 16개를 사용하였다. 사용된 임플란트 모두 직경 4.0 mm에 길이 10 mm 크기로 총 32개의 임플란트가 사용되었다.

1) N사의 A implant

Root form – tapered submerged type의 fixture 디자인을 갖고 있으며, SLA (Sandblasted, Large grit, Acid-etched) 표면처리 되어 있고, 상부에 micro thread가 없는 직경 4.0 mm, 길이 10mm의 임플란트 16개를 식립하였다.(Fig. 1)

2) C사의 B implant

Flat soulder tapered submerged type의 fixture 디자인을 갖고 있으며, RBM (Resorbable Blasted Media) 표면처리 되어 있고, 최상부에 machined surface, 상부에는 double micro-thread, micro-thread의 2중 구조를 갖고 있다. Fixture 직경은 4.0 mm, 길이는 10 mm의 임플란트 16개를 식립하였다.(Fig. 2)

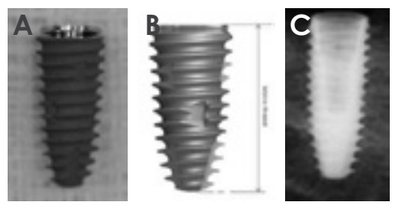

Figure 1. N company A implant. (A) Picture of implant, (B) Illustration of structure of implant, (C) X-ray image of implant.

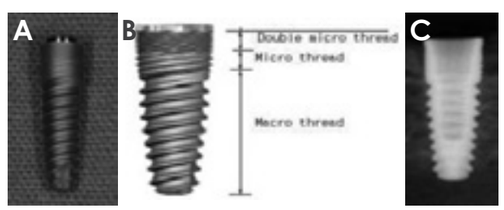

Figure 2. C company B implant. (A) Picture of implant, (B) Illustration of structure of implant, (C) X-ray image of implant.

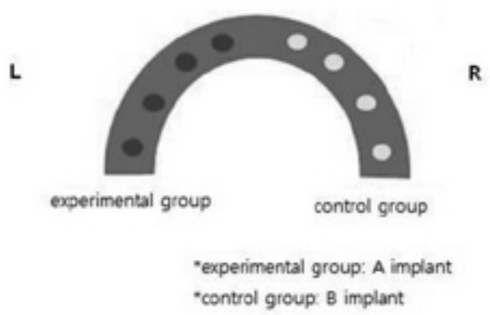

Figure 3. Diagram showing the installation of implants location.

3. 실험방법

Ketamine (10 mg/kg)으로 전신마취를 한 후 1/10으로 희석한 베타딘으로 구강내외와 수술부위를 소독하고, 구강내는 생리식염수로 세척한 후 1 : 100,000 에피네프린 첨가 2% 리도케인으로 침윤마취를 시행한 뒤 하악 좌우측 1, 2, 3, 4 소구치를 발거하고, 임플란트의 수술 kit와 Kavo® 의 전동 모터와 핸드피스, 그리고 N사의 임플란트 수술 기구들을 사용하여 임플란트를 식립하였다.

좌우측에 N사 임플란트와 C사 임플란트를 4개씩, 총 8개의 임플란트를 4마리의 실험견에 식립하였다.(Fig. 3) 식립된 임플란트는 식립 직후 0주, 2주, 4주, 12주차에 ITV, ISQ, PTV값을 각각 측정하였고 X-ray (periapical view) 촬영도 하였다. 또한 12주 후 측정이 끝난 실험견을 희생하여 조직탈회표본을 제작하여 BA, BIC값을 측정하여 조직형태계측학적 분석을 하였다.

4. 관찰 및 분석 방법

1) 육안적 관찰

연조직을 포함한 임플란트 식립 부위의 염증 유무, 임플란트의 노출 여부, 기타 이상 유무를 육안과 확대경을 이용하여 관찰하였다.

2) 방사선학적 관찰

매식체 주위의 방사선 투과상의 유무 및 변화, 주변골의 괴사와 변연골 소실 여부를 관찰하였다.

3) 임플란트 안정도 측정

임플란트 식립시 KaVo® 전동모터에 표시되는 Insertion Torque Value (ITV: 식립토크 값)를 기록하고 Resonance Frequency Analysis (RFA: 진동수 분석)를 3회, Periotest®를 5회 측정하고, 희생 후 RFA 3회, Periotest®를 5회 측정하여 식립 전과 비교하였다.

5. 비탈회표본 제작 및 조직형태계측학적 분석

1) 실험동물의 희생

임플란트 식립 후 12주에 실험동물을 희생시키고, 연조직을 포함한 임플란트 식립부위의 염증유무, 임플란트의 노출 여부, 기타 이상 유무를 육안과 확대경을 이용하여 확인하였다. 양측 하악골을 임플란트 식립 부위로부터 3 cm 거리에서 골막을 박리하고 부검용 톱으로 매식체를 포함한 골조직편을 조심스럽게 채취하였다.

2) 표본제작 및 관찰방법

(1) 비탈회표본 제작: 채취된 매식체를 포함하고 있는 골조직편을 10% 포르말린으로 고정시킨 뒤 2~4 mm의 두께로 자른 후 다시 고정시켰다. 고정된 조직은 에틸알코올로 24~32시간씩 처리하여 탈수시켰다. 탈수 후 에틸알코올(Sung Kwang Pharma, Co., Korea)과 레진(Technovit 4000, Kulzer)을 3 : 1, 1 : 1 그리고 1 : 3의 비율로 바꿔가면서 12시간씩 조직에 레진을 침투시켰다. 이후 플라스틱으로 만들어진 틀에 조직을 넣고 액체상태의 광중합레진(Technovit 4000, Kulzer)으로 채운 후 450 nm 파장의 U.V. 광선으로 레진블록을 제작하였다.

만들어진 레진블록을 플라스틱 틀로부터 제거한 후 거친 사포에 갈아 관찰하고자 하는 면을 노출시킨 뒤 반대쪽 면이 보고자 하는 면과 평행한 상태에서 자가중합레진(Technovit 4000, Kulzer)을 이용하여 반대쪽 면을 슬라이드에 붙이고, 보고자 하는 면을 광중합레진 접착제(Technovit 7210, Kulzer)를 이용하여 슬라이드에 접착시켰다. 이렇게 두 슬라이드가 평행한 상태에서 보고자 하는 면 쪽으로 두께가 200μm가 되도록 절단하여 접착제의 최종 두께를 제외한 조직의 두께가 30μm 정도가 되도록 grinding paper (P800, P1200, P2500의 순차적으로 사용)로 갈아내었다(EXAKT grinding System). 이때 이렇게 완성된 슬라이드는 Hematoxilin- Eosin 염색을 실시한 후 Vanox-S research microscope (Olympus, Japan)을 이용하여 관찰하였다.

(2) 조직형태계측학적 분석 및 관찰: 30 μm 두께의 표본을 제작하여 컴퓨터에 연결된 Leitz Microvid 장비를 이용하여 관찰하였다. 현미경으로 관찰하면서 임플란트의 표면과 골조직과의 접촉율과 나사산 사이의 골량을 측정하였다. 골접촉율(BIC)과 골량(BA)은 다음 식에 의해 백분율로 나타냈으며, 식립된 임플란트의 경부 1/3과 근단부 1/3에서, 양호한 골유착을 이룬 나사산 3개 부위(협-설로 6개의 나사산)에서 측정하여 평균치로 나타내었다.

BIC (Bone-Implant Contact ratio) 골로 덮이는 임플란트 표면의 비율(%)=(total contact surface/Implant circumference) × 100

BA (Bone Area ratio) 골수강 내에 망상골, 석회화된 골의 비율(%)=(total bone area/total tissue area) × 100

6. 통계 분석

자료에 대한 통계분석을 위해 SPSS ver. 20.0 프로그램을 사용하였다. 2가지 임플란트에 대해 각 주군별로 측정된 값을 T-test를 통해 임플란트 그룹별, 각 주군별 비교를 하였다.

결 과

1. 육안적 소견

임플란트 식립 직후 및 2주, 4주, 12주 모두에서 임플란트 식립 부위에 염증의 소견은 보이지 않았으며, 창상의 이개나 임플란트의 노출도 발견되지 않았다. 실험기간 동안 실패하여 탈락된 임플란트도 발견되지 않았다. 전체적으로 육안적으로 양호한 치유를 나타냈다.

2. 방사선학적 소견

임플란트와 골 사이에서 특별히 골이 흡수되거나 특이적인 형태는 발견되지 않았다. 모두 양호한 방사선학적 치유 소견을 보였다.

3. 안정도 검사결과 및 통계 분석 결과

본 연구에서는 임플란트의 표면처리가 초기안정성에 미치는 영향을 알아보고자 RMB 표면처리된 임플란트를 대조군으로, SLA 표면처리된 임플란트를 실험군으로 설정하여 성견의 하악골에 식립한 후, 안정도를 측정하는 여러 가지 방법(ITV, ISQ, PTV)을 사용하여 식립 직후, 식립 후 2주, 식립후 4주, 식립 후 12주에 각각 안정도를 측정하였다. 식립 12주 후에는 성견을 희생시켜 조직형태계측학적 평가를 시행하여 BIC와 BA값을 측정하였다. 결과값은 다음과 같다.

1) Insertion Torque Value (ITV: Ncm)

임플란트 식립 직후 Kavo 임플란트 엔진에 측정된 토크값을 측정한 것으로 N사 임플란트의 값이 41.83 Ncm, C사 임플란트의 값이 36.75 Ncm로 나왔다. N사 임플란트의 ITV 값이 C사 임플란트보다 통계적으로 유의한 수준으로 5.13 만큼 높게 나왔다.(Fig. 4)

2) 각 주 군별 N사 임플란트와 C사 임플란트 간의 ISQ 값의 차이

N사 임플란트의 ISQ 값은 식립 직후에는 75.88, 식립 후 2주에는 74.63, 식립 후 4주에는 77.31, 식립 후 12주에는 81.19로 각각 측정되었다. C사 임플란트의 ISQ 값은 식립 직후에는 73.38, 식립 후 2주에는 67.25, 식립 후 4주에는 72.50, 식립 후 12주에는 75.69로 각각 측정되었다. 각 주 군별 두 임플란트 사이에는 각각 ISQ값이 통계적으로 유의한 수준으로 모두 N사 임플란트의 수치가 더 높게 나왔다.(Fig. 5)

3) 각 주 군별 N사 임플란트와 C사 임플란트 간의 PTV 값의 차이

본 연구에서는 그래프의 왼쪽 수치의 음과 양을 반대로 표현하여 안정도의 상승 하락을 ISQ 값과 비슷한 양상으로 나타내었다. N사 임플란트의 PTV 값은 식립 직후에는 −2.38, 식립 후 2주에는 −1.75, 식립후 4주에는 −2.25, 식립 후 12주에는 −3.44로 각각 측정되었다. C사 임플란트의 PTV 값은 식립 직후에는 −2.13, 식립 후 2주에는 +0.25, 식립 후 4주에는 −1.88, 식립 후 12주에는 −3.25로 각각 측정되었다. 식립 후 2주에서 N사의 PTV 값이 −1.75로 C사의 PTV 값 +0.25보다 통계적으로 유의한 수준으로 1.5만큼 낮게 나왔고, 다른 시기에서는 N사와 C사의 통계적 유의성이 없었다.(Fig. 6)

4) N사 임플란트의 각 주군별 ISQ 값 및 PTV 값의 차이

N사 임플란트의 ISQ 값은 식립 직후에는 75.88, 식립 후 2주에는 74.63, 식립 후 4주에는 77.31, 식립 후 12주에는 81.19로 각각 측정되었다. PTV 값은 식립 직후에는 −2.38, 식립 후 2주에는 −1.75, 식립 후 4주에는 −2.25, 식립 후 12주에는 −3.44로 각각 측정되었다. 식립 직후

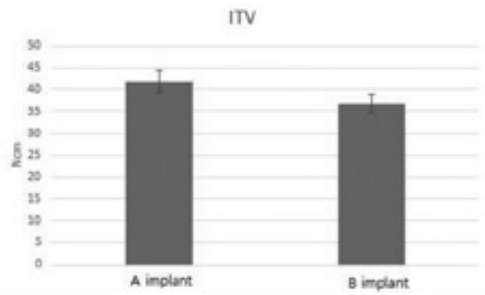

Figure 4. Graph of ITV (Insertion Torque Value) at installation period.

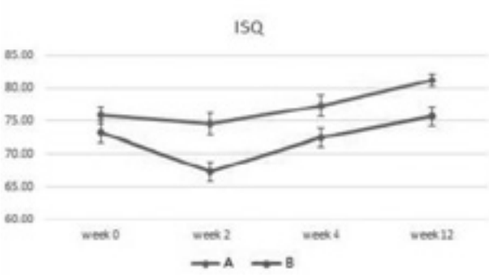

Figure 5. Graph of ISQ (Implant Stability Quotient) of placed implants by healing period.

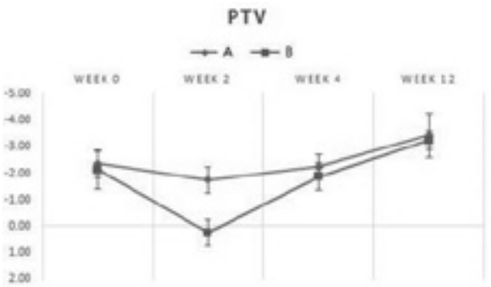

Figure 6. Graph of PTV (Periotest® Value) of placed implants by healing period (attention to X-axis value).

와 식립 후 2주 사이의 ISQ 값과 PTV 값은 모두 통계적으로 유의성이 없었다. 그리고 식립 후 2주와 식립 후 4주 사이에서 ISQ 값은 통계적으로 유의하게 식립 후 4주의 ISQ 값이 증가하였으나, PTV 값은 통계적 유의성을 띄지 않았다. 식립 후 4주와 식립 후 12주 사이에는 ISQ 값과 PTV 값 모두에서 통계적으로 유의한 수준으로 식립 후 12주의 수치가 더 높았다.

5) C사 임플란트의 각 주군별 ISQ 값 및 PTV 값의 차이

C사 임플란트의 ISQ 값은 식립 직후에는 73.38, 식립 후 2주에는 67.25, 식립 후 4주에는 72.50, 식립 후 12주에는 75.69로 각각 측정되었다. PTV 값은 식립 직후에는 −2.13, 식립 후 2주에는 +0.25, 식립 후 4주에는 −1.88, 식립 후 12주에는 −3.25로 각각 측정되었다. 식립 직후와 식립 후 2주 사이의 ISQ 값은 통계적으로 유의하게 식립 직후의 값이 더 크게 나타났으며, PTV 값은 통계적으로 유의하게 식립 후 2주의 값이 더 크게 나타났다. 그리고 식립 후 2주와 식립 후 4주 사이에서 ISQ 값은 통계적으로 유의하게 식립 후 4주의 ISQ 값이 증가하였으나, PTV 값은 식립 후 2주의 값이 더 크게 나타났다. 식립 후 4주와 식립 후 12주 사이에서 ISQ 값은 통계적으로 유의하게 식립 후 12주에서 높았으며, PTV 값은 통계적으로 유의한 수준으로 식립 후 4주의 수치가 더 높았다.

6) 조직분석계측학적 분석

임플란트 식립 12주 후, 실험견을 희생하여 조직형태계측학적 분석을 통해 BA와 BIC 값을 측정하였다. 각각의 임플란트에서 전반적인 골융합 상이 양호하였고, 임플란트와 융합되어 있는 골 조직은 혈관을 포함하는 골수강 구조가 현저히 감소된 성숙 치밀골로 구성되었다. 골원의 중심이 확장된 골수강이 부분적으로 관찰되나 N사 임플란트(Fig. 7)에서 C사 임플란트(Fig. 8)에 비해 골원 구조가 보다 명확하고 치밀하였다. 또한 임플란트 계면이 보다 성숙된 골조직에 의해 골성융합을 이루고 있음이 확인되었다.

N사 임플란트의 BA값은 51.31, C사 임플란트의 BA 값은 42.06으로 N사의 수치가 통계적 유의하게 9.25만큼 높았다.(Fig . 9) 또한, N사 임플란트의 BIC값은 71.6, C사 임플란트의 BIC 값은 59.4으로 N사의 수치가 통계적으로 유의하게 12.2만큼 높았다.(Fig. 10)

고 찰

Bränemark 등은 임플란트의 성공적인 골유착과 하중

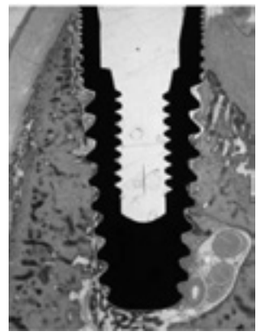

Figure 7. Histologic features at week 12 after N company implant installation (bone stain, original magnification ×20).

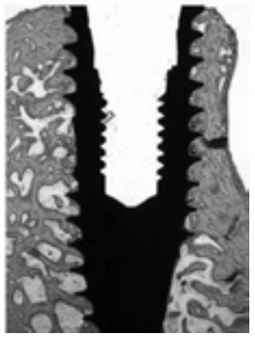

Figure 8. Histologic features at week 12 after C company implant installation (bone stain, original magnification ×20).

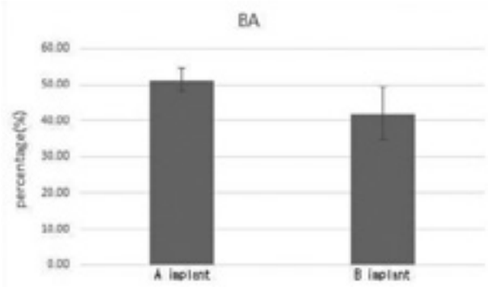

Figure 9. Graph of BA (Bone Area ratio) at week 12.

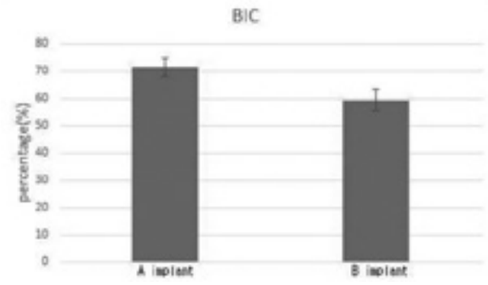

Figure 10. Graph of BIC (bone to implant contact ratio) at week 12.

후의 꾸준한 안정을 위해서는 임플란트 식립 후 최소 3~6개월에 임플란트에 하중을 가하도록 권장하였다[10]. 결과적으로 발치 후 3개월을 기다리고 하중부여 시기까지 고려하면, 전체 임플란트 치료는 끝날 때까지 6~12개월이 소요되게 된다. 이 전통적인 치료 기간은 임플란트 디자인, 표면처리 방법, 수술테크닉 등의 발달과 환자의 요구가 맞물리면서 그 기간이 점점 단축되게 되었다. 하지만 이러한 즉시 및 조기 하중부여 테크닉은 모든 환자에게 적용 가능한 술식은 아니며, 성공률을 높이기 위해서는 무엇보다 적절한 증례 선택이 중요하다. 또한 즉시 및 조기 하중부여시에 높은 성공률을 얻기 위해서는 임플란트의 골유착 과정에서 발생하는 임플란트 안정도의 기계적, 생물학적 변화에 대해 심도 있는 이해가 필요하며, 임플란트 식립 과정에서 식립 시 초기 안정도 및 술 후 안정도를 높이는 노력을 하여 임플란트의 성공률을 높여야 한다. 즉시 및 조기 하중부여시, 임플란트의 성공기준은 임플란트를 식립할 때의 초기 고정도와 일차 및 이차 치유과정 중에 얻어지는 골유착에 의해 결정된다. 이러한 초기 고정 및 일차, 이차 치유과정에 영향을 미칠 수 있는 인자들에는 식립 시 임플란트의 식립토크, 임플란트 디자인, 나사산의 형태 및 위치, 표면처리의 특징 등이 있다.

이러한 많은 인자들에 의해 영향을 받는 임플란트의 안정도는 객관적으로 수치화하여 측정할 필요가 있다. 임플란트의 안정도 측정에는 많은 연구들에서 다양한 방법들이 소개되어왔다[11]. 그 중 식립토크(Insertion torque; ITV), 공진주파수 분석법(Resonance Frequency Analysis; RFA – ISQ), Periotest (PTV) 등이 안정도 측정에 비교적 객관적인 역할을 한다고 연구되었다[12]. 본 실험에서는 임플란트와 골과의 골유착시기에 어떠한 하중을 부여하지 않고 치유시켰다. 임플란트의 골유착 초기에 가해지는 하중에 의해 미세한 움직임이 발생하면 이러한 미세한 움직임은 골유착에 유해한 환경을 제공한다는 Ivanoff 또는

Brunski 등의 연구에서 볼 수 있듯이[13,14], 즉시 및 조기 하중 부여를 시행했을 때의 골 유착 형태 및 안정도를 측정하는 추가적인 실험이 필요하다고 하겠다. 또한, 본 연구에서는 PTV의 값이 ISQ 값과는 다르게 통계적으로 유의미한 차이를 보이지 않아 PTV 값이 안정도를 측정하는 결정인자로서의 의미와 신뢰도에 대한 고찰이 필요할 것으로 사료된다[15].

Boyan 등의 연구[16]에서는 임플란트의 표면조도에 따라 골 유착이 더 성공적으로 이루어 졌으며, 그 결과는 BIC (bone to implant contact ratio)를 통하여 간접적으로 측정할 수 있음을 보고하였다. 또한, Buser 등의 연구에서는 조직형태계측학적인 분석을 통하여 임플란트의 표면 거칠기를 증가시키는 것은 골과 임플란트의 접촉을 증가시키는 경향이 있음을 보고하였다[17]. 본 실험의 결과에서, N사의 SLA 표면처리된 A 임플란트의 BA, BIC값이 통계적으로 유의하게 C사의 임플란트에 비해 높은 수치를 보이는 것은 이러한 임플란트의 표면처리의 차이에서 오는 임플란트 표면조도와 관계가 있는 것으로 사료된다. Huang 등은 연구에서 ISQ 값과 BIC 값의 양의 상관관계에 대해 보고하였고[18], Abrahamsson 등은 ISQ 값과 BIC 값과의 관계는 아직 불명확하다는 연구를 발표하는 등, 아직 정립된 연구는 없는 것으로 보고되고 있다[19]. 본 실험결과 중, 높은 ISQ 값을 보이는 임플란트에서 12주 후 골수강 내에 망상골, 석회화된 골의 비율(BA)와 골로 덮이는 임플란트 표면의 비율(BIC)의 값이 꾸준히 비례하는 것을 알 수 있다. 그러므로 향후 ISQ 값과 BA, BIC 값의 상관관계에 대한 추가 연구도 필요할 것으로 생각된다[20].

결 론

본 실험의 결론으로는, N사의 A 임플란트의 ITV 값이 C사 임플란트보다 통계적으로 유의하게 높았으며, N사의 A 임플란트와 C사 임플란트 모두 시간이 지날수록 통계적으로 유의하게 ISQ와 PTV 값이 증가되는 양상을 보였다. 식립 2주후에 측정한 ISQ와 PTV값에서 N사의 A 임플란트가 C사 임플란트에 대해 통계적으로 유의한 수준으로 높게 나타났다. 또한, 12주 후 조직형태계측학적 분석을 통해 N사의 A 임플란트의 BA와 BIC가 통계적으로 유의한 수준으로 C사 임플란트의 BA, BIC높게 나타났다. 이로써, N사의 A 임플란트가 C사 임플란트보다 초기 안정성 및 전체적인 안정성에서 높게 나타났으며, 이러한 결과는 N사의 A 임플란트가 초기 안정도 감소량(stability dip)을 줄여 즉시 및 조기하중 부여에 유리한 조건을 갖는다고 결론지을 수 있다.

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Retrospective Results of Implants for Partially Edentulous Posterior Jaws According to Time Points of Early Loading

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Jong-Hwa Kim and Jin-Yong Yang contributed equally to this work.

Purpose:

This study evaluated the survival and success rates and marginal bone loss conditions of earlyloaded implants in the posterior maxilla and mandible of partially edentulous patients.

Materials and Methods:

Implants (n = 299) were placed in 105 patients at two research centers. Provisional fixed dental prostheses were provided to the patients between 1 week and 2 months after implant placement. The implants were classified into four groups according to the loading time (1 to 2, 2 to 4, 4 to 6, and 6 to 8 weeks). Periapical radiographs were taken via a parallel imaging technique, and the peri-implant marginal bone level was measured on the radiographic images.

Results:

Most implants were lost within 1 month, and one implant was removed at 36 days after loading. The cumulative survival rate of the implants was 97.0%. Implants loaded in the maxilla at 1 to 2 weeks after prosthesis insertion had significantly lower survival rates than any other group (P = .013). There were no significant differences in marginal bone levels among the implant groups classified according to loading time. Conclusions: Early loading is a safe and predictable procedure for implant-supported restoration of posterior partial edentulism. However, care must be taken in early loading within 2 weeks after maxillary implant insertion.

Key words:

early loading, implant, partial edentulism, mandible, maxilla

Traditionally, the successful osseointegration of dental implants required a two-stage protocol with a 3- to 6-month healing period before prosthesis placement, with the implant being submerged beneath the mucosa during first stage to prevent micromovement.[1] However, the two-stage approach has several disadvantages, such as the need for a second surgery and an extended waiting time prior to prosthesis placement. Early or immediate implant loading has therefore become a relatively common procedure, because early and immediate loading protocols allow the patient to resume normal masticatory function as quickly as possible after surgery.

Success rates for immediately loaded implants were first documented for completely edentulous mandibles in the 1970s and 1980s.[2,3] A cumulative success rate of 88% was observed in a 1986 study for 1,739 immediately loaded implants.[2] Attempts have recently been made to improve the success rates of immediate and early loading protocols in carefully selected cases through the development of novel implant designs and surfaces, as well as new surgical techniques.[4–6] Although some studies showed negative results regarding such loading protocols,[7,8] most dealt with single-implant restorations. Many additional studies are now available concerning efficacious immediate and early loading procedures for partial edentulism. However, immediate loading protocols generally exhibited a lower implant survival rate than delayed loading protocols,[9–11] and early loading protocols for partially edentulous patients typically showed high success and/or survival rates.[11–17]

Early loading was conducted at least 6 weeks after implant insertion in the majority of the studies dealing with implant restoration for partial edentulism.[11,13,14,17–19] Few studies describe early loading before 6 weeks.[12,16] Early loading has been reported before 2 weeks, but the cases were investigated for 18months at most.[20–22] At present, there is insufficient evidence in the literature regarding early loading in the partially edentulous posterior maxilla, compared with that in the mandible.[18,19]

The purpose of this study was to evaluate the survival rate, success rate, and marginal bone loss conditions of early-loaded dental implants in the posterior maxilla and mandible of partially edentulous patients at various loading times. The null hypothesis underlying this study was that there would be no difference in the investigated clinical outcomes for the early-loaded implants according to the loading time.

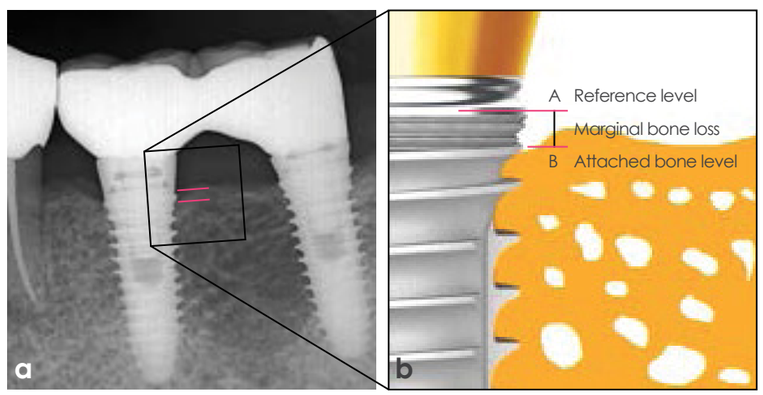

Fig 1 Periapical radiograph and schematic diagram demonstrating the measurement of marginal bone loss. (a) Design characteristics of the inserted implants, including a tapered apex and reverse buttress threads, are visible on the radiograph. (b) The schematic diagram shows the measurement of marginal bone loss. The difference between the implant platform (reference level, A) and the attached bone level (B) is equivalent to the marginal bone loss. The mean value of mesial and distal marginal bone loss is defined as the marginal bone loss associated with the implant.

MATERIALS AND METHODS

Treatment records were reviewed, and the retrospective investigation was approved by the Institutional Review Board of Seoul National University Bundang Hospital (Seoul, Korea) (No. B-1007-106-109). The patients were selected based on the inclusion criteria of good general health and sufficient bone to allow for the placement of implants at least 7 mm in length. To be included in this study, a minimum implant stability quotient (ISQ) value of 65 and an insertion torque of 35 Ncm were required for all implants (CMI EB implants, Neobiotech). The implants used had a tapered apex design, a reverse buttress and self-tapping threads, an external hex connection, and a blasted surface created by resorbable blast media (Fig 1). The dental implants were placed with early loading in the posterior regions of both jaws. Patients with systemic diseases such as uncontrolled diabetes, medical conditions such as pregnancy or radiation therapy in the head or neck, were heavy smokers, required bone augmentation procedures, had uncontrolled periodontitis, or exhibited high masticatory or parafunctional forces were excluded from the study.

Surgery was performed under local anesthesia (1:100,000 epinephrine) or conscious intravenous sedation with 1% propofol and midazolam, if required by the patient's general condition. One experienced surgeon at each center performed all operations, and each surgeon followed the procedures for implant insertion by using the same implant drill kit (CMI EB implant kit, Neobiotech), as recommended by the manufacturer. Screw-retained acrylic resin (Jet Tooth Shade, Lang Dental) provisional restorations were inserted between 7 and 56 days (8 weeks) after implant insertion, according to the definition of early loading established by the 2008 ITI Consensus Conference, which was a prosthesis in contact with the opposing dentition and placed at least 1 week after implant placement, but no later than 2 months afterward.23 The implants were early-loaded with occlusal contacts in centric closure and without eccentric contacts. The beginning of loading was defined as the time of provisionalization, and the early-loaded implants were classified according to the loading time (1 to 2 weeks, 2 to 4 weeks, 4 to 6 weeks, or 6 to 8 weeks after implant insertion). Final implant-supported restorations were delivered after 12 weeks. All prosthodontic procedures were performed by one prosthodontist at each center.

Implant success was defined by the criteria set forth by Albrektsson and associates[24]: (1) the absence of implant mobility; (2) the absence of any continuous peri-implant radiolucency; (3) the absence of recurrent peri-implant infection, pain, neuropathy, paresthesia, or protrusion into the maxillary sinus or mandibular canal; and (4) the ability of the implant to support a prosthesis. Regardless of the circumferential conditions, implants and superstructures that remained in place at the point of final observation were considered survival cases. Implants that were removed for any reason or that exhibited 1.5 mm or greater resorption of the marginal bone were classified as failures.

Periapical radiographs were taken using commercially available film holders and a parallel imaging technique during the investigation period. The periimplant marginal bone level was evaluated in each patient (IMPAX, Agfa). Measurements were performed on the radiographic images at the time of surgery and early loading, at 3 and 6 months, and every year thereafter for an average of 3.1 years after loading. Marginal bone height was determined from these images by measuring the distance from the implant platform, defined as the reference level, to the most coronal level of bone-to-implant contact on both the mesial and distal sides of the implant (Fig 1). A representative value for the marginal bone loss around the implant was then calculated by obtaining the mean of these two measurements for each implant.

The t-test was used to compare marginal bone loss with respect to implant length (short or long). Short implants were characterized by a length of 10 mm or less, and long implants were characterized by a length of greater than 10 mm. The nonparametric Kruskal-Wallis test was performed to detect any significant differences in marginal bone level changes among the implants grouped by loading time (1 to 2, 2 to 4, 4 to 6, or 6 to 8 weeks). Cumulative survival rates of the investigated implants were evaluated with survival analysis by the life table method. The chi squared test was used to compare survival and success rates of the early loaded implants according to the loading time, and Fisher's exact test was applied to compare survival and success rates of the short and long implants. For all tests, P values of less than .05 were considered statistically significant.

RESULTS

The total number of patients included in this early loading study was 105 (61 men and 44 women). The patients ranged in age from 28 to 83 years (mean age, 59.4 ± 11.9 years). The 105 patients were treated at two centers, Seoul National University Bundang Hospital and a private practice in Seoul, Korea. During the period from January 2007 to December 2009, a total of 299 implants with diameters of 3.5 to 5 mm and lengths of 7 to 13 mm were placed. These implants were earlyloaded with provisional prostheses at a mean of 32.6 days after surgery. The follow-up period was on average 36.9 months (3.1 years; range, 11 to 59 months). The lengths and diameters of the inserted implants are presented in Table 1.

Crestal Bone Evaluation

Mean marginal bone losses resulting from implant surgery at follow-up times of 3, 6, 12, 24, and 36 months were 0.09 mm (SD, 0.17 mm), 0.18 mm (SD, 0.22 mm), 0.23 mm (SD, 0.25 mm), 0.27 mm (SD, 0.24 mm), and 0.28 mm (SD, 0.25 mm), respectively. Marginal bone loss showed almost no change after 24 months. No significant differences were found in marginal bone levels between short and long implants or among the implants grouped by loading time (Table 2).

Implant Success and Survival Rates

During the first year after implant placement, eight implants were lost within the first month, and one implant was lost between 1 and 2 months after loading. Four implants failed at the site of the maxilla, and five implants failed at the site of the mandible. At the last follow-up observation, 290 out of 299 implants still had functional loading. The cumulative survival rate of the early-loaded implants was 97.0% (Fig 2). All implants that survived met the implant success criteria described by Albrektsson and colleagues.[24] The success rate was, therefore, equal to the survival rate. Four failed implants in the maxilla were observed in the 1 to 2 week loading group (n = 3 implants) and the 2 to 4 week loading group (n = 1 implant). The implant survival rate in the maxilla was 88.9% at 1 to 2 weeks after loading, 96.8% at 2 to 4 weeks after loading, and 100% in the other loading groups. Significant differences were found in the survival rates in the maxilla

Table 1. Locational and Dimensional Features of the Implants

Location	Implant diameter (mm)	Implants by length (mm)				
		7.0	8.5	10.0	11.5	13.0
Maxilla	3.5	-	-	-	2	-
	4.0	1	3	15	39	16
	5.0	5	6	23	30	18
Mandible	3.5	-	-	1	-	-
	4.0	3	7	23	58	2
	5.0	6	8	23	9	1

Table 2. Marginal Bone Loss by Loading Time

Location	Follow-up (mo)	Loading time (wk)								P*
		1–2		2-4		4-6		6-8		
		Mean (mm)	n	Mean (mm)	n	Mean (mm)	n	Mean (mm)	n	
Maxilla	6	0.20 ± 0.17	27	0.20 ± 0.19	31	0.20 ± 0.16	53	0.21 ± 0.16	47	.996
	12	0.22 ± 0.21		0.22 ± 0.19		0.26 ± 0.20		0.26 ± 0.15		.816
	24	0.28 ± 0.22		0.29 ± 0.20		0.29 ± 0.19		0.32 ± 0.16		.928
Mandible	6	0.14 ± 0.29	19	0.11 ± 0.20	45	0.23 ± 0.33	37	0.14 ± 0.23	35	.384
	12	0.25 ± 0.40		0.16 ± 0.25		0.28 ± 0.36		0.16 ± 0.24		.505
	24	0.27 ± 0.17		0.21 ± 0.30		0.29 ± 0.34		0.19 ± 0.27		.735

*Kruskal-Wallis test.

Table 3. Survival and Success Rates by Loading Time

Location		Loading time (wk)								P*
		1–2		2-4		4-6		6-8		
		%	n	%	n	%	n	%	n	
Survival rate	Maxilla	88.9	27	96.8	31	100	53	100	47	.013
	Mandible	100	19	91.8	49	97.4	38	100	35	.132
Success rate	Maxilla	88.9	27	96.8	31	100	53	100	47	.013
	Mandible	100	19	91.8	49	97.4	38	100	35	.132

*Chi-square test.

Table 3. Success Rates of Short and Long Implants

	Success (n)	Failure (n)	Success rate (%)	P*
Short implant	120	4	96.8	
Long implant	170	5	97.1	.854
Total	290	9	97.0	

*Fisher's exact test.

(P = .013, Table 3). In the mandible, however, no significant differences were observed in the survival rate among the groups classified according to the loading time (Table 3). The cumulative survival rates of the short and long implants were 96.8% and 97.1%, respectively (Fig 3). No significant differences were found for either the survival or the success rate between the two groups (Table 4).

No significant differences were found in the number of implant failures between the two centers. The investigated 128 implant-supported restorations were splinted fixed dental prostheses without fixed partial dentures (n = 102 prostheses) or single implant restorations (n = 26 prostheses). At the last follow-up, two prostheses in the maxilla (both single implant restorations) and one in the mandible had failed. After prosthesis delivery, complications were monitored, and ranged from cement wash (n = 3 prostheses), screw loosening (n = 4 prostheses), prosthesis fracture (n = 5 prostheses), and cheek biting (n = 3 prostheses).

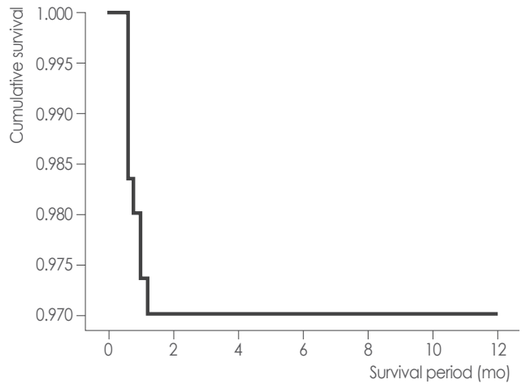

Fig 2 Cumulative survival rate of the investigated implants. Survival analysis was performed by the life table method. The survival rate did not change after 12 months (data not shown). Most implant failures occurred within 1 month after early loading. Only one implant failed at 36 days after loading.

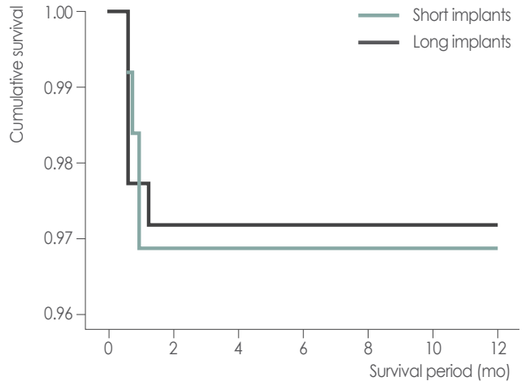

Fig 3 Comparison of the survival rates between short and long implants. Survival analysis was performed by the life table method. No significant difference was found in survival rates between long and short implants. The cumulative survival rate of short implants was 96.8%, and that of long implants was 97.1%.

DISCUSSION

The results of this study suggest the potential necessity of subdividing the time points that correspond to early loading of dental implants. For example, the implant survival rate was significantly lower for early loading at 1 to 2 weeks post-implantation in the posterior maxilla compared with later time points, indicating that precautions must be taken when undertaking particularly early loading procedures in this region. In support of this idea, decalcified bone spicules were mainly found within the extracted socket at 1 and 2 weeks after tooth extraction in an investigation by Amler and colleagues, whereas bone mineralization within the entire socket wall was evident after about 3 weeks.[25] Additional prospective studies are therefore needed for a detailed exploration of factors influencing survival rates in early loaded implant-supported prosthesis in the maxillary posterior area.

Overall, this study showed that implants inserted in partially edentulous posterior areas of the arch may be successfully loaded at early time points. Only 9 out of 299 implants failed within 2 months of loading, resulting in a success rate of 97.0%. No other implants were lost since that time, yielding a cumulative survival rate of 97.0%. These results indicate that implant success following early loading is comparable to that of implants loaded after the conventional 3 to 6 month healing period, similar to previously reported outcomes regarding early loading protocols. Indeed, high success rates of about 98% to 99% have been documented for early loading.[14,22,26] Furthermore, a prior investigation reported that the cumulative survival rate of early loading at 2 months after placement of 405 implants was 97.7% in the posterior area of the jaw,[17] and another reported that the 1-year survival rate was 97.2% for 36 early loaded implants at 43 days after placement in the posterior maxilla.[16] Early loading has gen-

erated predictable outcomes in some clinical studies, with survival rates similar to those for delayed loading.[14,17,27]

Primary implant stability at the time of insertion is a key prerequisite for successful immediate or early loading procedures.[6] Primary implant stability is largely dependent on bone quality, as well as implant design, surface, and placement technique. A tapered design and surface modifications can reportedly help to improve primary implant stability even when bone quality is poor, contributing to the achievement of high implant survival rates.[27,28] The implant used in this study had a tapered body, a deep thread depth, a reverse buttress thread shape, a self-tapping design, and a rough surface. These characteristics hypothetically promoted the superior primary stability of the implants and their favorable clinical outcomes, although this has not been conclusively demonstrated for all of the biomaterial properties described.[29–32] Further studies are required to investigate the relationship between implant design and early loading, in addition to the limitations of implant design.

The authors observed no significant differences in the measured values of marginal bone loss among the implant groups categorized by loading time. However, results regarding marginal bone loss vary from study to study. For example, the average marginal bone loss associated with anterior maxillary single tooth restoration was 0.14 mm in the experimental group during an observation period of 6 to 18 months postinsertion.[33] Conversely, a comparison between early and conventional loading groups revealed mean marginal bone losses of 0.86 and 0.77 mm around implants loaded 6 and 12 weeks, respectively, after insertion,[34] whereas crestal bone losses of 0.57 and 0.72 mm were shown for mandibular posterior implants loaded 1 and 6weeks, respectively, after insertion.[35] Such divergent results can be caused by differences in contact conditions (eg, full occlusal contact, light contact or noncontact).[11] Surgical techniques can also influence the extent of marginal bone loss; notably, some bone loss during standard submerged implant procedures is suspected to stem from the exposure of the marginal bone during the second surgery.[36] Two-stage implants resulted in 40% of the initial bone resorption after the second surgery, whereas most bone resorption occurred around one-stage implants within the first few months.[37] The position of implant placement, the accuracy of the radiographic investigation and implant geometry are also thought to affect the degree of marginal bone loss.

This study demonstrated that implant length had no significant effect on the success rates and marginal bone level changes of early loaded implants, similar to the results of some previous studies.[38,39] Other prior studies described the failure of shorter implants, concluding that implant lengths of at least 10 mm are necessary for immediate and early loading.[40,41] An additional study recommended the use of wide-diameter implants and implants longer than 8.5 mm to better counteract high masticatory load and lateral forces.[42] However, the majority of the published studies showed that the impact of implant length on clinical success was limited.[9,43–46] As implant geometry and surface became upgraded to improve the initial stability and bone-implant interface, implant length was considered to have less influence on the clinical success. The current investigation suggests that implant length may not affect implant success when the implant is 7.0 mm in length or longer.

CONCLUSIONS

Early loaded implants showed successful results in patients with posterior partial edentulism. However, lower survival rates for early loading were observed at 1 to 2 weeks after implant insertion in the posterior maxilla. This suggests that particular care is warranted when implants are early loaded within 2 weeks after placement in the posterior maxillary region. Conversely, implant lengths of 7.0 mm and above (up to 13.0 mm) had no apparent effect on implant failure in regard to early loading.

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Influence of Implant transmucosal design on early peri-implant tissue responses in beagle dogs

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Key words: bone resorption, connective tissue contact, dental implants, transmucosal design

Abstract

Objectives:

This study was undertaken to evaluate the influences of concave, machined and concave-roughened profiles of transmucosal implant designs on early peri-implant tissue responses. Materials and Methods: Implants were used and classified by transmucosal profile and surface type as straight-machined implants (SM), concave-machined implants (CM), or concave-roughened implants (CR). A total of 30 implants (10 per each type) with matching transmucosal profiles were placed directly on alveolar crests in randomized order in the edentulous mandibular ridges of three beagle dogs. Healing abutments were connected 4 weeks after implant placement, and prostheses were connected 8 weeks after implant placement and functionally loaded. All animals were sacrificed at 16 weeks. Peri-apical radiographs were obtained and measured to evaluate peri-implant marginal bone levels. Histological specimens were prepared to measure bone resorption, connective tissue contact, epithelial tissue height, biological width, and length of implant-abutment junction to the apical portion of junctional epithelium.

Results:

Radiographic and histometric analysis showed that least bone resorption occurred around CM implants and greatest bone resorption around SM implants ($P < 0.05$). Histometric analysis showed that highest connective tissue attachment and shortest biological width had formed around CM implants.

Conclusion:

Concave-machined profiled implants with a transmucosal design may induce less bone resorption and better connective tissue attachment around implants than the straight-machined profiled implants during the early healing phase.

To ensure the long-term success of implant treatment, good initial stability, osseointegration, and soft tissue healing immediately after placement are essential, and functionality and esthetic excellence should be maintained by protecting osseointegration through robust biological sealing of neighboring soft tissue after loading (Meffert 1988; Mombelli & Lang 1998).

Recently, various factors have been suggested to influence the preservation of periimplant bone (e.g., biological width, platform switching, design of implant cervical area, fine threads, insertion depth, nanoroughness, abutment design, and the avoidance of microlesions in soft tissues around implants), and the number of studies performed to improve soft tissue attachment is increasing (Hermann et al. 2007; Oh et al. 2002). Studies on beagle dogs have reported that a biological barrier comprised of at least soft tissue is required to protect implant osseointegration, as occurs with natural teeth, so that bone resorption to accommodate soft tissue occurs until soft tissue develops a biological dimension and that although biological width, including the epithelial attachment similar to that in natural teeth, remains stable around implants, junctional epithelium increases and connective tissue attachment and sulcular depth decrease over time (Berglundh & Lindhe 1996; Cochran et al. 1997; Hermann et al. 2000). It is known that if stable soft tissues, which consist of 2-mm-thick junctional epithelium and 1- to 1.5-mm-thick connective tissue, are integrated with implants, they can play a role as a protective barrier against bacterial invasion (Berglundh et al. 1991; Glauser et al. 2005). In one study, it was reported that epithelium was further attached to implants as junctional epithelium inferior to non-keratinized sulcular epithelium with a hemidesmosome (connection site) and produced collagen fibers and enzymes (McKinney et al. 1988). In addition, it has been reported that through connective tissue attachment, numerous fibroblasts form a focal adhesion contact on implant surfaces at the cellular level. In this previous study, areas on the surfaces of implants had a 20-nm-thick proteoglycan layer and dense connective tissue parallel to the implant surface appeared externally, all of which formed a biological seal (Groessner-Schriber 2006). When this connective tissue was damaged by repetitive replacement of the abutment, the connective tissue layer moved downward to secure the biological width, due to the downward migration of epithelial cells, and marginal bone was resorbed (Abrahamsson et al. 1997).

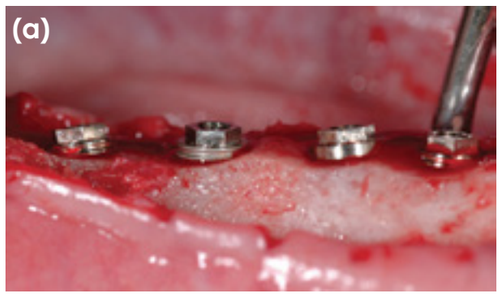
Numerous implant designs and procedures have been developed and used in clinical practice to achieve a good soft tissue seal, and numbers of studies conducted on this topic are increasing (Hermann et al. 2007; Tenenbaum et al. 2003; Touati et al. 2005). Recently, two implant design factors, that is, the microgap between an implant and the abutment and the superficial features of implants, have been suggested to be related to marginal bone resorption (Alomrani et al. 2005). Regarding the microgap, platform switching is known not to cause marginal bone resorption because in platform switching, the microgap is repositioned horizontally on the interior side, and thus, the a-ICT would not contact marginal bone at the abutment–implant interface (Lazzara & Porter 2006). One study on the superficial features of implants reported firm attachment of soft tissue could prevent downward growth of epithelial cells through implants, as Sharpey's fibers do in natural teeth, and that a rough surface is effective at achieving osseointegration and soft tissue attachment (Kim et al. 2006). The current trend in implant design favors the reduced area offered by machined surfaces or the removal of non-machined surfaces and the use of the platform switching concept. A microrough or nanorough surface extends to the implant shoulder and thus promotes osseointegration over the entire length of the implant. In addi-

connected. The flap was then sutured using 4-0 Vicryl. Eight weeks after implant placement, the healing abutment was removed using the same anesthesia and sedation procedures, and the abutment was fixed with a torque of 30 Ncm. A prosthetic crown made of Co-Cr metal alloy was then constructed to be similar to natural dentition and adhered to the abutment using FujiCEM (G.C. Co., Tokyo, Japan) and allowed to function (Fig. 2). After 8 weeks of functional loading, test animals were sacrificed using a pentobarbital sodium overdose. Then, after perfusion fixation using a 10% formaldehyde solution via the carotid artery, the mandible block was cut and harvested.

Table 1. Distribution of examined implants

Group	SM	CM	CR	Total
Dog1	4	4	2	10
Dog2	4	2	4	10
Dog3	2	4	4	10
Total	10	10	10	30

SM, straight-machined implant group; CM, concave-machined implant group; CR, concave-roughened implant group.



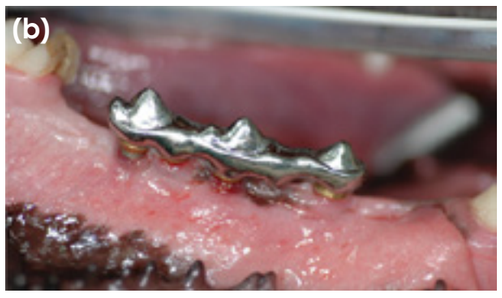


Fig. 2. Clinical features of implant placement (a) prosthesis setting (b). The lowest border of transmucosal profile of the implant was at the alveolar crest level.

Radiographic measurements

Under anesthesia and sedation, radiographs were taken using a portable X-ray system (Port-X II, Genoray Co., SungNam, South Korea) at the following times: immediately after surgery, immediately after connecting the healing abutment (4 weeks after implant placement), immediately after connecting the prosthetic crown (8 weeks after implant placement), and immediately before sacrifice (16 weeks after implant placement). A parallel imaging technique, that is, with the film parallel to the implant and perpendicular to the cone, was used.

To measure the height of marginal bone, one trained and blinded investigator measured the distance from the implant apex to the top of marginal bone using PACS software (Digi-X ver. 2.7.5.1, Hanjin Digi-X Co., Seoul, South Korea) at mesial and distal sides, twice at intervals of 2 weeks, and bone resorption was calculated by abstracting the means of measured values from implant length.

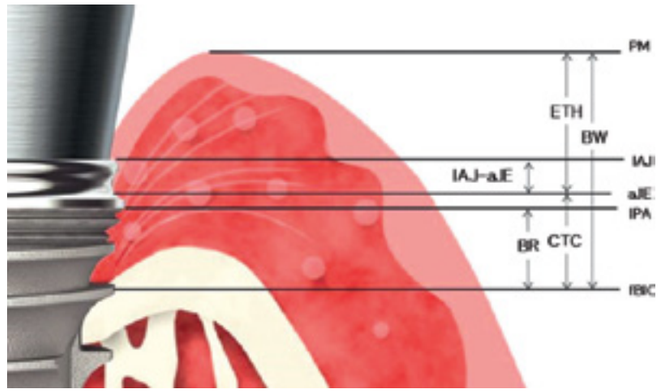


Fig. 3. Histometric landmarks and measurements: implant-abutment junction (IAJ), initial position of alveolar bone (IPA), marginal portion of mucosa(PM), apical portion of junctional epithelium(aJE), first bone–implant contact (fBIC), bone resorption(BR), connective tissue contact(CTC), epithelial tissue height(ETH), biological width (BW) from the implant-abutment junction to apical portion of the junctional epithelium (IAJ-aJE).

Histometric analysis

Harvested specimen blocks were fixed in neutral buffered formalin solution (Sigma Aldrich, St. Louis, MO, USA) for 2 weeks, dehydrated using an alcohol series, and embedded in Technovit 7200 resin (Heraeus KULZER, South Bend, IN, USA).

To obtain specimens of the central part of implants, embedded specimens were cut along the long axis of the implant in the mesiodistal direction into 400-μm-thick slices. Slices were trimmed using an EXAKT grinding machine (KULZER EXAKT 400CS, EXAKT, Norderstedt, Germany) into 30-μm-thick final specimens. These specimens were then stained with Masson's trichrome, and digital images of were taken using a light microscope (Leica DMLB, Leica, Wetzlar, Germany) with a built-in CCD camera (Polaroid DMC2 Digital Microscope Camera, Polaroid Corporation, Cambridge, MA, USA) at magnifications of 912.5, 950, and 9100. Images were saved, and the following landmarks were selected (Fig. 3).

IAJ: implant-abutment junction
IPA: initial position of alveolar bone
PM: marginal portion of mucosa
aJE: apical portion of the junctional epithelium
fBIC: first bone–implant contact

One trained and blinded investigator measured the following items at mesial and distal sides using i-Solution ver. 8.1 (IMT i-Solution, Inc., Coquitlam, BC, Canada).

IPA-fBIC: bone resorption (BR)
aJE-fBIC: connective tissue contact (CTC)
PM-aJE: epithelial tissue height (ETH)
PM-fBIC: biological width (BW)
IAJ-aJE: from the implant-abutment junction to the apical portion of the junctional epithelium

Statistical analysis

Statistical analysis was performed using spss ver. 18.0 (SPSS, Chicago, IL, USA). To analyze measurements taken at mesial and distal sides in individual test animals and measurements of individual implants, groups were compared using Kruskal–Wallis test. When the Kruskal–

tion, a micro-thread is used to reduce alveolar bone resorption by distributing the masticatory force applied to the cervical part of implants (Hermann et al. 2007). For the two-piece implant, which is the most widely used in clinical practice, the microgap would be posi¬tioned in important connective tissue area within the biological width if such soft tissue improvement design is applied to the abutment, and downward movement of the epithelium due to destruction of the connective tissue attachment may cause bone resorption in cases requiring frequent detachment of the abutment in clinical practice. In addition, studies that have used finite element analysis have reported that in platform switching, stress on the alveolar ridge area next to the interface between the implant and a conical or concave implant decreases, whereas much stress is delivered to the screw and abutment, which could lead to fracture; and thus, strength reinforcement is required (Maeda et al. 2007; Quaresma et al. 2008). In the present study, a transmucosal design that employed a concave profile and a roughened surface was created to improve soft tissue integration, reduce bone resorption, and to overcome the aforementioned problems. The implant with a transmucosal design had a concave profile at the lateral area of the cervical part, immediately below the implant platform, and a machined surface or a roughened surface in the same area to reduce fine damage to connective tissue caused by detachment of the abutment, while main¬taining the thickness of the cervical part of the abutment.

This study was conducted to assess the influence of these two types of implant design on the initial response of peri-implant tissues by using comparative radiographic and histological analyses of marginal bone resorption and soft tissue healing patterns of different transmucosal designs in a canine model.

Materials and methods

Test animals and implant designs

In this study, three healthy beagle dogs (with¬out periodontal disease) aged 1.5–2 years and weighing 12–15 kg were used. Animal selection and management and the surgical protocol were approved by the Ethics Committee on Animal Experimentation at Chonnam National University (CNU IACUC-YB-R-2010-10). The implants used in this study were of the tapered-screw type with an RBM surface (Ra = 1.2–1.5) and a coronal micro-thread: an external-hex-connection-type implant (Neobiotech Co., Seoul, Korea). The fixture's distance from the platform to the apex was 6.0 mm, the implant diameter was 3.5 mm, and hexagon height and diameter were 0.7 and 2.7 mm, respectively. This fixture was connected with cemented-type abutment (collar: 2 mm, height: 4 mm) with an internal-hex-connecting portion (connected by a titanium fixture screw). The implants were classified into the following three groups according to the design of the cervical portion: the straight-machined (SM) implant group, the concave-machined (CM) implant group, and the concave-roughened (CR, Ra = 0.5) implant group. There were 10 implants per group. The concave profiles (depth 0.1 mm and width 0.5 mm) that were used in the transmucosal parts of the CM and CR groups were as described in Fig. 1.

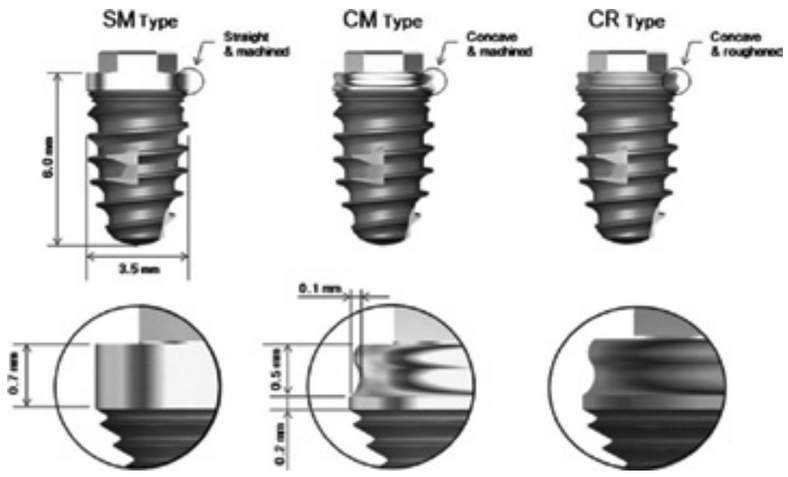


Fig 1 EB-implants(NeobiotechCo)withthreedifferenttransmucosaldesigns.SMtype:straightandmachined,CMtype:concaveandmachined,CRtype:concaveandroughened(Ra=0.5).

Test procedure

Tooth extraction from test animals was performed in a sterilized operating room under 1-2% Isoflurane (Aerane® Ilsung Pharm. Co., Seoul, South Korea) and oxygen general anesthesia after anesthesia induction using an intramuscular injection of 48 lg/kg of medetomidine (Domitor® Pfizer, Exton, PA, USA), 3 mg of tiletamine/zolazepam (Zoletil® Virvac, Carros, France), and 5.4 mg/kg of tramadol. To prevent infection, 20 mg/kg of cefazolin (Cefazolin® Chongkundang Pharm. Co., Seoul, Korea) was intravenously injected and lactated Ringer's solution (5 ml/kg/h) was administered until the end of surgery. Local infiltration anesthesia of mucosa was performed using 2% Lidocaine HCL (Yu-Han Co., Gunpo, South Korea) containing 1 : 100,000 epinephrine. The root furcation areas of mandibular premolars and first molars were cut using a fissure bur, and mesiodistal roots were carefully extracted. After visualizing residual root, 4-0 Vicryl (Vicryl, Ethicon, Miami, FL, USA) sutures were placed to aid healing. After extraction, 2 mg/kg of carprofen (Rimadyl® Pfizer) and 20 mg/kg of amoxicillin were administered for 1 week; oral sterilization was performed 1–2 times a day using 2% chlorohexidine in a syringe; and a soft diet was given. After a 2-month healing time, for implant placement, general and local anesthetics were administered to test animals using the above described method, and a crestal incision was performed. A full-thickness flap was then raised to separate it from gingiva, and the alveolar crest was flattened by cutting cortical bone as little as possible using a denture bur. Bone was then removed using a guide drill, a 2.0-mm first drill, a 3.0-mm pilot drill, and a 3.2-mm final drill (Neobiotech Co) in the implant surgical at 1200 rpm under saline irrigation. Following this, 10 implants were randomly placed in each dog (five in the left half of the mandibular arch, and five in the right half) at a torque of 30 Ncm (Table 1). Implants were placed at least 3 mm apart and in such a way that the interface between the lower area of the transmucosal part and the microthread matched the crest of alveolar bone.

To make prosthetic crowns, a cemented-type abutment (4 mm height fabricated with grade 4 titanium, Neobiotech Co) was connected to the implant and a lateral impression of the entire mandible was taken. The abutment was then removed, the cover screw was tightened, and the flap was firmly sutured using 4-0 Vicryl. Forty-eight hours after surgery, penicillin G procaine and penicillin G benzathine (1 ml/5 kg) were injected intramuscularly. In addition, after surgery, for plaque control, oral sterilization was performed once or twice daily using 2% chlorohexidine in a syringe, and a fluid diet was given. Four weeks after the implant placement, the cover screw was removed under the same anesthesia and sedation procedures as that described above, and the healing abutment was

Wallis test was statistically significant, multiple comparison analysis was performed as a post hoc test, using the Mann–Whitney U-test. And to analyze the time lapse factor of radiographic measurements in each group, the Friedman v^2 test was used. Values of $P < 0.05$ were taken to indicate statistical significance.

Results

Clinical findings

All 30 implants with prosthetic crowns functioned well without complications or failure of osseointegration until sacrifice, although healing after implant placement differed slightly between animals. Some implants had calculus deposition, and neighboring soft tissues usually exhibited mild redness or gingival swelling.

Radiographic analysis

According to radiographic measurements, 65% of total bone resorption occurred in the first 4 weeks, 22% in the following 4 weeks, and 13% in the following 8 weeks. During the entire period, the CM group showed least bone resorption and the SM group most bone resorption. The CR group showed most bone resorption over time (Table 2). Friedman v^2 tests were used in each implant group to analyze the repeated measured data. The test result indicated that there would be statistically significant difference among time lapses. The Kruskal–Wallis test was used for the analysis of the bone resorption difference among the implant groups. According to Kruskal–Wallis test, it showed that each implant group brought out significant difference in 4 and 16 weeks, respectively. ($P < 0.05$, Table 3 and 4). Then, we carried out the Mann–Whitney U-test; we could conclude that there were statistically significant difference between SM and CM implant group, and between CM and CR implant group, respectively. ($P < 0.05$, Table 5).

Table 2. Radiographic mean values (mm ± SD) for crestal bone loss of implants

Group	4 weeks	8 weeks	16 weeks
SM	1.08 ± 0.62	1.49 ± 0.55	1.61 ± 0.56
CM	0.54 ± 0.43	0.73 ± 0.47	0.81 ± 0.49
CR	0.87 ± 0.51	1.21 ± 0.55	1.46 ± 0.58

SM, straight-machined implant group; CM, concave-machined implant group; CR, concave-roughened implant group.

Table 3. The Friedman tests of time factor in radiographic analysis

Group	4 weeks	8 weeks	16 weeks	Test results
SM				
Measured data	20	20	20	$v^2 = 36.750$
Average rank (SD)	1.025 (0.1118)	2.150 (0.2856)	2.825 (0.2447)	df = 2
				P = 0.000
CM				
Measured data	20	20	20	$v^2 = 15.579$
Average rank (SD)	1.450 (0.7052)	2.050 (0.5356)	2.500 (0.3627)	df = 2
				P = 0.000
CR				
Measured data	20	20	20	$v^2 = 38.079$
Average rank (SD)	1.075 (0.1832)	1.950 (0.2236)	2.975 (0.1118)	df = 2
				P = 0.000

SM, straight-machined implant group; CM, concave-machined implant group; CR, concave-roughened implant group.

Table 4. The Kruskal–Wallis test results of implant type factor in radiographic analysis

Time lapse	Implant type	N	Sum of average ranks	Test statistics
4 weeks	SM	20	26.35	$x^2 = 7.309$
	CM	20	36.10	df = 2
	CR	20	29.05	P = 0.026*
8 weeks	SM	20	34.10	$x^2 = 4.900$
	CM	20	33.10	df = 2
	CR	20	24.30	P = 0.086
16 weeks	SM	20	32.38	$x^2 = 22.212$
	CM	20	18.50	df = 2
	CR	20	40.63	P = 0.000**

SM, straight-machined implant group; CM, concave-machined implant group; CR, concave-roughened implant group.
*Means statistically significant P value under 0.05 type I error.
**Means statistically significant P value under 0.01 type I error.

Table 5. The multiple comparison test result of implant type factor in radiographic analysis

Period	Implant type	SM	CM	CR
4 weeks	SM	–	0.015*	0.298
	CM	0.015*	–	0.081
	CR	0.298	0.081	–
16 weeks	SM	–	0.004*	0.019
	CM	0.004*	–	0.000*
	CR	0.019	0.000*	–

SM, straight-machined implant group; CM, concave-machined implant group; CR, concave-roughened implant group.
*Means statistically significant P value under a modified type I error.

Histological analysis

Of the 30 implants, 10 were not measured because of physical damage due to detachment of prosthetic crowns during tissue specimen preparation; 19 were measured at their mesial and distal sides; and one was measured only on one side. The total number of measurements on one side was 39, that is, 12 in the SM group, 14 in the CM group, and 13 in the CR group. Regarding mucosal membranes, junctional epithelial cells were observed beneath the keratotic sulcus epithelium, and connective tissues attached to implants had large numbers of collagen fibers and were similar to wound tissues that characteristically have low numbers of fibroblasts and vessels. In the SM group, nearly the entire transmucosal part came in contact with epithelial tissue, and in about 85% of the SM group, aJE was observed at the lower part, unlike that observed in the CM and CR groups. In the concave area of the CM group, good connective tissue was observed and the amount of attached connective tissue was greatest (Figs 4 and 5).

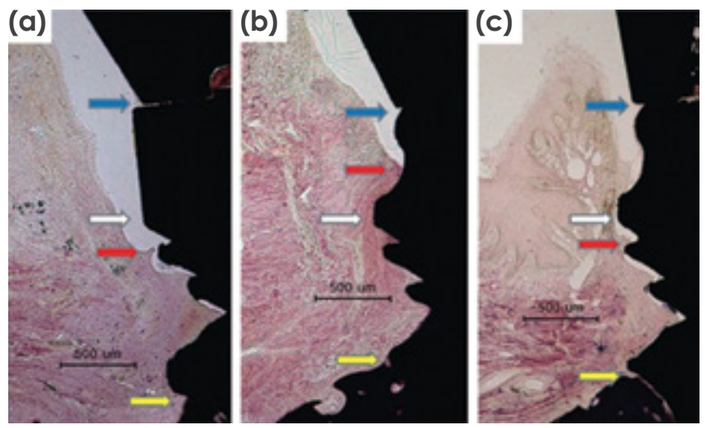


Fig. 4. Soft tissue contact around the cervical portion (Masson's trichrome stain, Original magnification 950). (a) SM group; (b) CM group; (c) CR group. Red arrow: aJE (apical portion of the junctional epithelium), blue arrow: IAJ (implant-abutment junction), white arrow: IPA (initial position of alveolar bone), yellow arrow: fBIC (first bone–implant contact).

Histometric analysis

The CM group showed lowest bone resorption (BR) and biological width (BW), the CM group showed the highest BR, and the CR group showed the longest BW and greatest epithelial tissue height (ETH). The distance between the implant platform and the apical portion of junctional epithelium was greatest in the SM group and least in the CM group. The Kruskal–Wallis test and a post hoc test showed a significant difference in the BR, ETH, BW, and IAJ-aJE, but not in the connective tissue contact (CTC) between groups. The BRs of the CM group and the other groups differed significantly, but not those of the SM and CR groups. IAJ-aJE differed significantly between the SM and CM groups, but not between the CR group and the other groups (Table 6).

Table 6. Histometric mean values (mm ± SD) for each implant groups

Group	Bone resorption	Connective tissue contact	Epithelial tissue height	Biological width	IAJ-aJE
SM	1.44 ± 0.54[a]	1.04 ± 0.40	1.84 ± 0.56[a,b]	2.88 ± 0.66[a,b]	1.24 ± 0.44[a]
CM	0.60 ± 0.38[b]	0.91 ± 0.40	1.44 ± 0.49[a]	2.36 ± 0.63[a]	0.48 ± 0.31[b]
CR	1.15 ± 0.56[a]	0.99 ± 0.36	2.19 ± 0.51[b]	3.18 ± 0.63[b]	0.73 ± 0.76[a,b]

SM, straight-machined implant group; CM, concave-machined implant group; CR, concave-roughened implant group.
Within the same column, the means with the same superscript letters are not statistically different from one another. IAJ-aJE: from implant-abutment junction to apical portion of junctional epithelium.

Discussion

This study was conducted to assess the influences of concave-machined and concave-roughened profiles of the transmucosal portion just below the implant platform on initial bone resorption and soft tissue attachment after implant placement, to overcome the weak structure of the cervical portion of the abutment due to platform switching and conical connection and to overcome lack of soft tissue adherence due to the repetitive detachment of the abutment. Also, in a recent study, implants with an external-hex connection showed faster bone loss during the early healing stage than implants with the internal mores tapered connection (Weng et al. 2011). We sought to determine early marginal bone resorption and soft tissue healing patterns by transmucosal design for implants with an externalhex connection.

In humans, the first 3–4 months after implant placement is a critical period for osseointegration, and during this period, bone loss in the alveolar ridge is most intensive. Bone resorption during the first 4 weeks is known to be mainly due to tissue response to surgical injuries, such as those associated with drilling heat, periosteum elevation, and implant placement pressure (Hermann et al. 1997; Oh et al. 2002). Most of the initial bone loss starts within 2 weeks and is closely related to wound healing. Studies have reported that initial bone loss is related to connective tissue rather than to epithelial cells and that decreased blood flow, persistent inflammation, and increased scarring increase bone loss (Weber et al. 1996; Joly et al. 2003; Berglundh et al. 2007). Connective tissue, which is important for the maintenance of the marginal bone, forms completely within the first 4–6 weeks after implant placement, and the epithelial cell layer is fully formed after 6–8 weeks (Berglundh et al. 2007). In the present study, 22% of bone resorption occurred during the first 4–8 weeks, which we believe is related to soft tissue healing after secondary surgery. In addition, during the 8 weeks following the first 8 weeks, bone resorption was mild (13%) and the influence of functional loading was insignificant, presumably because osseointegration and soft tissue healing had been achieved. Furthermore, the amount of bone resorption was found to change with time. Radiographic analysis showed that the amount of bone resorption differed significantly at weeks 4 and 8 and at weeks 8 and 16, which suggests bone resorption differs over time or that total bone resorption could differ depending on the times after secondary surgery and prosthetic crown connection. This suggestion implies that times of secondary surgery and prosthetic crown connection after implant placement influence the wound healing process and could significantly influence initial bone resorption. In addition, our analysis showed the higher bone resorption between weeks 8 and 16 in the CR group than in the other groups was due to the significant influence of the interaction between time and the roughness of the transmucosal portion of the implant. Accordingly, future differences in bone resorption for different implants could be estimated even during the functional loading period after prosthetic crown connection.

Previous studies have reported on different abutment designs, such as the concave profile, the conical connection, and the platform switching designs, effectively reduce bone resorption by separating the microgap from alveolar bone and by improving the amount and attachment of connective tissue (Tenenbaum et al. 2003; Touati et al. 2005; Kim et al. 2010). However, in the present study, during the entire healing period, the CM group showed about half the bone resorption of the SM group, which indicates that the concave profile of the transmucosal portion of the implant could reduce initial bone resorption substantially as compared with the other profiles. The significantly different bone resorptions displayed by the SM and CM groups were caused by the concave profile, which was employed in the transmucosal portion of the implant used in this study. Furthermore, the concave profile was considered to have caused intergroup differences in bone resorptions by widening the distance between the microgap and alveolar bone and by providing a healing space for connective tissue, because the concave profile is positioned just above alveolar bone. The significantly different bone resorptions observed in the CM and CR groups were

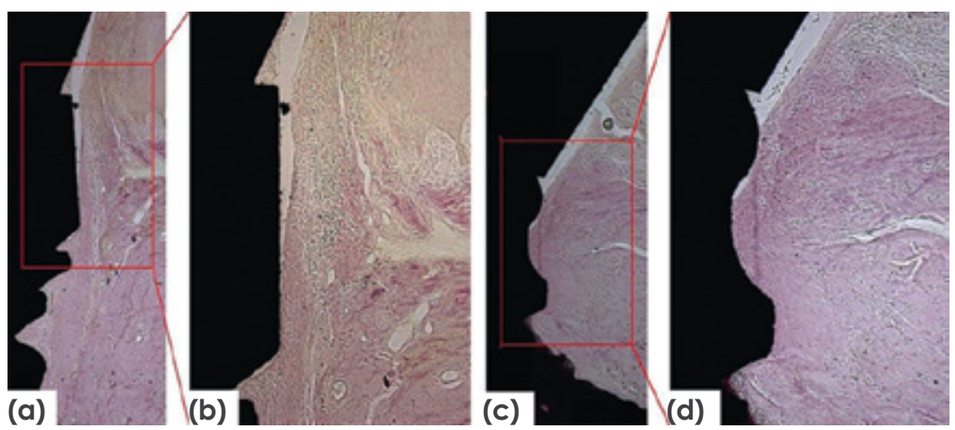


Fig. 5. Junctional epithelium and connective tissue contacts of the SM (a,b) and the CM implants (c,d). For the CM implant, dense connective tissue was found to be attached in the concave area. (Masson's trichrome stain, original magnifications 950 (a,c) and 9100 (b,d)).

deemed to have been due to difference between the surfaces of the transmucosal portions of implants. In this study, the transmucosal portion was located in the supra-alveolar crest because we wanted to determine early marginal bone resorptions and soft tissue healing patterns for the different transmucosal designs of implants with an external-hex connection, as shown in Fig. 2. This study design was possible to make the insufficient oral hygiene control after the healing abutment connection, which resulted in the plaque deposition, consequential inflammation, and downward movement of the epithelium. Consequentially, the design of this study might have more increased bone resorption in the CR group than in the CM group; this is contrary to the results of previous studies, in which a rough surface was found to be effective at promoting osseointegration and soft tissue attachment (Abrahamsson et al. 2002; Kim et al. 2006; Rossi et al. 2008). Actually, many researchers have shown that exposed rough titanium surfaces enhance microbial adhesion (Quirynen et al. 1993; Quirynen & Bollen 1995; Kuula et al. 2004; Sardin et al. 2004).

Based on our statistical analyses of radiographic and histometric results, the concavemachined profile of the transmucosal portion of the implant that was used in this study appears superior in terms of reducing bone resorption in the lower area, as it could be more advantageous than the straightmachined profile with respect to connective tissue contact during the wound healing period, and thus, soft tissue, particularly connective tissue, could be positioned higher. It is considered that this profile aids connective tissue formation and attachment by playing the role of a scaffold for tissue when connective tissue forms and that it allows neighboring connective tissues to remain hanging due to the elasticity of connective tissue after it has formed and stabilized. It is noteworthy that in this study, bone resorption was significantly different in the three groups, that is, it depended on the shape of the transmucosal portion above alveolar bone. It is considered that further studies on this topic are required. However, it is possible that the conditions of jawbones and differences in tissue healing due to inflammation or infection had strong influences on measurement values because of the small numbers of test animals and implants used. Most previous animal model studies on the effects of the cervical shape and surficial designs of two-piece implants have compared the influences of cervical design using implants made by different manufacturers by placing the platform as high as the alveolar bone ridge. Moreover, the majority of studies on platform switching have addressed the effects of platform design of the cervical portion of the lower abutment. This study is meaningful because unlike previous studies, the concave profile was used in the cervical portion of the platform of the externalconnection-type implant, and the implant was placed such that the concave profile was positioned just above the alveolar bone ridge as a novel transmucosal portion. Further studies on a longer and deeper concave profile within the allowed range of the structural strengths of the transmucosal portion of the implant or with a concave profile with a nanorough or nanogrooved surface are required to determine whether outcomes could be improved. The short observation period and small number of test animals used in this study were undoubtedly limitations. If histological assessments and histometric analyses were performed at the same time as radiographic measurements in a larger number of test animals, changes in soft tissue could be analyzed in greater detail by quantifying changes in healing patterns, scar patterns, spatial shapes, qualitative compositions, and components of biological width.

Nevertheless, despite its limitations, this study showed firmer connective tissue attachment in the concave transmucosal portion in the CM group than in the SM and CR groups. Thus, the study shows that concavemachined transmucosal portion of the external-connection-type implant could induce less bone resorption and better promote connective tissue attachment than a straightmachined profile.

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Influence of implant transmucosal design on early periimplant tissue responses in beagle dogs.

Histologic Evaluation of a Retrieved Endosseous Implant: A Case Report

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An implant that had penetrated the nasal cavity of a 53-year-old woman was removed after 10 months. The implant had a resorbable blast media surface and an external connection. Histomorphometric evaluation showed that the mean bone-implant contact ratio was 88.08%, and excellent osseointegration was observed. The mean bone fill between threads was 78.46%.

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Osseointegration was initially defined as direct contact between living bone and an implant as seen under light microscopic examination. This was subsequently changed to a structural and functional connection between living bone and the implant surface.[1,2] More recently, Albrektsson and Zarb[3] defined it as the absence of specific symptoms clinically with the implant firmly held within the bone structure and maintained under normal loading conditions, such as masticatory function.

Histomorphometrically, the bone-implant contact (BIC) ratio and bone density have been applied to represent the level of bone formation between the implant threads and thus evaluate the level of osseointegration. The greater the volume of bone formation in the vicinity of the implant, the higher the BIC ratio and the better the implant withstands loading. The reported BIC ratio of implants after initial loading is 25% for type 4 bone quality (D4) and 80% for type 1 bone quality.[4] Recently, the osseointegration period of a rough surface was reported to be shorter than that of a smooth surface.

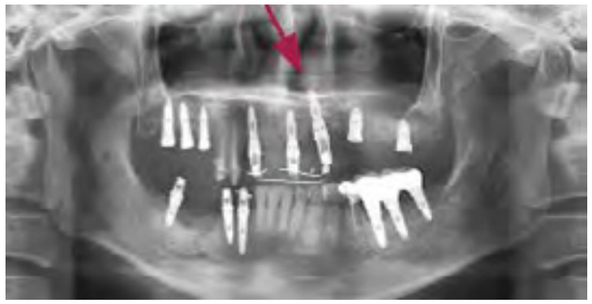


Fig 1 The implant placed in the maxillary left canine area had penetrated the nasal fossa.

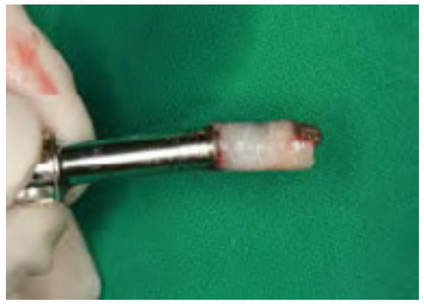


Fig 2 Appearance after removing the implant using a trephine bur.

Augmenting the surface roughness using various methods may enhance the resistance to shear force and maximize the initial fixation and osteoconduction effect.[5,6]

Since histologic evaluations of implant osseointegration have been conducted primarily in animals, less is known of the actual osseointegration reaction in humans.

The occasional case reports and histologic evaluations of implants removed from humans as a result of prosthesis failure and poor placement are a great help. In this case report, the authors evaluate an implant placed in the maxillary anterior area that was removed together with the adjacent bone to examine the osseointegration reaction by assessing the BIC ratio, bone density, and histologic findings.

Case report

A 53-year-old woman was referred to the Boston Hub Dental Clinic, Seoul, Korea, because she developed persistent discomfort near the nasal cavity after implant treatment performed at another dental clinic. The cause was found to be perforation of the nasal floor by an implant placed in the maxillary left canine area (Fig 1). The placement angle and depth were determined to be inappropriate for fabrication and maintenance of a maxillary prosthesis. This implant had been placed immediately after tooth extraction and subjected to early loading 6 weeks after placement by connecting provisional acrylic resin teeth enforced with wires to adjacent implants.

Ten months after implant placement, no movement of the implant or inflammation of the periodontal tissues was detected. The implant (SinusQuick EB, Neobiotech) was seen to have perforated the nasal cavity using panoramic radiographs and computed tomography scans. The surgical record of the referring dental clinic indicated that the implant was 11.5 mm in length and 4.0 mm in diameter. A provisional tooth was prepared using an osseointegrated posterior implant. Underlocal anesthesia, a full-thickness flap was elevated, and the implant was removed together with the adjacent bone using a trephine bur 4.5 mm in diameter. No BIC had developed at the implant apex (Figs 2 and 3). The removed sample was fixed immediately in 10% formalin solution and sent for histologic evaluation. At the time of implant removal, an additional implant was placed in an adjacent area.

Histologic findings

The implant specimen was fixed in 10% neutral-buffered formalin, dehydrated in a graded series of alcohols, and embedded in methyl methacrylate. The samples were cut parallel to the longitudinal axis of the implant in the mesiodistal plane using an Exakt cutting and grinding system (Exakt). The sections were ground to a thickness of 20 µm and stained using hematoxylin-eosin.

The following parameters were measured using image-analyzing software (Analysis LS starter version 2.8, Olympus): BIC (the length of the bone surface border in direct contact with the implant divided by the complete implant periphery) and interthread bone density (the area of bone inside the threads divided by the complete area inside the threads).

The implant showed osseointegration with the adjacent bone tissue (Figs 4 and 5). The BIC pattern appeared to produce broad-based direct contact. Well-organized lamellar bone containing osteocytes was observed along the implant surface (Fig 6). The mean BIC was 88.08%, and the mean interthread bone density was 78.46%.

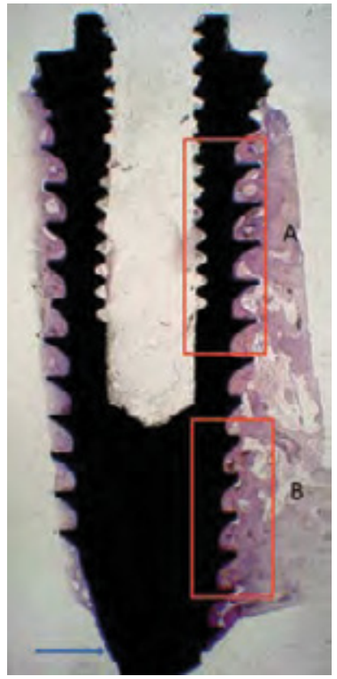
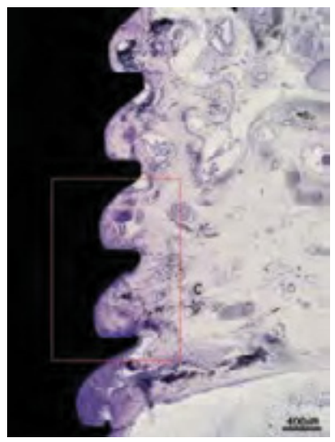


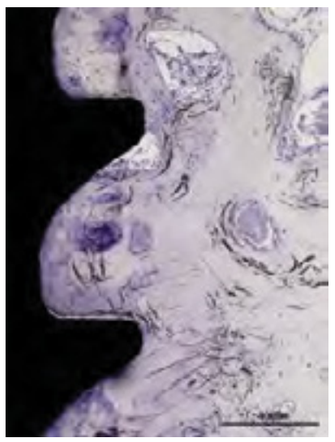
Fig 3 Histologic view of the implant (original magnification ×1.25). No BIC developed at the implant apex (arrow).

Fig 4 Higher magnification of box A in Fig 3.

Fig 5 Higher magnification of box B in Fig 3.

Fig 6 Higher magnification of box in Fig 5.





Discussion

Implant surface texture and design are important factors for initial osseointegration. The microscale rough topography of a porous implant can favorably affect angiogenesis, cellular migration, activity, and function, resulting in greater BIC and mechanical interlocking.[7,8]

Landi et al[9] reported a histologic analysis of a failing three-part dental implant. The coronal section of the implant consisted of a long, smooth collar, and the central and apical parts were threaded and lightly tapered. Bone loss was visible in the most coronal area. The alveolar bone loss stopped at the level of the fourth thread. Sakakura et al[10] performed a histomorphometric evaluation of a threaded, sandblasted, acid-etched implant retrieved from the mandible of a 68-year-old man because of fracture of the abutment screw after functioning for 40 months. This showed 75.40% BIC and 89.30% bone fill within the limits of the implant threads.

Sennerby et al[11] examined the structure of the bone-titanium interface of seven retrieved oral implants placed in humans and removed after 1 to 16 years. The implant threads were well filled (79% to 95%) with dense lamellar bone. A large proportion of the implant surface (56% to 85%) achieved direct contact with mineralized bone. Suzuki et al[12] performed a clinical and histologic evaluation of immediately loaded posterior implants in nonhuman primates. After 90 days, the samples were evaluated histologically. The control group showed 50.34% to 64.13% BIC versus 43.23% to 75.72% (mean, 62.40%) for immediately loaded implants. Grassi et al13 evaluated the histologic human bone integration on machined and sandblasted, acid-etched, titanium surfaces in type IV bone. Implants were placed, and samples were collected after a 2-month healing period. The mean BICs were 20.66% ± 14.54% and 40.08% ± 9.89% for the machined and sandblasted, acidetched surfaces, respectively. The bone density in the thread area was 26.33% ± 19.92% and 54.84% ± 22.77% for the respective surfaces. Lazzara et al[14] performed a human histologic analysis of Osseotite (Biomet 3i) and machined surface implants. After a 6-month healing period, samples were collected and evaluated histomorphometrically. The mean BIC for the Osseotite surface was 72.96% ± 25.13%, and that for the machined surface was 33.98% ± 31.04%. Brunel et al[15] observed a 60% to 70% BIC for titanium plasma-sprayed implants removed from the maxilla after 14 months. After 9 months, Degidi et al[16] reported 60% BIC for a porous anodized implant subjected to immediate loading.

Jung et al[17,18] evaluated the relationship between implants that had penetrated the maxillary sinus cavity and sinus complications. There were no clinical signs of sinusitis in any patient. However, computed tomography showed postoperative sinus mucous thickening around 14 of 23 implants. Although sinus membrane perforation is not related directly to the occurrence of sinus complications, it has been reported that dust or bacterial accumulation around the implant apex, with excessive exposure, may cause delayed sinusitis. However, few studies have examined the histology of implants that have penetrated the nasal cavity or its complications. In this case, no osseointegration was seen in the apex region of histologic specimens of an implant that was removed 10 months after penetrating the nasal cavity.

The SinusQuick external-connection implant system with a resorbable blast media surface has a rounded form for sufficient soft tissue sealing in small 0.5-mm spaces and microgrooves to augment the fixation force of the maxilla while minimizing bone loss. The implant body is tapered-straight-tapered; the thread has a deep, thin, inverted triangular shape to maximize the bone volume between threads, with easy self-tapping abilities and excellent resistance to vertical occlusal forces and lateral pressure. In this case, the mean BIC ratio was 88.08%. Excellent osseointegration was achieved, and the mean bone fill between threads was 78.46%. In the case reported by Sakakura et al,[10] the sandblasted, large-grit, acid-etched implant removed after 40 months had a 75.40% BIC ratio and 89.30% bone density. Remarkably, despite the short 10-month healing period, the implant in this study showed excellent osseointegration in comparison with the 79% to 95% bone density between threads reported by Sennerby et al11 for seven implants removed after 1 to 16 years.

Conclusions

A resorbable blast media surface implant removed 10 months after nasal cavity penetration was observed histologically. No BIC developed at the implant apex. Histomorphometric evaluation showed that the mean BIC ratio was 88.08%, with excellent osseointegration. The mean bone fill between threads was 78.46%.

Acknowledgment

The authors reported no conflicts of interest related to this study.

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Influence of Transmucosal Designs of Dental Implant on Tissue Regeneration in Beagle Dogs

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Abstract

This study was conducted to evaluate the influence of concave machined and concave microgrooved profiles of the transmucosal portion of implants on early peri-implant tissue regeneration. We assessed implants with 3 different transmucosal profiles: the bevel group that had only a bevel in the transmucosal part, bioseal group and bioseal/ groove group that had a micro-groove in the S-shaped portion of the implant. A total of 36 implants (12 of each type) were placed in the edentulous mandibular ridges of 6 beagle dogs. We used radiographs to investigate the mesio-distal change of the marginal bone. Bucco-lingual bone resorption and soft tissue reactions were evaluated histologically. Radiographic and histological analysis did not show any difference in mesio-distal or bucco-lingual marginal bone resorption among any of the 3 groups ($p > 0.05$). The bioseal and bioseal/groove groups had more rigid connective tissue attachment than that in the bevel group. However, the bevel group had significantly long junctional epithelium attachment and the bioseal and bioseal/groove groups had long connective tissue attachment ($p < 0.05$). Implants with S-shaped concavity of the transmucosal portion resulted in a firmer connective tissue barrier, and thus, a better soft tissue regeneration, than implants with straight bevel.

Key words:

transmucosal design, marginal bone resorption, biologic width, connective tissue, junctional epithelium

1. Introduction

Various factors must be considered for long-term implant treatments to be functionally and esthetically successful. The initial stability of the implant, osseointegration, and soft tissue healing are essential for successful treatment, and the function and aesthetics of implants must be maintained by protecting osseo-integration after loading with a firm biological seal of the surrounding soft tissues.[1]

The causes of early marginal bone resorption include periosteal elevation, bone reduction, excessive stress, bacterial invasion, and invasion of the biological width after implant surgery.[2] Peri-osteal elevation after surgery may affect the blood supply; if there is rich cancellous bone at the site, its impact on the absorption of the cortical bone is insignificant.[2] While there are claims that trauma due to drilling during implant insertion causes initial alveolar bone loss,[3] there are often cases in which the bone increased.[2] If an overload is transferred to the bones that surround the implant, early marginal bone resorption occurs,[4,5] however relatively weak loading or progressive loading prevents bone resorption.[6,7] Bacteria are the fundamental cause behind the loss of surrounding bones in the dentulous regions; but the role of bacteria in bone loss associated with implants is limited and it is difficult to view bacteria the cause of early marginal bone resorption.[8-10]

It has been shown that even in implants, marginal bone resorption occurs until the formation of the least amount of soft tissue, called biological width, which prevents osseointegration.[11] There have been numerous studies of the impact of the biological width on the surrounding tissues in implants.[12-15] Although the biological width of implants is generally stable, over time it typically increases in the junctional epithelium attachment and decreases in the connective tissue attachment.[14,15] Connective tissue attachment is more important than junctional epithelium attachment for preserving marginal bone.[16]

The design of the cervical portion of implants, located at the boundary between the soft and hard tissues may affect soft tissue reaction and marginal bone preservation.[12,13,16] Platform switching is a technique that connects an abutment with a small diameter to the platform of the inserted implant.[17,18] It reduces marginal bone resorption, not only by preventing the apical down-growth of the barrier epithelium, but also by reducing the stress applied to the marginal bone.[19-21] Moreover, the concave design of the transmucosal part of the implant is shown to increase soft tissue thickness and enable firm attachment of the connective tissue.[16] The surface roughness of the cervical portion of implants or microthread design of implants reduces marginal bone resorption.[22,23] Thus, implants with cervical designs have recently been used extensively in clinical practice.[22-24]

Smooth implant surfaces may allow pronounced downgrowth of epithelial tissue, unlike rougher surfaces.[25] Less epithelial downgrowth and longer connective tissue seal is associated with implants that have shallow horizontal grooves than that associated with machined implants.[26] A grooved surface might have a conductive effect on connective tissue adhesion during healing, which would inhibit epithelial downgrowth.[27] Because microtextured implants may enhance the tissue healing response through their structural resemblance to the natural extracellular matrix network,[28,29] and because pillars may reduce inflammation and formation of capsules around implants,[30] microtextures may inhibit epithelial downgrowth.[26,27]

Existing studies on the design of the cervical portion of implants, which compared implants from different manufacturers showed a certain degree of difference in portions other than the cervical portion and not only in the size but also in the design; further, these studies could not attribute the impact of using different implants solely to the design of the cervical portion.[12,16,22-24] Furthermore, even among studies on the design of the cervical portion of the implant, very few are on the design of the inferior transmucosal portion of platform switching.

We evaluated the influence of design of the transmucosal portion of inferior implants with platform switches on changes in marginal bone and soft tissue regenerations. For this in vivo investigation, we produced and used implants in the form of a straight bevel around the transmucosal portion of the inferior platform switch; implants with a concavity in the form of an "S" for long attachment of connective tissues; or implants with a microgroove in the form of an "S"; further, the manufacturer, size, and overall design were identical for all implants.

2. Materials and Methods

2.1 Implant Design

We used implants (Neobiotech Co., Seoul, Korea) with 3 designs of the transmucosal portion. The bevel group had only a bevel in the transmucosal part; the bioseal group had a smooth S-shaped design; and the bioseal/groove group had an S-shaped design with a micro-grooved surface (Table 1). In addition to the transmucosal portion, the implants consisted of a tapered screw with an internal cone connection. In all 3 groups, the transmucosal portion was a machined surface, but the rest of the insertion region consisted of surface-treated resorbable blasting media (RBM) (RA = 1.2-1.5: Fig 1).

Table 1. Implant fixtures used in this study.

Group	n	Description of the transmucosal part	Length (mm)	Diameter (mm)
Bevel	12	Bevel and machined surface	7.5	3.5
Bioseal	12	S-shaped and machined surface	7.5	3.5
Bioseal/ groove	12	S-shaped and micro-groove	7.5	3.5

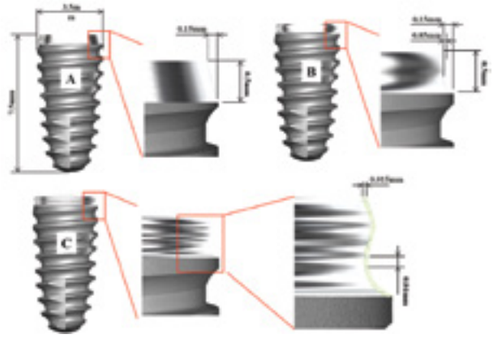

Figure 1. Design of the implant fixtures used in this study. (A) Bevel group; (B) Bioseal group; and (C) Bioseal/groove group. The implants in each group were identical in design, except for the transmucosal portions. The transmucosal portion of the bioseal/ groove group had the same size and shape as that of the bioseal group, but had 0.015 mm micro-grooves placed at 0.04 mm intervals along the surface.

2.2 Animal Study Procedure

We used 6 healthy beagle dogs (without periodontal disease) aged 1.5-2 years that weighed 12-15 kg. Animal selection, management,, and surgical protocol were approved by the Ethics Committee on Animal Experimentation of Chonnam National University (CNU IACUC-YB-R-2010-10). Tooth extraction from the test animals was performed in a sterilized operating room, while the animals were under general anesthesia. Anesthesia was induced using muscular injection of 48 μg/kg of medetomidine (Domitor®, Pfizer, USA), 3 mg of tiletamine/ zolazepam (Zoletil® Virvac, France), and 5.4 mg/kg of tramadol. Anesthesia was maintained using 1-2% Isoflurane (Aerane®, Ilsung Pharm. Co., Seoul, Korea) and oxygen. To prevent infection, 20 mg/kg of cefazolin (Cefazolin®, Chongkundang Pharm. Co., Seoul, Korea) was intravenously injected into each animal, and

a lactated ringer's solution (5 mL/kg/h) was administered throughout the surgery. Further, local infiltration anesthesia using 2% Lidocaine HCL (Yu-Han Co., Gunpo, Korea) with 1:100,000 epinephrine was administered into the mucosa. The root furcation area of all of the mandibular premolars and first molars were cut using a fissure bur, and the mesidodistal roots were carefully extracted. After the residual root was identified, the root furcation area was sutured using 4-0 Vicryl (Vicryl, Ethicon, Miami, USA) to aid healing. For 1 week after tooth extraction, 2 mg/kg of carprofen (Rimadyl®, Pfizer, USA) and 20 mg/kg of amoxicillin were administered daily oral sterilization was performed 1-2 times a day using a syringe filled with 2% chlorhexidine, and animals were provided with a soft diet.

After approximately 4 weeks of healing, each animal was administered a local anesthetic and was under conscious sedation, which is the same method as that for tooth extraction in humans. A full-thickness valve was detached with a crestal incision to the edentulous jaw, and the bone width for the insertion of the implant was secured by flattening the alveolar ridge. Six implants were randomly selected from among the total of 36 implants (12 in each group), and were inserted into each dog. Implants were placed such that there was more than 3 mm between implants. The output torque of the implant surgery engine (NSK Surgic XT, NSK, Tochigi-ken, Japan) was set at 30 Ncm, and the implants were not fully inserted using the engine. Final insertion was performed under direct observation by using a hand torque wrench (Neobiotech Co., Seoul, Korea), such that the boundary portion between the transmucosal portion and the thread was along the alveolar ridge line. Afterwards, a healing abutment (ISH404, Neobiotech Co., Seoul, Korea) was immediately fastened and sutured using a 4-0 absorptive suture (Vicryl®, Ethicon, Somerville, NJ, USA; Fig 2).

Penicillin G procaine and penicillin G benzathine (Deasung Microbiological Lab. Co., Seoul, Korea) were intramuscularly injected (1 mL/5 kg) both immediately after tooth extraction and insertion of the implant and after 48 hr. For 1 week after surgery, oral sterilization was performed twice a day using 2% chlorhexidine in a 10 mL syringe; scaling was performed at 4week intervals. The animals were fed a soft diet.

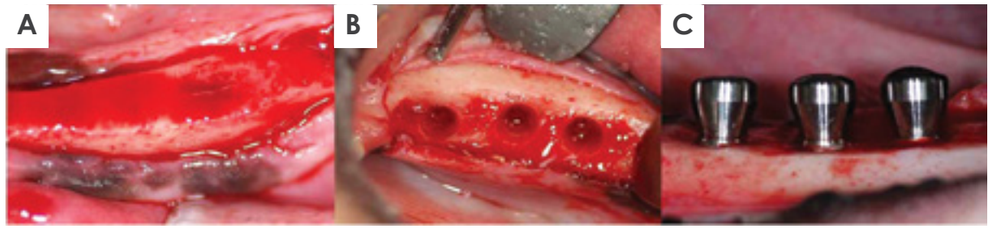

Figure 2. Surgical procedures: (A) Flattening edentulous ridge; (B) Drilling; and (C) After fixation.

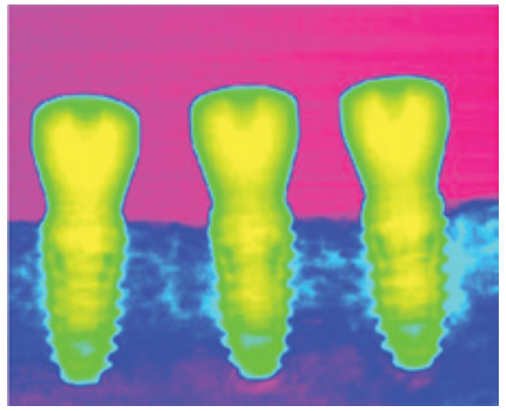

Figure 3. Gray-scale color-coding for radiographic analysis.

2.3 Radiographic Measurement

Radiographic images were obtained a total of 4 times from each animal using a paralleling technique and a portable radiography machine (Port II, Genoray Co., Sungnam, Korea). Radiographs were obtained while animals were under anesthesia and sedation immediately after implant insertion and 4, 8, and 12 weeks later. After the gray-scale image was colorcoded using digital radiography software (CDX-View, PointNix, Seoul, Korea: Fig 3), the implant length and the marginal bone level (the distance from the implant platform to the uppermost marginal bone) were measured from the mesio-distal region, and the marginal bone resorption was calculated by comparing it with the length of the actual implant (7.5 mm) using the following formula:

$$\text{Marginal bone level (mm)} = \frac{\text{Marginal bone level in the radiography image (mm)}}{\text{Implant length in the radiography image (mm)}} \times 7.5\ (\text{mm})$$

*Marginal resorption capacity (mm) = Marginal bone level of the measurement point (mm) - Marginal bone level upon surgery (mm)

2.4 Tissue Specimen Production & Measurement

Twelve weeks after implant insertion, animals were sacrificed by injection of an excessive amount of pentobarbital sodium. A block was extracted from each animal by cutting the mandible. The harvested specimen block was fixed in a neutral buffered formalin solution (Sigma Aldrich, St. Louis, MO, USA) for 2 weeks and then dehydrated in a series of increasingly concentrated alcohol solutions. The specimen block was then embedded in Technovit 7200 resin (Heraeus KULZER, South Bend, IN, USA).

To obtain a specimen of the central part of the implant, the embedded specimen was cut into 400 μm-thick slices along the long axis of the implant in the bucco-lingual direction. Slices were trimmed using an EXAKT grinding machine (KULZER EXAKT 400CS, EXAKT, Norderstedt, Germany) into 30 μm - thick final specimens.

Specimens were stained with hematoxylin-eosin, and digital images of each specimen were taken using a light microscope (Leica DM LB, Fluorescence, Germany) with a built-in CCD camera (Polaroid DMC2 Digital Microscope Camera, Polaroid Corporation, Cambridge, MA, USA) at magnifications of ×12.5, ×50, and ×100. The following landmarks were selected (Fig 4).

PM: Marginal portion of the mucosa
aS: Apical extension of the sulcus
aJE: Apical portion of the junctional epithelium
fBIC: First bone-implant contact
The following measurements were obtained using the selected landmarks (Fig 4).
JE: Length of the junctional epithelium (aS/aJE, mm)
CT: Length of the connective tissue (aJE/fBIC, mm)
BW: Biological width (PM/fBIC, mm)
Marginal bone resorption capacity was ob-

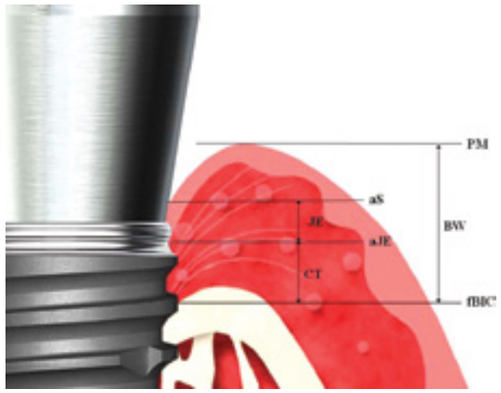

Figure 4. Histometric measurement. PM: marginal portion of the mucosa; aS: apical extension of the sulcus; aJE: apical portion of the junctional epithelium, fBIC: first bone-implant contact; JE: length of the junctional epithelium (aS/aJE); CT: length of the connective tissue (aJE/fBIC); and BW: biological width (PM/fBIC).

Table 2. Mesiodistal marginal bone resorption, as determined by radiographic analysis.

Group	Marginal bone resorption (mm)		
	Week 4	Week 8	Week 12
Bevel	0.36±0.29^{aA}	0.34±0.31^{aA}	0.18±0.10^{aA}
Bioseal	0.45±0.24^{aA}	0.36±0.22^{aA}	0.07±0.07^{aB}
Bioseal/groove	0.39±0.21^{aA}	0.31±0.29^{aA}	0.08±0.05^{aB}

Different lowercase letters in the same column indicate significant differences between the bevel and bioseal groups at the same time (analysis of variance [ANOVA]; $p < 0.05$).
Different uppercase letters in the same row indicate significant differences over time using the Kruskal–Wallis test with the Duncan post-hoc test ($p<0.05$).

tained by buccolingually measuring the length from the boundary portion between the implant collar and suture thread to the first boneimplant contact (fBIC).

2.5 Statistical Analysis

We used SPSS version 17.0 (SPSS, Chicago, IL, USA) for all statistical analyses. ANOVA was used to compare groups. If ANOVA indicated significant differences between groups, multiple comparison analysis was performed using the Scheffe & Bonferroni test as a post-hoc test.

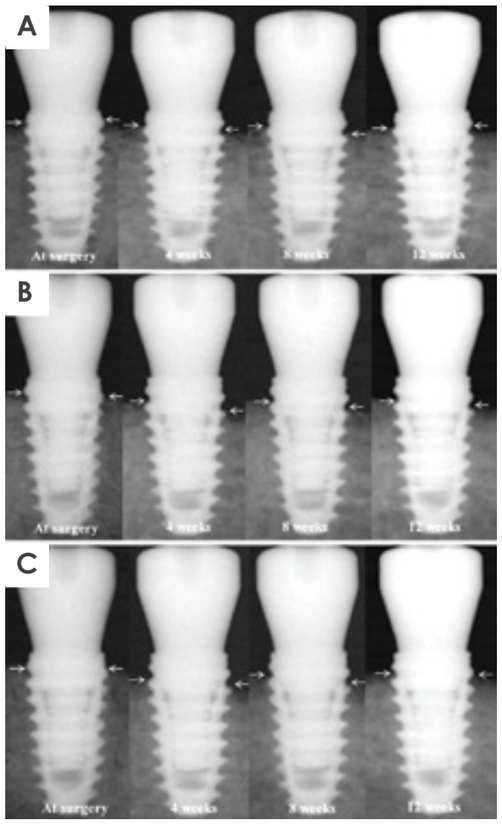

Figure 5. Radiographic analysis of each group. (A) Bevel group; (B) Bioseal group; and (C) Bioseal/groove group. The white arrows indicate the mesiodistal marginal bone level. Images were obtained from the same specimen in the same group by period. Bone resorption was observed at 4 weeks after surgery in all the groups, but bone increased again by12 weeks after surgery.

3. Results

3.1 Radiographic Analysis

Mesiodistal marginal bone resorption capacities are shown in Table 2. No differences were observed between groups at any X-ray point ($p > 0.05$). A representative X-ray radiograph of each group is shown in Fig 5. The resorption capacity of the mesiodistal marginal bone did not change over time in the bevel group ($p > 0.05$), but did change over time in the bioseal and bioseal/groove groups. In these 2 groups, increase in the marginal bone was observed at 12 weeks than at 4 and 8 weeks ($p < 0.05$; Table 2).

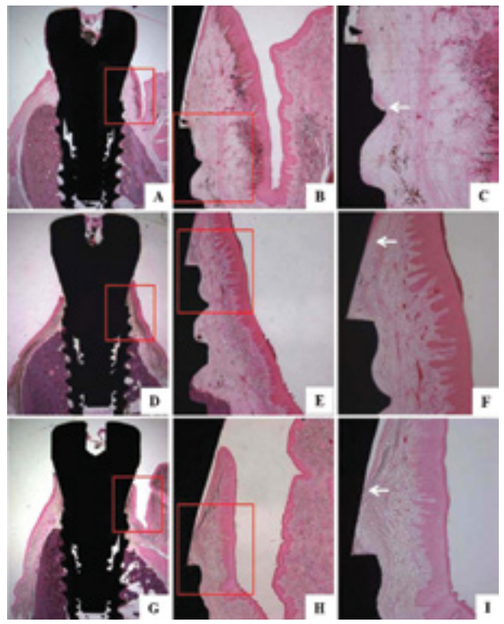

Figure 6. The junctional epithelium and connective tissue contact of each group (hematoxylin and eosin staining). A, B, and C: Bevel group. D, E, and F: Bioseal group. G, H, and I: Bioseal/groove group. Magnification: A, D, and G, ×12.5. B, E, and H, ×50. C, F, and I, ×100. The connective tissue of the bioseal group was firm and dens. In addition, the bioseal group show increased connective tissue volume (white arrow: apical portion of the junctional epithelium).

3.2 Histological Analysis

Very good soft tissue attachment was observed in all 3 groups. In the mucosal membrane, junctional epithelial cells were observed beneath the keratotic sulcus epithelium. The connective tissue that was attached to the implants had a large amount of collagen fibers and was similar to wound tissue, which characteristically has a low number of fibroblasts and vessels. However, there was firmer connective tissue attachment in the bioseal and bioseal/groove groups than in the bevel group (Fig 6). In the bevel group, detachment of soft tissue from the implant was observed in the transmucosal portion of 4 of the 12 specimens. However, in the remaining 2 test groups, firm attachment was maintained in all specimens. Tissue specimens were produced by an expert, and it was unique that a specimen of such pattern was produced only in the bevel group (Fig 6C).

Table 3. Histometric analysis of buccolingual marginal bone resorption.

Group	Marginal bone resorption (mm)	
	Buccal	Lingual
Bevel	0.81±0.15	0.25±0.19
Bioseal	0.78±0.19	0.21±0.11
Bioseal/groove	0.73±0.15	0.20±0.17
P	0.172	0.905

Analysis of variance (ANOVA) was used to assess differences between groups.

Table 4. Histometric analysis of soft tissue.

Group	Histometric measurement (mm)		
	JE	CT	BW
Bevel	1.35±0.19^{A}	1.02±0.31^{A}	3.33±0.34^{A}
Bioseal	0.84±0.27^{B}	1.81±0.24^{B}	B 2.83±0.23^{A}
Bioseal/groove	0.88±0.31^{B}	1.77±0.32^{B}	3.09±0.41^{A}

Within the same column, means with the same superscript letters do not statistically differ from one another. JE: length of the junctional epithelium; CT: length of the connective tissue; and BW: biological width

3.3 Histometric Analysis

The results of histometric analysis are shown in Table 4. In the bevel group, the junctional epithelium was significantly longer and the connective tissue was significantly shorter than in the other 2 groups ($p < 0.05$). No difference was observed, however, between the bioseal group and the bioseal/groove group ($p > 0.05$). There was no difference between the biological widths of the 3 groups ($p > 0.05$).

4. Discussion

The general method of assessing the success of implants in clinical practice is to assess the soft and hard tissue around the implant.[31-33] The preservation of the implant marginal bone is an especially important yardstick of the success or failure of an implant, and there are numerous reports of assessment of the success of implants through periodic X-ray imaging.[31,32]

It is essential to maintain the soft tissue around the implant in a healthy condition to preserve the marginal bone, and approximately 2 mm of junctional epithelium and 1-1.5 mm of firm connective tissue form a biological width that serves as a protective membrane that protects the marginal bone from the invasion of microorganisms.[34-35] The junctional epithelium is attached to the implant through the hemidesmosome from the inferior sulcus epithelium.[36] The attachment tissue between the junctional epithelium and the collagenous bundle parallel to the implant surface forms a biological seal.[37] Previous studies indicate that designs that include a concave profile for the abutment, conical connection, and platform switching, which puts some distance between the fine gap and the alveolar bone, improves the amount and attachment of the connective tissue, thereby reducing bone resorption.[18,38,39] In this study, in which we used conical-connection-type implants with platform switching, bone resorption was minimal in all groups during the early response, and there was no difference between the 3 groups. The implant insertion was made deep enough to allow the boundary portion of the transmucosal portion and the thread to match the alveolar ridge line. This was intended to induce soft tissue attachment from the implant transmucosal portion. Further, even if the insertion was performed such that the boundary of the transmucosal portion and the suture thread would match the alveolar ridge, placement errors may exist, which is difficult to identify with the naked eyes. Therefore, the marginal bone level was determined by radiography immediately after implant insertion, and the bone resorption rate was calculated by comparing the initial radiography images to those obtained at every 4 weeks. While the standardized peri-apical intra-oral radiographs that we used in this study facilitate observation of hard tissues, it is difficult to view soft tissues using this method. Additionally, while these radiographs allow for easy observation of changes in the marginal bone over time, the area of observation is limited to the mesiodistal region of the implant. Therefore, the buccal cortical bone portion, where substantial actual bone resorption occurs, cannot be observed using this method. Therefore, we used an optical microscope to observe slices of the buccolingual marginal bone and the surrounding soft tissue that were harvested 12 weeks after surgery. Buccal and lingual marginal bone resorption occurred to some extent, but the resorption was not significantly different between the 3 groups. This result corresponds to the radiological analysis results for the 12th week, the period in which the laboratory animals were sacrificed. Group analysis of the mesiodistal marginal bone resorption by period showed that marginal bone resorption was observed at 4 weeks in the bevel group, but did not change over time. On the other hand, after marginal bone resorption was observed at 4 weeks in the bioseal group, the marginal bone was restored by 12 weeks. Only 0.07 mm of marginal bone resorption was observed unlike with the initial insertion. Therefore, it seems the S-shape of the transmucosal portion of the implant influences the early recovery of the marginal bone. While this difference was statistically significant, the marginal bone resorption at 4 weeks was more marked in the bioseal group than in the bevel group, and additional studies are needed regarding its cause.

There was closer connective tissue attachment in the bioseal and bioseal/groove groups than in the bevel group. Moreover, in some bevel group specimens, the junctional epithelium and the connective tissue dropped from the implant surface. Although soft tissue may drop away from the implant surface due to the tissue specimen production process, all tissue specimens were produced by a skilled tester and detached specimens were discovered only in the Bevel group. It can therefore be inferred that the concave shape of the transmucosal portion induced closer junctional epithelium and connective tissue attachment than the straight shape of the bevel group.

The connective tissue attachment in the bevel group was shorter than in the other 2 groups, but the junctional epithelium attachment was long in the bevel group. In Beagle dogs, the length of the connective tissue attached to implants is 1-2 mm.[28] In this study, the length of the connective tissue was 1.81±0.24mm in the bioseal group and 1.77±0.32 mm in the bioseal/ groove group. Both of these groups had longer connective tissue than was observed in the bevel group (1.02±0.31 mm). Therefore, a concave S shape in the transmucosal portion of implants induces longer connective tissue attachment than a straight bevel, and the stereotactic exterior of the concave S shape increases the volume of the connective tissue. While the biological width in the bioseal group was approximately 0.5mm shorter than in the bevel group, the difference was not statistically significant. Previous studies also found that implant design did not influence the biological width.[16,40] The biological width in the implant encompasses both vertical and horizontal spaces.[15] An S-shaped depression at a depth of 0.15 mm can provide an approximately 0.3 mm platform switching effect, and if this is considered, the difference in the biological widths between the bioseal and bevel groups becomes smaller.

The junctional epithelium attachment in the bioseal group was shorter than in the bevel group because the connective tissue was stabilized early, thus preventing inferior movement of the epithelial tissue during the post-operative tissue remodeling. Blocking downward movement of epithelial tissue is important in order to preserve the marginal bone because such movement is highly likely to cause marginal bone resorption.13,41 When the results of our radiological analyses are viewed in the light of the continuing recovery of the marginal bone after early marginal bone resorption in the bioseal group, the early stabilization and firm attachment of the connective tissue prevent the inferior movement of the junctional epithelium and marginal bone resorption. Previous studies have reported that a horizontal micro-groove or microtexture can reduce osteolysis and create a much firmer connective tissue attachment.26-28 In our study, there was no difference in connective tissue attachment or bone loss between similarly designed implants with microgrooves (the bioseal/groove group) placed at 0.04 mm intervals and those with no grooves (bioseal group). This is a limitation of this study, which showed an early response in the tissues that surrounded the implant on the 12th week. Although the difference is not clear, occlusal loading must be applied in the future and its role must be further verified over a longer study period.

In this study, we showed that an S-shaped concavity in the transmucosal portion of implants induces a more favorable soft tissue response than a simple straight bevel. On the other hand, because there was no difference in actual bone resorption, we were unable to determine if there was a difference in soft tissue response with regard to the actual marginal bone change. Further study of the influence of soft tissue responses on marginal bone change under functional loading is required.

5. Conclusion

Implants with an S-shaped concavity of the transmucosal portion were associated with a more favorable soft tissue response through the formation of a firmer connective tissue barrier than were implants with a straight bevel.

Acknowledgment

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Early loading of splinted implants supporting a two-unit fixed partial denture in the posterior maxilla: 13-month results from a randomized controlled clinical trial of two different implant systems

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Key words:

dental implants, early loading, resonance frequency analysis, implant stability dip, insertion torque, posterior maxilla, resonance

Abstract

Objectives:

The aim of this study was to evaluate early-loaded implants supporting a two-unit fixed dental prosthesis in the posterior maxilla and to compare the clinical and radiological outcomes of two different implant systems in terms of success rates, implant stability quotient (ISQ) values, and peri-implant parameters.

Materials and methods:

Thirty patients with the unilateral loss of two consecutive maxillary posterior teeth were randomly assigned to two different implant systems: SLActive Bone level implant (Institut Straumann AG, Basel, Switzerland) in the control group and CMI IS-II active implant (Neobiotech Co., Seoul, Korea) in the experimental group. The patients received provisional and definitive two-unit fixed prostheses at 4 weeks and 6 months after implant surgery, respectively. The peak insertion torque was recorded at surgery. The stability of each implant was evaluated during surgery and at 2, 3, and 4 weeks and 6 and 13 months after implant placement by means of ISQ values. In addition, periapical radiographs and peri-implant parameters were taken throughout the trial.

Results:

Overall, comparable results were obtained between the control and experimental groups in terms of insertion torque, ISQ values, marginal bone loss, and peri-implant soft tissue parameters. All 60 implants had 100% of success rate. The average insertion torque was 36.83 6.09 (control) and 35.33 3.20 (test) Ncm. The ISQ values remained steady until 4 weeks and then increased with statistical significance during 4 weeks to 13 months after surgery. Both groups exhibited no stability dip during

the early phase of healing. The average marginal bone loss from the baseline of implant placement for the control and experimental groups was 0.38 and 0.45 mm after 4 weeks and 0.98 and 0.61 mm after 13 months. All of the soft tissue parameters were within normal limits.

Conclusions:

The results of this study indicate that the concept of early loading at 4 weeks after placement in the posterior maxilla can be an effective treatment option, even in the areas of low bone density, when implants satisfy the inclusion criteria of minimum insertion torque and ISQ of 30 Ncm and 65, respectively.

Introduction

Traditional implant protocols require an unloaded healing period of 3–6 months for successful osseointegration. However, recent advances in implant dentistry have reduced the lengthy healing time, introducing immediate and early loadings as a predictable treatment option. Compared to traditional protocols, short-term loading protocols decrease a period of the esthetic and functional handicap and the number of necessary surgeries, which can be beneficial for both patients and clinicians. During the last decade, numerous clinical studies have demonstrated that immediate or early loading is a predictable treatment option with success rate comparable to the conventional approach (Cochran et al. 2004; Esposito et al. 2013).

Regardless of different loading protocols, achieving optimal osseointegration is a key for implant success. Implant stability is an essential factor for the healing process, osseointegration, and ultimately success of implants. Implant stability can be categorized by the healing time and mechanism as primary stability and secondary stability (Simunek et al. 2010). Primary stability is known to be mechanical retention upon implant placement, whereas secondary stability is related to the subsequent biologic response resulting from bone healing at the bone–implant interface (Atsumi et al. 2007).

Previous studies investigated the pattern of implant stability during osseointegration. In general, total stability is shown to decrease during the initial stage of healing and then increase as healing progresses (Bischof et al. 2004; Schliephake et al. 2006; Huwiler et al. 2007). This is associated with the varying proportions of biologic and mechanical components during the healing process (Simunek et al. 2012). During the initial healing phase, dominant mechanical stability decreases, but thereafter biologic stability becomes prominent as a result of new bone apposition (Simunek et al. 2010). Therefore, a transient “dip” in total stability occurs when early biologic stability cannot make up for lost mechanical stability (Lai et al. 2008; Simunek et al. 2012).

This pattern of implant stability is influenced by various factors such as patient behavior, bone quality, insertion torque and implant design (Simunek et al. 2010, 2012). In the present clinical study, two different implant systems were used: SLActive Bone level implant (Institut Straumann AG) in the control group and CMI IS-II active implant (Neobiotech Co.) in the experimental group. For Straumann, SLActive Bone level implants, recent studies have shown that the chemically modified SLA surface has superior hydrophilicity yielding improved cell response, protein adsorption, and osteogenic effect (Buser et al. 2004; Schwarz et al. 2007; Ganeles et al. 2008). As a result, the manufacturers have claimed that the stability dip and healing time can be reduced, suggesting an early-loading protocol in the posterior maxilla. On the other hand, Neobiotech CMI IS-II active implants place particular emphasis on various macro- and microdesign features such as deep buttress thread, macrothread in the coronal one-third of the implant, conical implant–abutment seal, selftapping tapered apex, and a sand-blasted and acid-etched rough surface. These microscopic and macroscopic characteristics of both implant systems are reportedly known to improve implant stability and osseointegration during the healing process.

The objective of this randomized clinical trial was to evaluate early-loaded implants supporting a two-unit fixed dental prosthesis in the posterior maxilla and to compare the clinical and radiological outcomes of these two different implant systems in terms of success rates, implant stability quotient (ISQ) values, and peri-implant parameters including changes in marginal bone level. The primary hypothesis evaluates whether the experimental implants satisfy non-inferiority compared to the control implants under early-loading conditions in the posterior maxilla.

Material and methods

Experimental design

Two different types of implants were used in this study: SLActive Bone level implant (Institut Straumann AG) in the control group and CMI IS-II active implant (Neobiotech Co.) in the experimental group. Figure 1 showed the characteristics of the two implant systems. The control implants were 4.1 or 4.8 mm in diameter and 10 mm in length, while the experimental implants were 4.0, 4.5, or 5.0 mm in diameter and 10 mm in length.

Implant stability was evaluated using the peak insertion torque value (ITV) and ISQ. Periapical radiographs were taken to determine marginal bone loss around the implants using

	Control group: Straumann SLActive Bone level Implant system	Experimental group: Neobiotech CMI IS-II active Implant system
		
Body shape	Straight body	Tapered Body
Thread shape	V-shape	Deep Buttress
Pitch height	0.8 mm	0.8 mm
Thread height	0.3mm	0.3 mm
Implant-Abutment Interface	Internal CrossFit	Internal Octa
Inclination angle of the thread flank	15°	15°
Surface treatment	Chemically modified SLA surface	SLA surface
Microthreads	None	Bioseal

SLA, Sandblasting with Large grit and Acid etching

Figure 1. Characteristics of the two implants systems with respect to thread design and surface treatment: SLActive Bone level implant (Institut Straumann AG, control group) and CMI IS-II active implant (Neobiotech Co., test group).

a putty jig. Another outcome variable included peri-implant soft tissue assessment such as probing depths, widths of keratinized mucosa, and plaque and calculus indices.

Study population and entry criteria

A total of 128 potential participants were recruited to Seoul National University Dental Hospital via advertisement in a major daily newspaper. Fifty-two patients, 26 each in the control and experimental groups, were selected for the surgery. The inclusion criteria were age of 18 years or more, the absence of two consecutive maxillary posterior teeth, sufficient residual bone height of 6 mm or more, the presence of the intact occlusal plane opposed with the edentulous surgical site, and a lack of TMD or any other occlusal disorders. The exclusion criteria were pregnancy, history of recent myocardial infarction, uncontrolled systemic diseases, blood diseases, psychiatric conditions, patients allergic to implant materials, advanced periodontal diseases around surgical sites, sinusitis, <1 mm buccal or lingual residual width after implant placement, insertion torque of <30 Ncm or >50 Ncm, ISQ < 65, bone grafting exceeding 5 mm, a high degree of parafunctional habits, and a lack of interocclusal space.

The control group consisted of 26 patients and received SLActive Bone level implants. On the other hand, the experimental group included 26 patients, and each subject was treated with two CMI IS-II active implants (Fig. 2). All surgical procedures were performed according to the Declaration of Helsinki on experimentation involving human subjects. The study protocol was reviewed and approved by the Institutional Review Board of Seoul National University Dental Hospital (IRB No. CDE12001). The participants were informed about the nature of the study and signed the informed consent.

Installation of implant and evaluation of implant stability

The entire protocol is outlined in Fig. 2. Patients were randomly assigned to one of the two implant systems before surgery according to the random distribution table. The preoperative examination included a panoramic radiograph, computerized tomography (CT), and intra-oral examination. Antimicrobial prophylaxis was administered with amoxicillin 500 mg twice daily for 3–7 days starting 1 h prior to surgery. For each patient, two assigned implants were consecutively placed in the maxillary posterior region under local anesthesia according to the manufacturer's instructions. If necessary, maxillary sinus augmentation was performed using a crestal approach kit (SCA kit; Neobiotech Co.) and a synthetic bone graft material, Calpore (Kyungwon Medical, Seoul, Korea), to engage the cortical inferior wall of the sinus for increasing ITV. In both groups, the length of implants was 10 mm. Implants of Ø 4.1 and Ø 4.8 mm were used in the control group while Ø 4.0, Ø 4.5, and Ø 5.0 in the experimental group.

The peak insertion torque value was recorded during surgery. Primary stability was assessed by measuring ISQ as an outcome variable. The magnetic resonance frequency analysis (RFA) was recorded using a Mentor device (Osstell AB, G€oteborg, Sweden). The target values for the peak insertion torque and ISQ were 30–50 Ncm and >65, respectively. Healing abutments were installed, and the soft tissue was sutured in place. Periapical radiographs were taken.

Postoperative care

The sutures were removed after 7–10 days. Adequate oral hygiene and a soft diet were recommended. The patients were instructed to use 0.1% chlorhexidine mouthwash and, if necessary, analgesics for pain control. The ISQ measurements and periapical radiographs were taken at 2, 3, and 4 weeks after surgery. When the last ISQ reached to be >65, the prosthetic procedure was commenced.

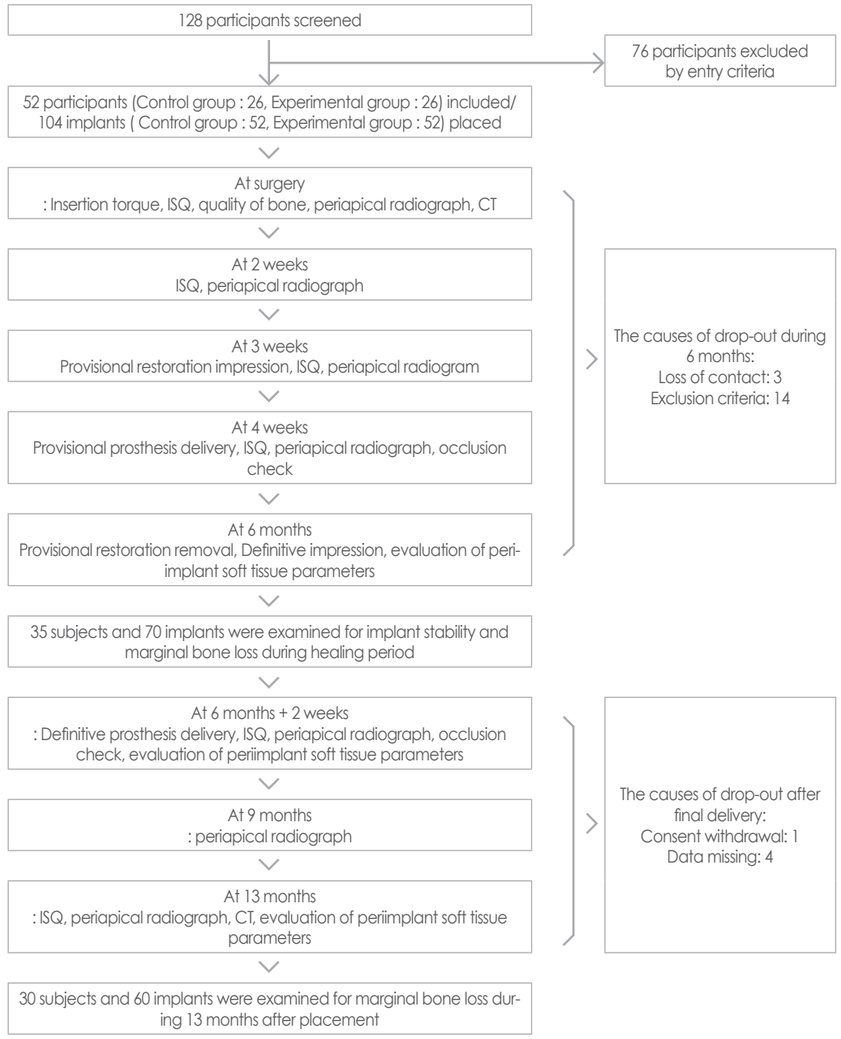


Figure 2. Flow diagram of the early-loading protocol used in this study.

Prosthetic procedure

The impression for the provisional restoration was made 3 weeks after surgery if the ISQ value was greater or equal to the one taken at surgery. After a healing period of 4 weeks, the ISQ values were measured again, and the cases below the 65 ISQ threshold value were excluded from the study; otherwise, a two-unit screw-retained provisional restoration was fabricated with acrylic resin (JetTM Tooth Shade Powder; Lang Dental Mfg. Co., Inc., Wheeling, IL, USA) and torqued to 20 Ncm over temporary abutments [RC Temporary Abutment, Institut

Straumann AG (control), IS Non-hex Temporary Abutment, Neobiotech Co. (experimental)]. Slight occlusal contact was established with shim stock in maximum bite force, and any premature contact was avoided in excursions. Then, periapical radiographs were taken at the delivery of the prosthesis, and 6 months from implant insertion.

After 6 months from implant insertion, 17 participants were excluded because they could not fulfill the protocol standards, and 35 subjects were ready for the final impression stage. A final impression on the definitive abutments [RC Cementable Abutment, Institut Straumann AG (control); SCRP Multi Abutment, Neobiotech Co. (experimental)] was made with additional polysiloxane in single step with regular body wash (Empress™ Vinyl Polysiloxane Impression Material, 3M ESPE Dental products, St. Paul, MN, USA) and putty (Exafine Putty Type, GC Corporation, Tokyo, Japan). On the day of delivery, the ISQ measurement with the Osstell device was repeated for each implant. A definitive fixed screw- and cement-retained prosthesis (SCRP) was fabricated and delivered within 2 weeks after making the impression. The occlusion and lateral contacts were adjusted for the even distribution of the occlusal force over the fixed prosthesis.

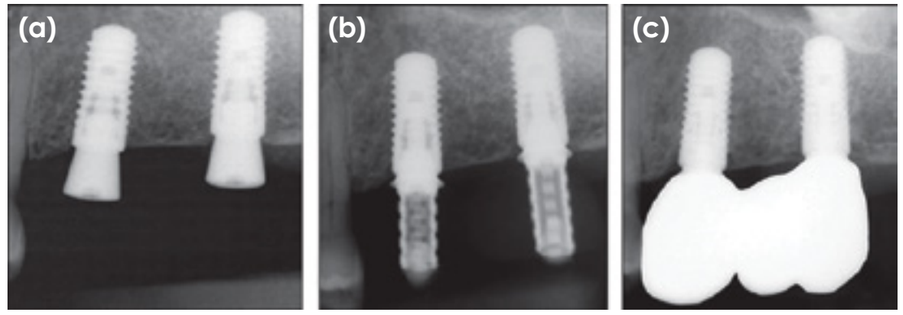


Figure 3. Standard periapical radiographs of implants placed in a patient in the control group (SLActive Bone level implant, Institut Straumann AG): (a) at surgery, (b) at 4 weeks, and (c) at 13 months.

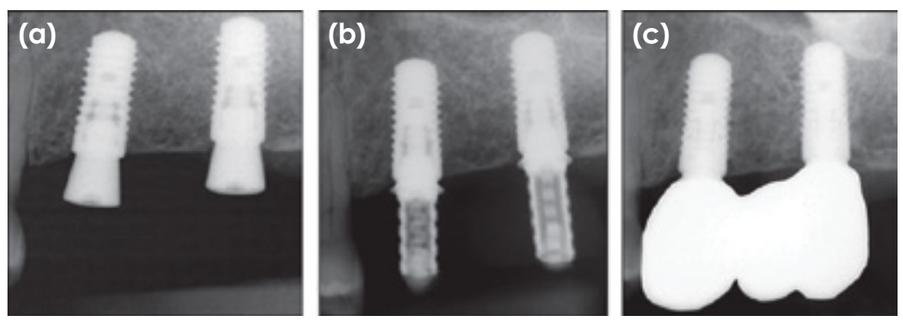


Figure 4. Standard periapical radiographs of implants placed in a patient in the experimental group (CMI IS-II active implant, Neobiotech Co.): (a) at surgery, (b) at 4 weeks, and (c) at 13 months.

Measurement of marginal bone loss

Marginal bone loss was evaluated using standard periapical radiographs taken with the use of a putty jig during surgery and at 4 weeks and 13 months after the operation (Figs 3 and 4). To obtain the marginal bone level, the enlargement ratio of each image was calculated from the manufacturer-specified thread pitch of 0.8 mm that is known for each implant system used in this study. The distance from the first thread (reference point) to the level of the alveolar bone crest was measured in the mesial and distal surfaces of the implant and converted to the actual value using the enlargement ratio. This value was then compared with the measurement taken at surgery (baseline).

Follow-up procedures and implant success

The patients were scheduled for recall visits at 9 and 13 months after implant surgery. The clinical and radiographic examinations were performed during the follow-up period. The occlusion was checked, and the ISQ values were measured at the final appointment. In addition, soft tissue parameters, such as plaque index, sulcus bleeding index, and widths of keratinized mucosa (KM), were assessed, and periapical radiographs were taken.

The following criteria described by Buser et al. (1997) were applied to evaluate implant success: (1) the absence of clinically detectable mobility; (2) the absence of pain or other symptoms of discomfort or ongoing pathologic processes; (3) the absence of recurrence of peri-implantitis with suppuration; and (4) no evidence of continuous radiolucency around the implant.

During this follow-up period after the operation, one subject withdrew the consent to continue participating in the study and four additional subjects were excluded due to data missing. As a result, the data from 60 implants in 30 participants were used for the final statistical analysis of the present study.

Statistical analysis

The statistical analysis comparing the two groups was performed based on the Per Protocol (PP) analysis. The chi-square test for categorical variables and the independent two-sample t-test or the Mann–Whitney Utest for continuous variables were used for comparative evaluation depending on the normality of the distribution. The normality was examined using the Shapiro–Wilk method. Two-way repeated-measures analyses of variance in the general linear model were performed after the verification of sphericity using the Huynh–Feldt method to evaluate differences in the patterns of ISQ change over time. The level of significance was set at P-value <0.05.

Results

Participants and implant placed

Seventy-six of a total of 128 screened candidates were excluded by the entry criteria. During 6 months after surgery, 17 participants dropped out because they could not fulfill the protocol standards. After delivery of definitive prostheses, one subject withdrew the consent to continue participating in the study, and four additional subjects were excluded due to data missing (Fig. 2). Therefore, the results of 60 implants in 30 patients were examined for the final analysis of our 13-month randomized clinical trial.

Demographic characteristics of the participants

The demographic and clinical characteristics of the study population for each implant system are presented in Table 1. The mean age of 15 patients (22 men and eight women) in the control group was 62.47 7.83, while the experimental group was composed of 15 patients (18 men and 12 women) with a mean age of 60.53 8.52 years. In both groups, the bone quality

Table 1. Demographic data of study participants

		Type of implant		
	Variables	Control (Straumann, SLActive bone level implant system)	Experimental (Neobiotech CMI IS-II active implant system)	P-value*
Implant based (N = 60)	Implant number	30	30	
	Age (mean SD)	62.47 ± 7.83	60.53 ± 8.52	0.459
	20–60	10	16	0.192
	Over 60	20	14	
	Sex			
	Male	22	18	0.412
	Female	8	12	
	Location			
	2nd premolar	5	2	0.432
	1st molar	15	15	
	2nd molar	10	13	
	Bone quality			
	D1	0	0	1.000
	D2	0	0	
	D3	19	18	
	D4	11	12	
Participant based (N = 30)	Participant number	15	15	
	Age (mean SD)	62.47 ± 7.83	60.53 ± 8.52	0.624
	20–60	5	8	0.462
	Over 60	10	7	
	Sex			
	Male	11	9	0.700
	Female	4	6	

SD, standard deviation.
"Control" indicates the Standard Straumann Dental Implant system and "Experimental" the Neobiotech CMI IS-II active Implant system.
Data, except for age, are presented as the number of implants or participants. The units of age are year.
*The P-values were calculated using the chi-square test for all variables except age. The P-value for age was calculated using the Mann–Whitney U-test.
Bone quality was assessed based on the classification system of Lekholm & Zarb (1985) during the drilling sequence.

of the surgical sites was classified as D3 or D4 based on Lekholm & Zarb (1985) during the drilling sequence. The statistical analysis showed that there were no significant differences in age, sex, surgical location, and bone quality between the two groups (P-value >0.05).

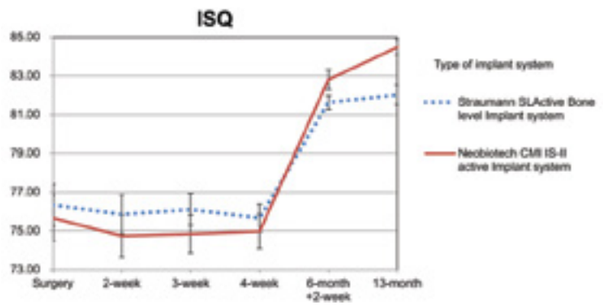
Comparison of implant stability between the two implant systems

Primary stability was evaluated using the peak insertion torque and ISQ at surgery (Table 2). The control group had slightly greater average insertion torque and ISQ values at implant insertion than the experimental group, but no statistically significant differences were observed between the two systems (P-value >0.05). The ISQ values continued to be assessed during follow-up appointments for a postoperative period of 13 months, as shown in Fig. 5. For the first 4 weeks after surgery, the ISQ values of the control group were steadily greater than those of the experimental group, but there were no statistically significant differences between the two groups (P-value >0.05). As the provisional restorations were delivered at 4 weeks after the operation, the ISQ values of the experimental group had started rising and finally exceeded those of the control samples by the end of the clinical trial. In particular, the differences in the ISQ results from the two implant systems at 6 months and 13 months after surgery achieved statistical significance with P-values of 0.053 and 0.003, respectively, as compared with previous visits. Likewise, within each implant group, the ISQ values showed little change until 4 weeks but then led to a significant increase during 4 weeks to 13 months after the operation (P-value <0.001). Therefore, it was possible to conclude

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

	Type of implant				
	Straumann, SLActive bone level implant system		Neobiotech CMI IS-II active implant system		
	N	Mean ± SD	N	Mean ± SD	P-value*
Insertion torque (Ncm)		36.83 ± 6.09		35.33 ± 3.20	0.387
ISQ at surgery	30	76.34 ± 5.89	30	75.66 ± 6.41	0.663

ISQ, implant stability quotient; SD, standard deviation.
*The P-values for insertion torque and ISQ were calculated by the t-test.



	N	Surgery	2-week	3-week	4-week	6-month + 2-week	13-month
Straumann SLActive Bone level Implant system (Mean ± SD)	30	76.34±5.89	75.84±5.52	76.10±4.48	75.66±3.98	81.62±2.00	82.02±2.75
Neobiotech CMI IS-II active Implant system (Mean ± SD)	30	75.66±6.41	74.73±5.91	74.83±5.38	74.97±4.80	82.80±2.84	84.47±2.14
P-value* between two subsequent visits			0.334	0.716	0.534	<0.001*	<0.001*
P-value* between two subsequent visits and implant groups			0.775	0.704	0.711	0.053*	0.003*

*The P-values were calculated using the two-way repeated measures ANOVA.
ISQ, implant stability quotient; SD, standard deviation

Figure 5. Comparison of secondary stability in terms of the pattern of change in implant stability quotient (ISQ) during the 13-month observation period after implant surgery.

Table 3. Comparison of marginal bone loss between the two implant systems

		Type of implant				
		Straumann, SLActive bone level implant system		Neobiotech CMI IS-II active implant system		
Duration	Area	N	Mean(mm)±SD	N	Mean(mm)±SD	P-value*
During the 4 weeks after surgery	Proximal	30	0.35 ± 0.78	30	0.41 ± 0.84	0.935
	Distal	30	0.42 ± 0.85	30	0.50 ± 0.92	0.744
	Avg	30	0.38 ± 0.81	30	0.45 ± 0.87	0.870
13-month follow-up	Proximal	30	1.09 ± 0.89	30	0.69 ± 1.48	0.161
	Distal	30	0.86 ± 0.87	30	0.53 ± 1.47	0.285
	Avg	30	0.98 ± 0.88	30	0.61 ± 1.45	0.187

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

Table 4. Comparison of peri-implant soft tissue parameters between the two implant systems after 13 months of follow-up

	Type of implant				
	Straumann, SLActive bone level implant system		Neobiotech CMI IS-II active implant system		
Parameters	N	Mean ± SD	N	Mean ± SD	P-value*
Plaque index	30	0.43 ± 0.57	30	0.23 ± 0.43	0.151
Calculus index	30	0.13 ± 0.35	30	0.00 ± 0.00	0.04*
Sulcus bleeding index	30	0.40 ± 0.62	30	0.47 ± 0.57	0.522
Pocket depth	30	3.07 ± 0.66	30	3.11 ± 0.99	0.933
Width of keratinized mucosa (mm)	30	8.20 ± 2.27	30	8.53 ± 2.54	0.835

SD, standard deviation.
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; and score 3, abundance of soft matter.
Calculus index: score 0, no detection of calculus; score 1, supragingival calculus covering ≤1/3 exposed tooth surface; score 2, supragingival calculus covering >1/3 but <2/3 tooth surface, flecks of subgingival calculus in cervical margin; and score 3, supragingival calculus covering >2/3 surface, continuous band of subgingival calculus.
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; and score 3, heavy or profuse bleeding.
*The P-values were calculated using the Mann–Whitney U-test.

that both implant systems showed no "stability dip" during the early phase of healing.

Comparison of marginal bone loss between the two implant systems

Marginal bone loss after the implant insertion was evaluated for 60 implants using periapical radiographs taken at 4 weeks and 13 months after surgery (Table 3 and Figs 3 and 4). The average marginal bone loss from the baseline of implant placement for the control and experimental groups was 0.38 mm and 0.45 mm after 4 weeks and 0.98 mm and 0.61 mm after 13 months, respectively. After a 4-week healing period, the distal surface exhibited slightly greater bone loss than the mesial side, but by the end of the trial, the bone loss on the mesial surface became more prominent. However, no differences in marginal bone loss between the two implant systems gained statistical significance (P-value >0.05).

Evaluation of the peri-implant soft tissue parameters and success rates of the two implant systems

All of the mean values of the soft tissue parameters were within normal limits throughout the treatment period (Table 4). The average pocket depths and widths of keratinized mucosa were approximately 3.0 mm and 8.0 mm, respectively, in both treatment groups. The mean calculus index for the control group was 0.13, while none was found in the experimental group. There were no statistically significant differences in the soft tissue parameters except calculus index between the two implant systems (P-value = 0.04). However, the peri-implant soft tissues of all implants were clinically healthy with little plaque and calculus deposits and low tendency to bleed on probing. The success criteria described by Buser et al. (1997) were applied to evaluate implant success. At the end of the 13-month followup period, all 60 implants fulfilled the strict success criteria. Consequently, the overall 13-month success rates were 100%. The implants that were excluded from the study because of the postoperative exclusion criteria still fulfilled Buser's criteria at the end of treatment using conventional loading.

Discussion

Conventional loading protocols for implants generally recommend an undisturbed healing period of at least 5–6 months in the posterior maxilla. In recent years, there have been strong patient demands for a shorter treatment time, so immediate- or early-loading protocols have been widely accepted. However, it is relatively difficult to employ these short-term protocols to the posterior maxillary area due to poor bone quality (Esposito et al. 2007; Roccuzzo et al. 2009). Therefore, the current study was designed to evaluate early-loaded implants supporting a two-unit fixed dental prosthesis in the posterior maxilla and to compare the clinical and radiological performance of two different implant systems in terms of success rates, ISQ values, and various peri-implant parameters.

Implant stability of the two implant systems

Implant stability is composed of primary stability and secondary stability. Primary stability mainly achieved by mechanical retention is a crucial factor for successful healing and osseointegration particularly under accelerated loading conditions in poor bone quality (Roccuzzo et al. 2009). There have been several methods proposed to measure implant stability (Atsumi et al. 2007). In the present study, insertion torque and RFA were measured at the time of surgery to evaluate primary stability. The results showed no statistically significant differences in both insertion torque and ISQ of the two implant systems. Although no absolute values of insertion torque and ISQ have been established for optimal primary stability, previous literatures reported that ISQ values of 60–65 and insertion torque of at least 35 Ncm should be recommended for a successful immediate- or early-loading procedure (Sennerby & Meredith 2008; Esposito et al. 2013). Both implant systems used in this study had average insertion torque and ISQ values of more than 35 Ncm and 75, respectively, thus demonstrating sufficient primary stability.

Even though the implants in the control group were very technique sensitive to be placed in a narrowly prepared hole due to their straight body and weak thread design, the reason for obtaining excellent primary stability in the control group was to use the lateral osteotome

compaction technique. An implant was placed after the soft bone was prepared with undersized drilling and compacted laterally using a lateral osteotome instrument before implant placement. On the other hand, in the experimental group, optimal primary stability could be achieved by placing the implants directly in a 1- or 2-step undersized hole in diameter without the lateral osteotome compaction procedure. This procedure, called "selfcompaction" (Ahn et al. 2012), allows the experimental implants with a narrow and tapered apex and deep buttress thread design to perform effectively in D3-D4 cancellous bone.

During the healing process around an implant, secondary stability emerges from new bone apposition as primary stability at the time of implant placement gradually subsides (Zhou et al. 2009). To evaluate the pattern of change in secondary stability, longitudinal monitoring of ISQ values was performed for a postoperative period of 13 months. The general pattern of ISQ changes was similar across both implant systems. The ISQ values of each group were steady without a "dip" for the first 4 weeks after surgery and then increased significantly during 4 weeks to 13 months after the implants were loaded at 4 weeks. In addition, these longitudinal changes did not reveal statistically significant differences between the two implant groups until 6 months and 13 months after the operation. During the late postoperative period, the experimental group had greater ISQ values than the control group although the difference at 6 months showed border-line significance with P-value of 0.053. A similar result was reported in the previous study, where the authors described these changes in ISQ values over time based on the bone remodeling process in the peri-implant region (Huwiler et al. 2007). They explained that the turning point in the pattern of implant stability occurred after 2–4 weeks when bone remodeling changed from a resorptive to a formative state (Huwiler et al. 2007). However, these results should be interpreted with caution, because a lack of double blinding might have led to potential bias such as performance bias with the clinicians possibly being more familiar with one implant system than the other system. Furthermore, due to splinting of the two implants in each patient, the measurement interval was too large to detect the detailed pattern of the ISQ change during the later observation period after 4 weeks. Lastly, further evaluation of ISQ beyond the trial period may be necessary to obtain more thorough comparisons of the two implant systems, because the ISQ values were still increasing at the end of the study.

Implant stability is influenced by various factors, such as bone quality, the insertion technique, and the microscopic and macroscopic components of an implant (Akca et al. 2006). Both implant systems used in our study exhibited a high degree of primary and secondary stability, demonstrating almost no dip in implant stability. However, despite the similarity of their ISQ patterns, the underlying mechanisms leading to this observation may be different between the two groups. For Straumann, SLActive Bone level implants, multiple clinical and experimental studies have demonstrated favorable cell response, protein adsorption, and osteogenic effect of their super-hydrophilic implant surfaces (Buser et al. 2004; Ganeles et al. 2008; Lang et al. 2011; Wennerberg et al. 2011). This superior biologic response resulted in a faster increase in secondary stability of the control implant system ensuring a high level of stability without a dip. On the other hand, Neobiotech CMI IS-II active implants are designed with various macrodesign features such as deep buttress thread, conical implant–abutment seal, and self-tapping tapered apex. One of the key factors for successful stability and osseointegration is an even stress distribution within the peri-implant bone (Geng et al. 2001). Previous studies reported that the aforementioned macroscopic components diminish undesirable stress and strain around the implants and improve mechanical retention during the early phase of the healing process after the operation (Hansson 2003; Aloy-Prosper et al. 2011; Kim et al. 2013; Kumar et al. 2013). No stability dip was observed in both implant systems in this study. This phenomenon could result from two different paths: eliminating rapid decrease in primary stability and increasing secondary stability. The former is associated with establishing maximum bone-to-implant contact using the compaction technique, which could slow down the remodeling process. The latter process can be achieved by making fast new bone attachment to the bioactive surfaces.

Marginal bone loss and success rates of the two implant systems

The initial marginal bone loss after 4 weeks from the baseline level at surgery for the control group was smaller than that for the experimental group but increased, exceeding the experimental implants by the end of the trial at 13 months. However, the authors observed no significant differences between the two implant groups. The measured values were consistent with the results from previous clinical studies (Ganeles et al. 2008; Morton et al. 2010; Kim et al. 2013). The extent of marginal bone loss is influenced by various factors such as implant geometry, surgical techniques and locations, bone quality, and types of prostheses. Nonetheless, despite a lack of statistical significance, the slight divergence in the results can be explained by the macroscopic features of the experimental implant. It has macrothreads in the coronal part, which could contain the maximum amount of bone to distribute occlusal stress evenly to the crestal cortical bone, minimizing stress concentration per unit area.

In the present study, implants were inserted in the bone type 3 or 4 of posterior maxilla and loaded 4 weeks after surgery. At the end of the trial, the overall 13-month success rates were 100% for both the control and experimental groups. The peri-implant soft tissues were clinically healthy with minimal plaque and calculus deposits and tendency to bleed. These results were comparable to those of previous studies on early-loaded implants in the posterior maxilla (Ganeles et al. 2008; Roccuzzo & Wilson 2009; Kim et al. 2013; Markovic et al. 2014). The high success rates obtained in this study can be explained by high primary stability at placement. According to Meredith, primary stability can be used as a prognostic marker for successful osseointegration, particularly when bone quality is poor (Meredith 1998). He and many other authors have highlighted the importance of primary stability for the long-term success of implants (Meredith 1998; Roccuzzo et al. 2009). Therefore, it indicates that both implant systems used in this 13-month trial can achieve successful clinical results in the low-density bone of the posterior maxilla using an early-loading protocol.

Conclusions

It is generally assumed that the placement of implants in the posterior maxilla requires considerably more caution during surgery and prosthetic procedures. After an observation period of 13 months, all 60 implants achieved high implant stability, yielding a 100% success rate. Both implant systems exhibited no dip in implant stability when comparing their ISQ values. Overall, comparable results were obtained between the control and experimental groups in terms of insertion torque, ISQ values, marginal bone loss, and peri-implant soft tissue parameters. The results of the present study indicate that the concept of early loading at 4 weeks after placement in the posterior maxilla can be an effective treatment option,

even in the areas of low bone density, as long as the defined inclusion criteria are met; minimum insertion torque and ISQ of 30 Ncm and 65, respectively. In this study, a high degree of primary stability appears to be one of the prerequisites for a successful immediate- or early-loading procedure as previous literature has suggested (Meredith 1998; Roccuzzo et al. 2009). Furthermore, the use of splinted implants supporting a two-unit fixed prosthesis during the osseointegration period may play an important role in the high success rate of the procedure by promoting an even stress distribution in the surrounding tissue (Bergkvist et al. 2008; Shigemitsu et al. 2013; Hasan et al. 2015). However, despite the successful clinical results of the present study, additional well-designed randomized controlled clinical trials with a larger sample size and longer observation period are needed to further validate this treatment concept for implants in healed sites in the posterior maxilla.

Acknowledgement

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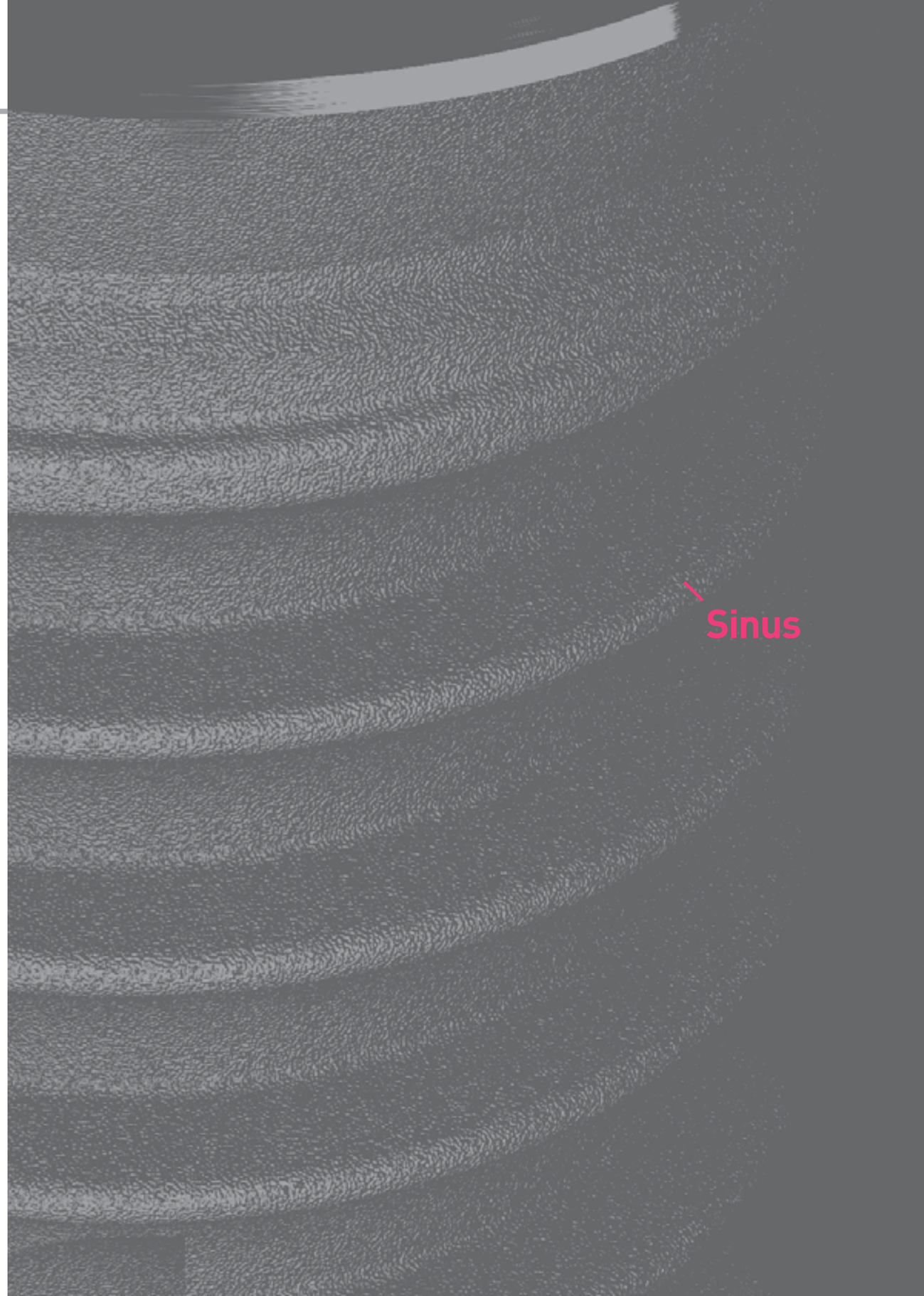

Osteotome Technique Using the SCA kit

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SUMMARY

Here, we introduce a procedure that can be performed with conventional drilling methods. The sinus membrane can be elevated quickly, safely, and simply by drilling via the sinus crestal approach (SCA), without using an osteotome malleting technique. In addition, a perforation of the required size can also be made in the inferior wall of the sinus. Therefore, this surgical tool permits CMI fixation (Crestal cortical fixation, Middle cancellous fixation, and Inferior cortical fixation), which is the best method for achieving a successful outcome in maxillary molar dental implant treatment. The surgical time is markedly reduced via the alveolar tip approach at a higher speed of 800-1200 rpm. This technique is safe and comfortable for both patients and surgeons.

KEY WORDS

osteotome technique, SCA kit

Introduction

The sinus membrane can he elevated quickly, safely, and simply by drilling via the sinus crestal approach (SCA), wi thout using an osteotome malleting technique. In addition, the inferior sinus wall can also be perforated at the required size. Therefore, this surgical tool permits CMI fixation, which is the best method for achieving a successful outcome of the dental implant in maxillary molar area. CMI fixation is a procedure in which a certain type of initial fixation is achieved during maxillary sinus surgery. Ideal initial fixation can be obtained in all structures, including the crestal cortical bone, middle cancellous bone, and inferior cortical bone.

The SLA kit has the ”3S” advantage: speed, safety, and simplicity (Table 1)

Table 1. Characteristics of the SCA kit

- Speed: The procedure is quickly performed at a high speed of 800-1200 rpm.
- Safety: Use of a drill stopper increases comfort and safety for both the patient and surgeon in the maxillary sinus elevation.
- Simplicity: The procedure can be performed simply with the use of conventional drilling methods following one- time reamer drilling.

SCA kit components

1 .Initial drill (Fig.1)

The initial drill is used to determine the correct drilling point and form a guide hole prior to using the S-reamer. To ensure that drilling is performed to the appropriate depth, it should be used with a drill stopper.

Fig. 1. Initial Drill

2. S-reamer (Fig.2)

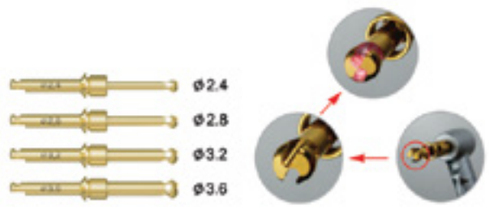

Fig. 2. S-reamer

The sinus (S)-reamer is an essential instrument in the SCA kit; it creates a hole of the required size in the sinus inferior cortical wall without damaging to the maxillary sinus membrane. The S-reamer, which derives its name from the S shape of drill’s edge, it specifically designed for sinus surgery.

The S-reamer can perform high-speed rotation at 800-1200 rpm because of the specific structure of the drill edge, it can be drilled effectively. A bone chip makes the edge of the S-reamer flat so that sinus membrane is not torn, even when they come into direct contact. In cases in which perforation occurs in the septum, the membrane is safe. As drilling is performed using a drill stopper, the S-reamer can be drilled safely and rapidly.

The S-reamer is available in four diameters: 2.4, 2.8, 3.2, and 3.6 and 4mm long. Selection of the appropriate diameter is essential for CMI fixation (Table2).

Table 2. Selection of S-reamer diameter based on the insertion depth of the implant within the sinus

- Regular fixture
  Insertion at a depth of 1-3 mm: 2.4 mm S-reamer
  Insertion at a depth of >4 mm: 2.8 mm S-reamer
- Wide fixture
  Insertion at a depth of 1-3 mm: 3.2mm S-reamer
  Insertion at a depth of >4mm: 3.6 mm S-reamer

The selection of an S-reamer is dependent on the diameter of the SinusQuick implant.

3. Drill stopper

The drill stopper is composed of 10 pieces of various sizes to ensure that drilling with the S-reamer can be performed at a depth ranging from 2 to 11 mm. A 1-mm gap stopper prevents the S-reamer from entering the maxillary sinus. This prevents the sinus membrane rupture due to physical force during S-reamer drilling.

The length of the drill stopper corresponds not to the length of the stopper alone but to the length of the instrument exposed when the drill stopper is connected to the S-reamer and bone condenser (Figs. 3, 4).

The drill Stopper is also compatible with the bone spreader and bone condenser should be installed to ensure that the membrane is not ruptured during the spreading or condensing of bones.

Fig. 3. Drill stopper

Fig. 4. Drill stopper

4. Depth gauge (Fig.5)

A depth gauge is an instrument that measures the height of residual bone following puncture with S-reamer. Both ends of the depth gauge are flat, it can be held against the interior side of the sinus wall. The depth can be measured when the depth gauge is inserted and hang on the sinus inferior wall.

Note that the depth gauge should not be inserted more than 1 mm beyond the residual bone.

Fig. 5. Depth gauge

5. Bone carrier (Fig.6)

The bone carrier is a tool that can be used to safety carry bone into the sinus hole.

Fig. 6. Bone carrier

6. Bone condenser (Fig.7)

A bone condenser is used to fill perforated holes with bone carried by a bone carrier. A stopper equal in length to the height of the residual bone should be used.

The bone condenser includes diameters of 1.0 and 2.2 mm. A small-diameter condenser should be used for cases involving the insertion of hard bone or large particles.

Fig. 7. Bone condenser

7. Bone inserter (Fig. 8)

During bone grafting, bone is inserted into the hole using a bone carrier. The bone inserter is a tool that pulls the bone into the sinus. It can be used safely together with a stopper to prevent damage to the membrane.

Fig. 8. Bone inserter

8. Bone spreader (Fig.9)

A bone spreader is a tool that allows safe elevation of the membrane by laterally spreading the inserted bone. Bone spreaders are available with diameters of 2 mm and 3mm.

A bone spreader should be used after the insertion of bone in volumes greater than 0.3cc. After a drill stopper equal in length to the height of residual bone, the bone spreader is slowly rotated to the left and right. When the bone material in a volume of 0.2-0.3 cc is added, the length of the drill stopper should be increased by 1 mm. This procedure should be repeated as required. For both vertical and lateral elevation of the membrane, when resistance is perceived during bone condensing, spreading should be performed.

Fig. 9. Bone spreader

Procedures

1. The residual bone height of the maxillary sinus should be measured by preoperative X-ray.
2. Stepwise drilling should be started to a depth of 1 mm less than the measured height. The final diameter of the hole drilled should be determined based on bone density.
3. For safety, a drill stopper 1 mm longer than the desired depth of drilling should be measured on the S-reamer.
4. The diameter of the S-reamer should be selected based on the diameter of the fixture and the depth of insertion into the sinus (Table 1).
5. The inferior wall doesn't perforate though the stopper reaches the crestal bone, the stopper should be replaced by a one size larger, and drilling should then be repeated.
6. When perforation is achieved can be determined. The height of residual bone should be measured using a depth gauge. The depth gauge should be inserted carefully along the lateral wall and hang on the inferior sinus wall. Thus, the height of residual bone can be measured accurately. The depth gauge should not enter the sinus wall by more than 1 mm.
7. When perforation of the inferior wall is confirmed, the nose should be obstructed and a nose blow test should be performed to confirm membrane perforation. If sinus membrane was not perforated, the bone material should be inserted, and the membrane should be elevated accordingly. When a large amount of bone is to be inserted, soft bone, such as a demineralized freeze-dried bone allograft (DFABA), should first be inserted relative to the degree of elevation. The membrane can then be safety elevated, and hard bone can be inserted.

Case Report
(CMI fixation without bone graft)

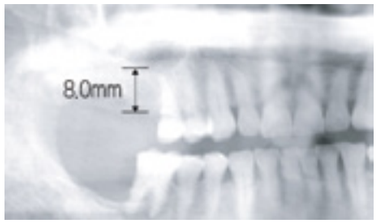

Fig. 10. The height of residual bone in teeth #16 and #17 was confirmed to be 8.0 mm. Following the addition of bone, a wide-body implant (5.0 X 10 mm) was placed.

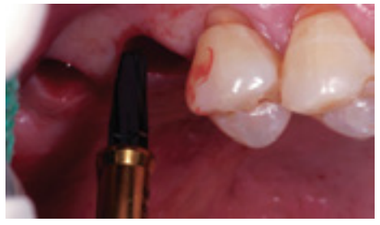

Fig. 11. Drilling is performed during flapless surgery using a drill that is 1 mm shorter than the depth of residual bone.

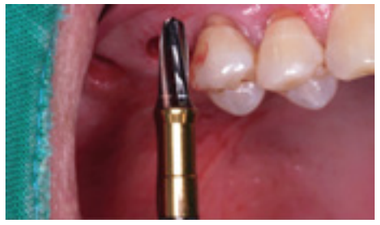

Fig. 12. In planning for wide-body implant placement, the hole should be enlarged as drilling is performed.

Fig. 13. A wide implant is inserted to depth of 3 mm following selection of a 3.2 mm S-reamer with an 8.0-mm stopper.

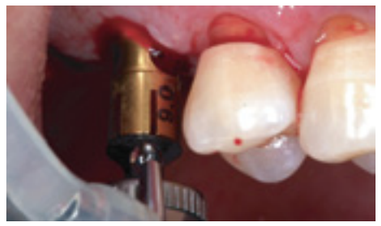

Fig. 14. No perforation occurred using an 8.0-mm drill stopper. As a result, a 9.0-mm drill stopper was used. However, no perforation occurred even after using a 10.0-mm stopper.

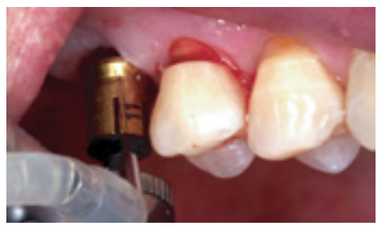

Fig. 15. The perforation was achieved to a depth of 11 mm, which was greater than predicted by 3.0 mm. Drilling should be performed in the direction of lateral wall. The nose was obstructed, and a nose blow was performed to confirm that the membrane of the maxillary sinus was not perforated.

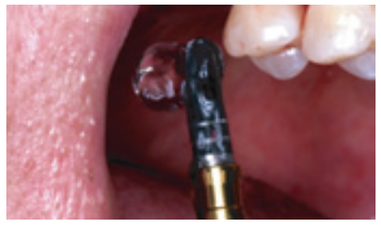

Fig. 16. For implant placement, final drilling was performed after S-reamer drilling. For CMI fixation, the placement protocol for a SinusQuick 5.0 X 11.5-mm implant was modified.

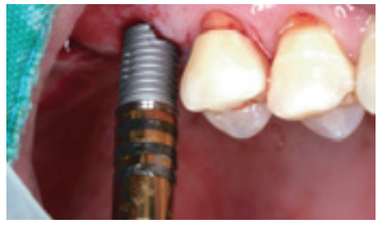

Fig. 17. A SiunsQuick 5.0 X 11.5-mm implant was placed without the addition of bone.

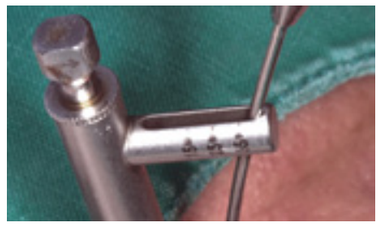

Fig. 18. Despite the use of D3-D4 bone, using CMI fixation of the SiunsQuick implant, the ideal initial fixation was achieved at a torque of 40 Ncm.

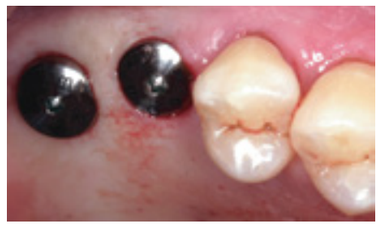

Fig. 19. After the ideal initial fixation, a healing abutment was mounted.

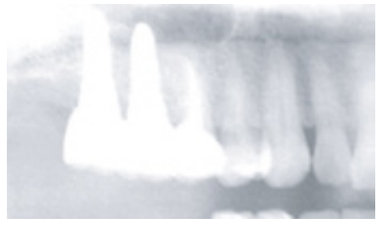

Fig. 20. The initial fixation was achieved following CMI fixation.

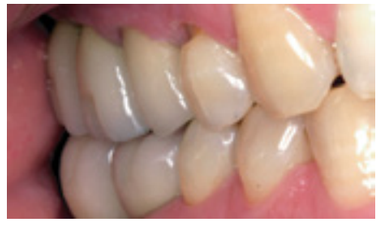

Fig. 21. Final delivery of the prosthesis after 2 weeks. As described here, even for cases in which panoramic measurement was performed incorrectly, use of the SCA kit safely allowed perforation of the inferior cortical wall without damage to the maxillary sinus membrane. Thus, CMI fixation could be achieved.

8. An appropriate amount of bone should be placed in the hole using a bone carrier. The bone should be inserted into sinus using a bone condenser along with a drill stopper.
9. The appropriate amount of bone to be inserted is determined based on the height of elevation. In general, at an elevation of 1 mm, a volume of approximately 0.1 cc of bone should be inserted.
10. According to the amount of bone inserted, spreading should be performed using a bone spreader for lateral elevation of the membrane. A bone spreader specifically designed for contra-angle bends should be rotated at a speed of 20-30 rpm for 10-20 s after using a drill stopper 1-2 mm longer than the residual bone. Generally, spreading should be performed after inserting at a volume of 0.3 cc.
11. Spreading should be performed whenever insertion involves a volume of 0.2-0.3 cc. For cases with additional insertion, the length of the stopper should be increased by 1 mm, and this maneuver should be repeated.
12. When the bone grafting is finished, a drill can be used to enlarge the hole.
13. Based on the density of cortical bone, countersinking should be performed (excluding IT type). In general, this should be done for D1-D2 bone quality. It doesn't matter skip the countersinking in D3 and D4 bone quality.
14. The implant should be placed when all drilling procedures have been completed.

Discussion

Various noninvasive surgical treatments have been introduced as alternatives to maxillary sinus bone elevation via an invasive lateral approach in clinic. The crestal approach is a representative alternative to the lateral approach.

Elevation of the maxillary sinus membrane via the crestal approach is a predictable surgical procedure with almost no postsurgical complications. To secure a long-term and stable prognosis, the selection of appropriate indications and extensive training in surgical technique are required. For cases in which the amount of residual alveolar bone is insufficient, excessive surgical attempts would lead to an increased likelihood of surgical failure[1].

The crestal approach is possible for cases in which the height of residual alveolar bone to the floor of the maxillary sinus exceeds 6 mm. When the mucosa of the maxillary sinus is elevated via the crestal approach, it is dangerous to attempt elevation >5 mm. Some authors favor a crestal approach, even for cases in which the height of residual bone is greater than 6 mm. When multiple implants are placed in the maxillary molar area, the lateral approach is safer and reduces the duration of surgery compared to the crestal approach[2].

Zitzmann and Schärer[3] recommended the osteotome technique when residual bone height exceeds 6 mm and an elevation of about 3 to 4 mm is expected. One-step or two-step lateral antrostomy must be performed in cases of more advanced resorption.

One of the methods associated with the crestal approach, the sinus crestal approach technique (SCA technique), can be drilled by rotation of the S-reamer at a speed of 800-1200 rpm to achieve the required size. This surgical procedure can be used for safe elevation without causing damage to the membrane of the

maxillary sinus. The kit includes four types of S-reamer (2.4, 2.8, 3.2 and 4.6 mm diameters), one depth gauge, 12 drill stoppers (1-12 mm), two bone condensers, one bone carrier, and tow bone spreaders with diameters of 2 mm and 3 mm.

CMI fixation (Crestal cortical fixation, Middle cancellous fixation, and Inferior cortical fixation) is a new implantation method to increase the success rate in areas where the bone is weak and available space is insufficient, such as the maxillary molar area.

CMI fixation achieves effective fixation in all three areas, using specific implants for which under-drilling and self-compaction techniques can be performed. As a result, even in cases in which the bone quality is poor, immediate loading as well as a one-stage approach can be attempted. When the crestal approach is attempted, CMI fixation can minimize patient discomfort while reducing the possibility of perforation of the maxillary sinus membrane.

However, because this method is a blind technique, it is associated with a risk of perforation of the maxillary sinus membrane. When the perforation is occurred, shorter implants placement or a lateral approach is recommended.

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Sinus Lateral Window Technique Using the SLA Kit

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SUMMARY

The sinus lateral approach (SLA) kit is a new instrument that creates a 4-6mm hole in the lateral antral wall. It is faster than other instruments developed to date. The sinus lateral window technique is safe because it reduces the risk of accidental perforation of the maxillary sinus membrane. The process of lateral wall formation is simple and does not require specialized skills. Here, we report our procedure.

KEY WORDS

Sinus lateral window technique, SLA kit

Introduction

The bone support for implants in the posterior part of the maxilla is often poor. This condition may be treated by augmentation of the maxillary sinus floor. The most common sinus floor augmentation technique used involves elevating the sinus floor and increasing the bone volume by inserting a bone graft through a window in the lateral antral wall1-4)

The sinus lateral approach (SLA) kit is a new instrument for easily and safely creating a lateral window to perform the sinus lateral window technique. The SLA kit is used for cases in which application of a sinus crestal approach(SCA)kit is difficult, including those in which the residual bone is shorter than 3-4mm, those in which the membrane is perforated during the crestal approach, or those in which multiple implants are placed simultaneously.

SLA kit components

1. LS-reamer (Fig.1, Table 1)

The lateral sinus (LS)-reamer is a drill used for forming bony window via the lateral approach without preserving the bone core. There are a total of six types of reamer with head diameters of 4.5 , 5.5 and 6.5 mm and lengths of 2mm and 3.5mm.

Fig. 1. LS-reamer

Fig. 2. C-guide & C-reamer

Table 1. Characteristics of the SCA kit

- The LS-reamer allows depth control and is , therefore, safe.
- With sufficient water irrigation, drilling can be performed at speeds of 2000~5000 rpm.
- The bone chip removed during formation of the window can be filled the groove. The LS-reamer prevents damage, even when coming into direct contact with the sinus membrane.
- During the drilling, a thin bone membrane is formed between the sinus membrane and the LS-reamer. This prevents damage to the sinus membrane.
- The perforated hole can be grossly confirmed. Therefore, specific structures, such as blood vessels or septa, can be observed during drilling, which ensures that the procedure can be performed safely.

Table 2. Characteristics and application of the C-reamer

- During the drilling, a round core is formed that is 1 mm smaller in diameter than the head of each reamer. This core can be replaced in the hole and covered the lateral wall of the maxillary sinus.
- The C-reamer is designed such that drilling cannot proceed to a depth greater than is required, as LS-reamer, and its use is safe even in the absence of a drill stopper.
- The cutting edge of the C-reamer is located on the frontal and lateral aspect of the head, and it can, therefore, be used for perforation at a speed of >2000rpm. The bone membrane is preserved at the edge, and the sinus membrane, therefore, cannot be damaged. The formed core is retained in the reamer head. Prior to rotation, it is recommended that this core be removed using an elevator following the appropriate drilling pattern.
- The holes are formed on the lateral side, which facilitates cooling during drilling. This prevents overheating and permits removal of the formed core.

2. C-guide and C-reamer (Fig.2)

The C-guide is a guide drill that is used to prevent sliding and ensure accuracy while using the C-reamer.

The C-reamer is a drill that leaves a round core when forming a window on the lateral wall of the maxillary sinus; the name ”C” was derived from the shape of this core. This drill was developed to allow the procedure to be performed safely and quickly and to promote the bone formation. The C-reamer has a total of four heads with diameters of 5.5mm and 6.5mm and length 1.5mm and 3mm(Table2).

3. Sinus Membrane Elevator

The Sinus Membrane Elevator was designed for effective elevation of the membrane through a small lateral hole formed by the LS-or C-reamer.

1)Elevator 1

Immediately after holes are formed, Elevator 1 plays a role in initially elevating the membrane on the medial and distal sides. The angle of the shaft is designed such that surgeons can easily access.

2) Elevator 2

Elevator 2 is used subsequent to Elevator 1. The side that is bent in the shape of a sickle is used to detach the lower and upper parts of the lateral wall from the holes. The contralateral side, which has a smooth slope of approximately 30˚, is used to elevate the overall floor of the sinus, the medial wall, and the membrane of the posterior wall.

3)Elevator 3

Elevator 3 was designed to safely detach the remaining membrane that was not previously elevated.

Simultaneous application of LS-and C-reamers

The lateral wall commonly has a thickness of 2mm. However, the lateral wall may also be thicker than 2mm in many cases, which may be problematic b ecause the LS-reamer and C-reamer were designed to penetrate to a depth no greater than 3.5mm. In such cases, following the formation of the hole with the largest diameter, 6.5mm, a reamer with a diameter of 5.5mm can be created the window >5mm in depth. Following the formation of a core with a depth of 2-3mm using a C-reamer, the bone core is removed by a chisel or a periosteal elevator. With the LS-reamer, the residual part is dissected, and a hole is formed. The bone core can be respositioned in the hole and covered.

Procedures

1.Radiography

The residual bone height of the maxillary sinus is measured by preoperative X-rays. If a CT scan is performed, the complex structures with in the maxillary sinus can be examined in detail. The location of the artery or the thickness of the lateral wall can also be determined.

2.Selection of SLA

SLA is selected for cases in which the residual bone height is less than 3-4mm, those in which the membrane is perforated via the crestal approach, those in which the sinus floor is convex, and those in which multiple implants are placed simultaneously.

3.Flap formation

A small vertical incision and restricted lateral flap are needed, but extensive flap formation is unnecessary. A semilunar incision may be sufficient for the lateral site for cases in which flapless surgery is performed.

4.Selection of an LS-reamer

It is best to select the LS-reamer for areas where arterial bleeding is of concern, the septum is present, or for cases in which the hole should include the lower region to the inferior cortical wall of the maxillary sinus. In some cases, the sinus membrane may be used following bone grafting.

5.Selection of a C-reamer

The C-reamer is used to obtain a core, and it should, therefore, be selected in cases for which a core is needed. Unless a core is necessary, the selection of an LS-reamer is preferred. The bone core can be repositioned following bone grafting.

6.Location of the lateral hole

If possible, the lateral hole should be located at the most anterior and inferior position possible. This location is ideal for elevating a flap effectively without causing damage to the membrane. If residual bone quality is high, it is recommended that a hole includes approximately 1mm of the inferior cortical wall. If necessary, multiple holes can be made.

7.Rotational speed

In the early stages, a rotational speed of 5000rpm is recommended to drill without vibration. To obtain this speed, however, a 1:1 contra-angle is needed. If a rotational speed of 2000rpm is used, vibration occurs in the early stages. To prevent this, the handpiece should be held firmly, a maximal speed of 2000rpm should be selected, and vertical force should be exerted until the drilling is stable.

8. Hole formation using the LS-reamer

With sufficient water irrigation, the depth of puncture should be checked while pumping-action drilling. The LS-reamer should be used for drilling until the lateral wall is completely perforated. At this point, a thin bone membrane can be visualized between the membrane and reamer. This is called the residual bone shield, and it plays an important role in preventing membrane damage. For cases in which large-diameter blood vessels are identified during

drilling, other holes can be drilled lower in the lateral wall to avoid these sites.

9.Hole formation with the C-reamer

With sufficient water irrigation, the depth of puncture should be checked while pumping-action drilling. In most cases, direct contact between the C-reamer and the membrane is considered safe. In comparison to the LS-reamer, however, use of the C-reamer is less safe. As a result, when a thicknedd of >3mm is encountered. The core should removed using a chisel or a periosteal elevator, and the remaining bone should be finished using the LS-reamer. The drilling is performed until the bone core can be removed by lever action of the elevator. Attempts should not be made to completely dissect the core with the C-reamer. The removed bone core should be preserved on wet gauze or in saline.

10. Sinus membrane elevator

The membrane should be elevated by the sequential use of Elevator 1-3, as described above. This should be done using conventional methods.

11. Graft material insertion and implant placement

The graft material insertion and implant placement should be performed using conventional methods.

Case Report

Surgical procedure based on extraction of the left maxillary second molar via the lateral approach

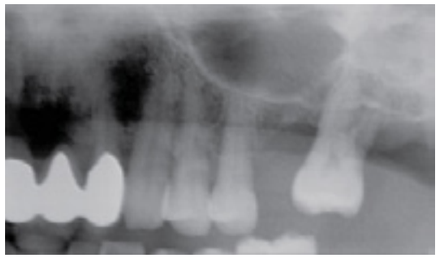

Fig. 3. Panoramic radiographs of patients requiring implant placement for the left maxillary molar and bone grafting for the maxillary sinus

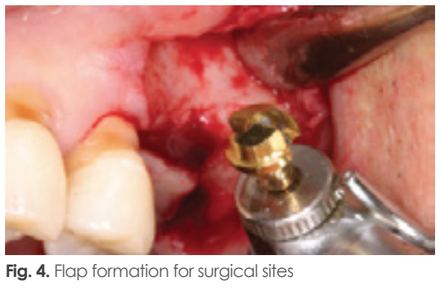

Fig. 4. Flap formation for surgical sites

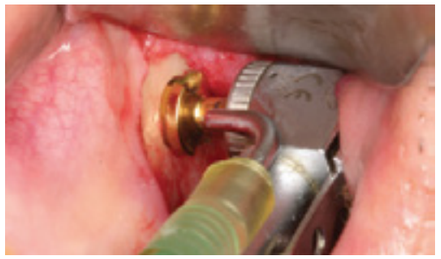

Fig. 5. Bony window formation using the LS-reamer

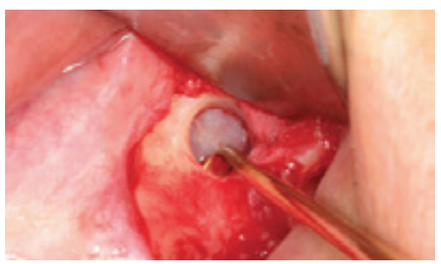

Fig. 6. Elevation of maxillary sinus membrane with the LS-reamer

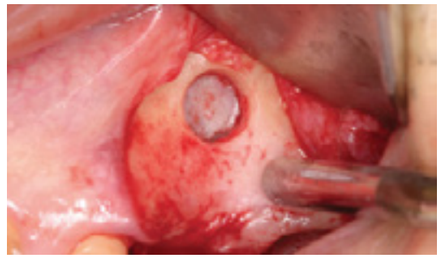

Fig. 7. Photographs illustrating the finding after elevation of the maxillary sinus membrane using a micro elevator

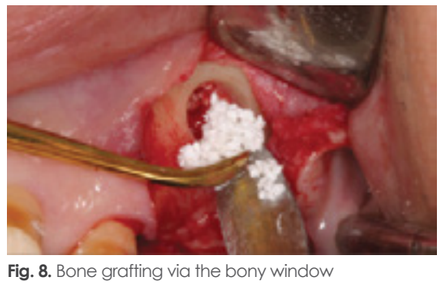

Fig. 8. Bone grafting via the bony window

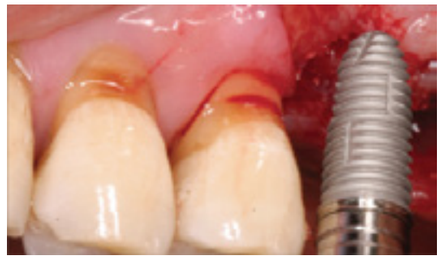

Fig. 9. The process of dental implant placement after bone grafting of the maxillary sinus

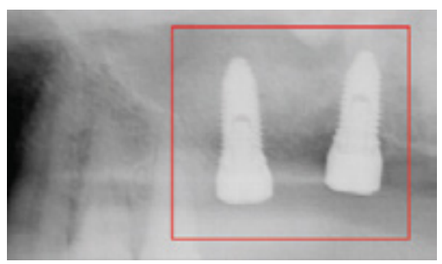

Fig. 10. Panoramic radiography after dental implant placement and maxillary sinus bone grafting

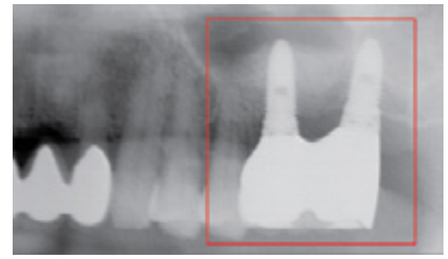

Fig. 11. Radiologic findings after prosthesis delivery

Fig. 12. Clinical finding after completed prosthesis

Discussion

Edentulous sites in the posterior maxilla are often compromised by reduced bone volume, which prohibits the placement of 10-mm implants without sinus augmentation2). For cases in which the height of residual bone is less than 5mm, excessive elevation of the maxillary sinus mucosa via the crestal approach is very dangerous and increases the possibility of treatment failure1).

The SLA kit has the “3S” advantage: speed, safety, and simplicity. It forms a 4-6mm hole at once, and is, therefore, faster than any other instrument reported to date. The perforation of the maxillary sinus membrane is unlikely with this approach. Therefore, it is considered

a safe procedure. This process of making a hole in the lateral wall is simplified and can be performed without specialized skills. The SLA technique resolves the burdensome features of the conventional types of the sinus lateral approach(Table 3).

Table 3. Advantages of the SLA technique

- No Requirement for extensive flap opening: The procedure can be performed with a minimal flap opening using the SLA-KIT.
- No need for a large window: A stable approach can be completed without requiring a large window.
- Does not require such instruments as a straight handpiece or round bur: Preparation is simplified because the surgeon need not use a straight handpiece or round bur. Damage to the membrane during window formation can be minimized.
- Minimal risk of arterial bleeding during window formation: The procedure can be performed while monitoring blood vessels in the area. Therefore, this is a safe procedure.
- Risk of membrane tearing during a window formation: The special shape of the reamer edge minimizes the risk of damage to the membrane.
- Risk of swelling and pain with extensive surgery: The degree of swelling and pain can be markedly reduced by minimizing surgical time and scope.
- Lack of confidence with regard to techniques of membrane elevation: Three types of custom-designed elevators can elevate the membrane both safely and effectively.

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Immediate loading with a new concept of maxillary sinus elevation : S-reamer Osteotome Technique.

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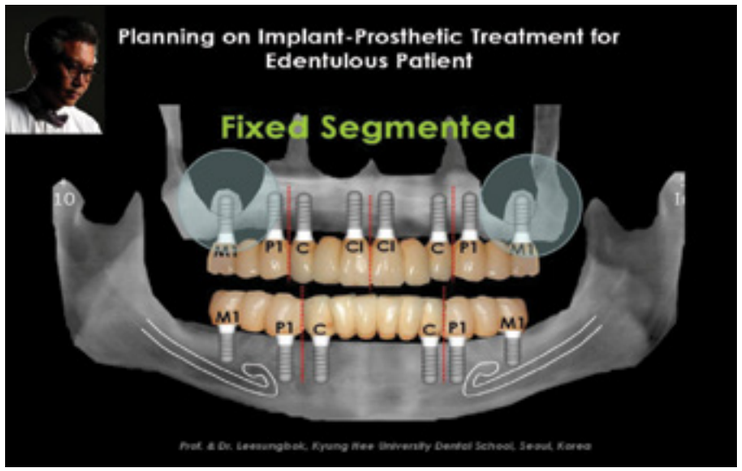
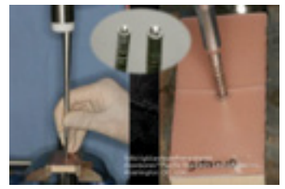
Background & Aim

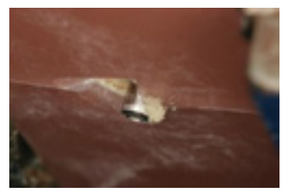
Once in a while, the malleting osteotome technique arises several post-operative complications such as discomfort and inner auditory organ damage. Also the possibility of damage on the sinus membrane with excessive fracture of sinus floor still remains.

This report introduced a new maxillary sinus floor elevation technique in which only the inferior cortical wall underneath the sinus would be perforated without tearing of maxillary sinus membrane by drilling instead of malleting using a rotary instrument, called S-reamer®(Neobiotec Co., Seoul, Korea).

The objective of this presentation is to show our scientific and clinical experience related to implant supported fixed restorations for the partially and fully edentulous jaws including a situation after sinus graft with S-reamer osteotome technique, and to assess the survival outcome of immediate loading protocols according to their treatment sequence and selected prosthodontic design.







In Vitro Study

Difference in Implant Stability According to Various Methods of Implant Bed Preparation (inpublishing)

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This study aims to compare primary implant stability according to the different surgical techniques in both monocortical and bicortical posterior mxilla models and to examine correlation between insertion torque values, resonance frequency analysis (RFA) and removal torque values. Sixty screw-shaped (CMI implant ; Neobiotech, Seoul, Korea) implants (4.0mm diameter and 10mm length) were inserted into solid rigid polyurethane blocks (Sawbones®); 10 implants for each group. It used a 0.32g/cm^3 block, which is equivalent to the mean bone mineral density of the posterior maxilla region, for the cancellous bone part. To mimic the cortical layer, it laminated 1mm thickness of short fibre-filled epoxy sheets on the cancellous bone part. Implants were divided into 6 groups : group 1, CM (Crest cortical and Middle cancellous) fixation; group 2, CM fixation with underdrilling; group 3, CM fixation with osteotome technique; group 4, CMI (Crest cortical, Middle cancellous and Inferior cortical) fixation; group 5, CMI fixation with underdrilling; and group 6, CMI fixation with osteotome technique. It measured insertion and removal torques and carried out RFA for measurement of primary implant stability. As the results, the highest insertion torque was observed in the group 5 and the hightest RFA value and removal torque were measured in the group 4. In the result of correlation analysis, no significant correlations has been found among most of parameters except group 5, demonstrating low correlations among insertion, RFA value and removal torque.

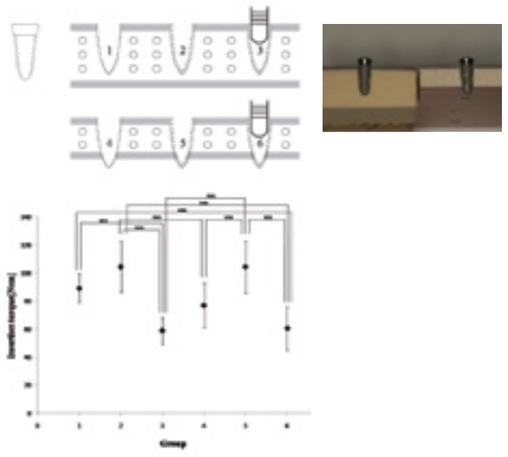


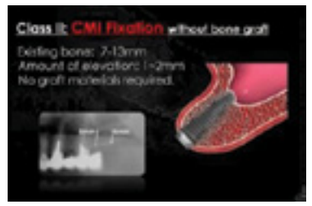
Diagram of different surgical procedure. The implant specimens were divided into 6 groups: group 1, CM (Crest cortical and Middle cancellous) fixation; group 2, CM fixation with underdrilling; group 3, CM fixation with osteotome technique; group 4, CMI (Crest cortical, Middle cancellous and Inferior cortical) fixation; group 5, CMI fixation with underdrilling; and group 6, CMI fixation with osteotome technique.

Mean and standard deviations of insertion torque for the 6 groups. The star shows significant differences with the One-way ANOVA (**P<0.05, ***P<0.01).

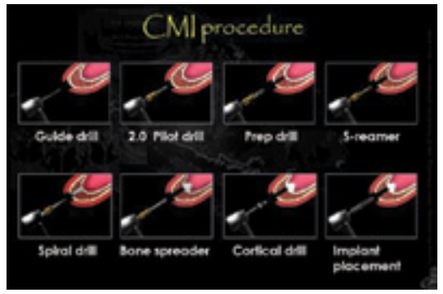
The highest insertion torque was observed in the group 5 and the hightest RFA value and removal torque were measured in the group 4.

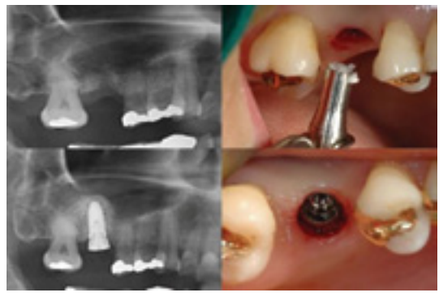
Clinical Study; Methods & Materials

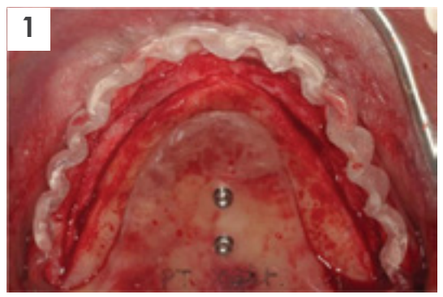
1. S-reamer used in this report was designed to remove the bone beneath maxillary sinus floor without tearing any maxillary sinus membrane.
2. 104 implants for 32 patients were placed with help of S-reamer in order to increase vertical bone dimension on the posterior maxillae, and had immediate restorations after implant surgery with this sinus elevation procedure at Kyung Hee University East-West Neo Medical Dental Hospital (Seoul, Korea) since 2006.
3. The bone chip is collected in the head of the reamer that has the letter 'S' shape, making the head surface smooth to prevent the tearing of the membrane.
4. The image of S-reamer was captured from the recorded video clip when it was drilling on the sinus wall of a pig in a simulation test. It revealed that moving drill did not tear the sinus membrane even though it was pushing over the border of inner sinus wall.

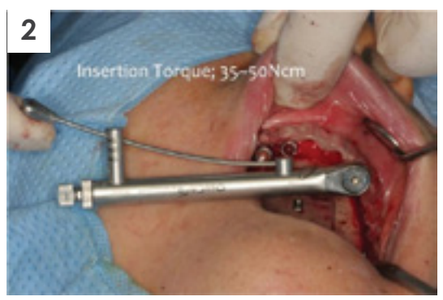


Clinical Procedure with S-reamer









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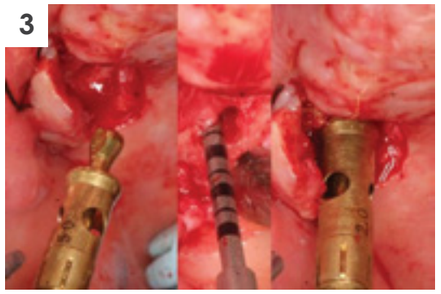

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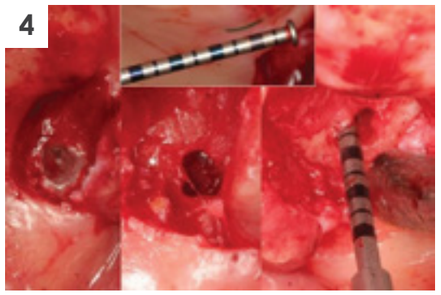

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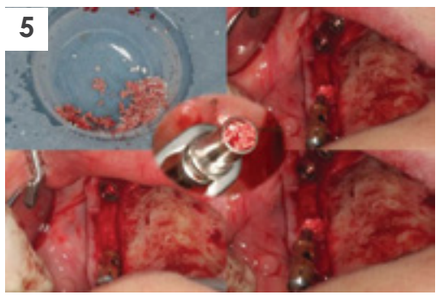

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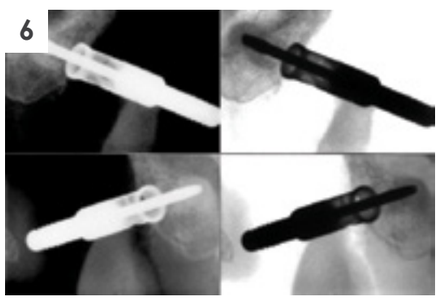

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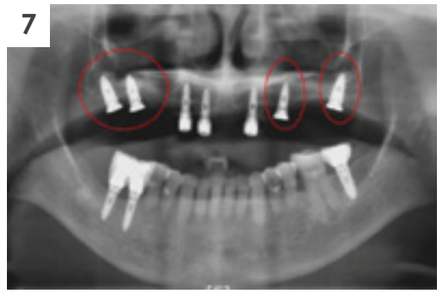

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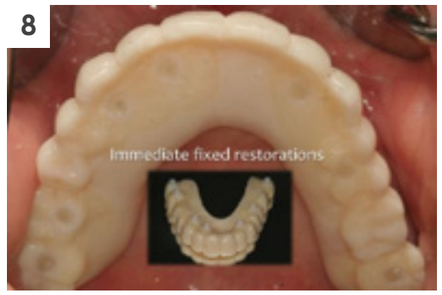

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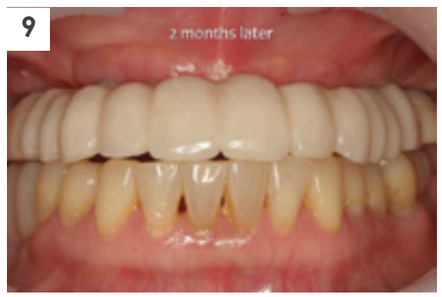

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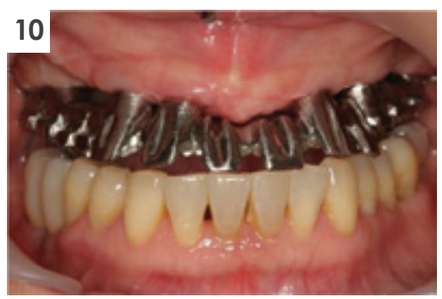

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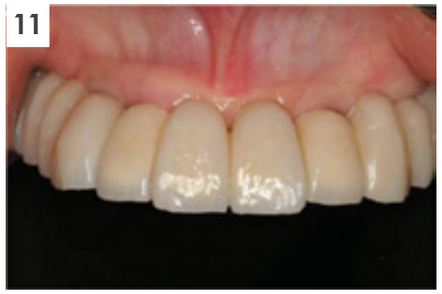

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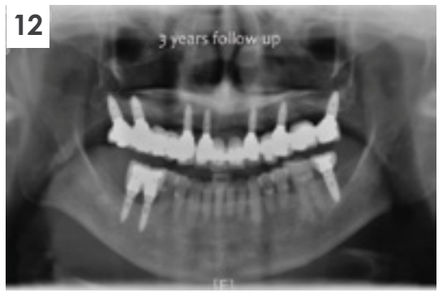
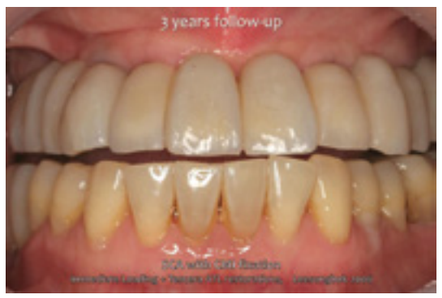
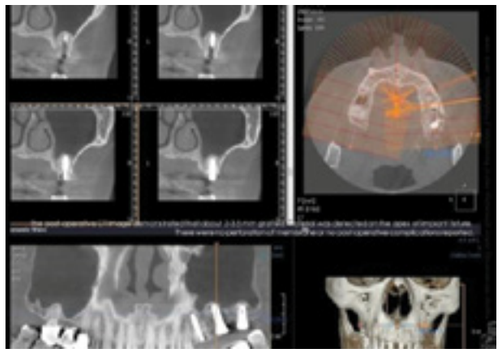
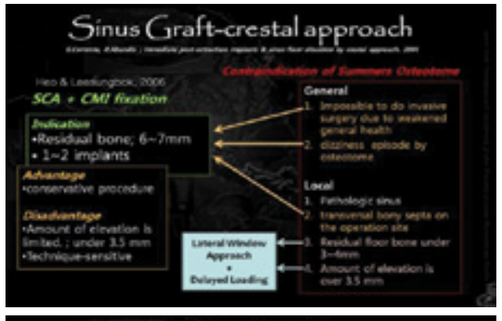


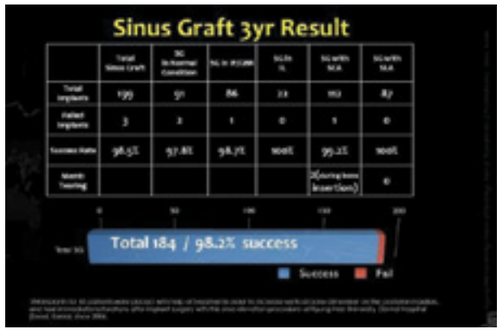


Results

1. The initial remained bone thickness between sinus floor and alveolar crest were various from 5 to 10mm.
2. As a result, 8mm to 10mm length of implants were installed according to site preparation including internal sinus augmentation.
3. The post-operative CT image demonstrated that about 2-3.5mm grafted material was detected on the apex of implant fixture.
4. There were no perforation of membrane or no post operative complications reported.



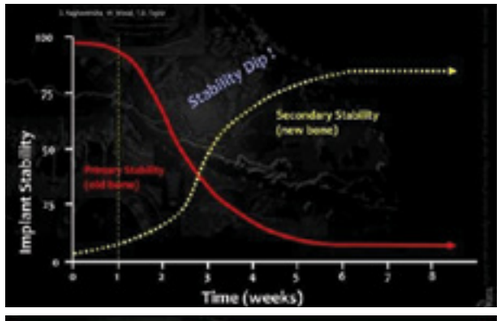


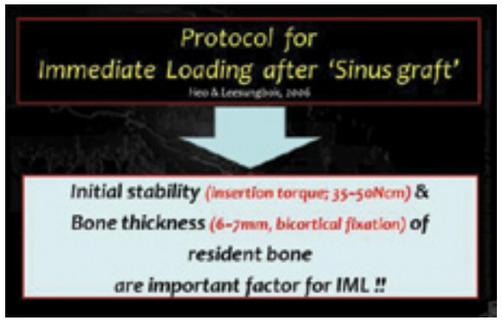


Conclusions and clinical implications

The newly designed "S-reamer osteotome technique" can be used as a predictable alternative treatment modality as compared with malleting osteotome technique as well as external lateral window approah.

This technique would be a minimal invasive sinus floor elevation procedure and an effective way to achieve immediate loading due to the sinus inferior cortical fixation on the posterior maxilla.





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A new crestal approach for sinus floor elevation: Case reports

Kaid 2009;28(1):41-48

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Introduction

The posterior maxilla often presents specific problems for placement of dental implants. Frequently poor bone quality with inadequate bone volume has rendered long-term success rates for implants[1)]. To overcome this situation, usually sinus floor elevation was carried out through the lateral approach technique or crestal approach, so called, osteotome method. The osteotome technique, first described in 1994, has been known for the primary advantage of being less invasive than lateral window approach[2)]. However, osteotome technique comes with the magnitude of forces and the amount of heat. This malleting osteotome technique has several post operative complications such as unpleasant discomfort and inner auditory organ damage once in a while[3)]. Also the possibility of damage on the sinus membrane still remains.

This report introduced a new sinus floor elevation technique in which only the inferior cortical wall underneath the sinus would be perforated without tearing of sinus membrane by drilling instead of malleting using a rotary instrument, called S-reamer. Sreamer®(Neobiotec Co., Korea) used in this report was designed to remove the bone beneath sinus floor without tearing any sinus membrane (Fig. 1A). The head of the reamer was designed like letter 'S' to prevent tearing of membrane by keeping the bone chip in the bone reservoir of the reamer head to make the head surface smooth (Fig. 1B). The image of S-reamer was captured from the movie when it was drilling on the sinus wall of pig (Fig. 2). It reveled that moving drill did not tear the sinus membrane even it was pushing over the border of inner sinus wall.

This technique would be a minimal invasive sinus floor elevation procedure and an effective way to achieve sinus inferior cortical fixation for this reason.

Case reports

Total ten patients were included for this report. Two of them were treated at a private dental clinic (Seoul, Korea). The others visited at Seoul National University Bundang Hospital. Crestal sinus lifting procedures using S-reamer and implant installation were performed in each of the patients.

Case 1

A 63-year old female patient complained difficulty of chewing due to missing teeth on left posterior area. Conventional oral examination was performed. Panorama radiographic image showed that residual bone height was not enough for conventional implant placement.

Initially 8.2 and 6.4 mm alveolar bone existed below the sinus floor respectively (Fig. 3A). To overcome insufficient alveolar bone for implant placement, sinus lift was assessed. Drilling was performed 1mm shorter than the existing bone length. Then, a certain diameter of the S-reamers matched to the diameter of an implant placed was chosen and a stopper 1mm longer than the existing bone was connected and drilled with 800-1200rpm until the stopper toughed on the alveolar crest (Fig. 3C).

Changing 1mm shorter stopper, drilling on the sinus inferior cortical bone was repeated until the cortical wall was perforated (Fig. 3B and C). This osteotome technique was accurately planned and measured because implant bed was prepared by only drilling not compressive malleting. To check any perforation of the cortical wall, a depth gauge was inserted carefully and measured the remnant bone height precisely (Fig. 3D).

Any perforation of sinus membrane should be recognized by blurring test. In this case Schneiderian membrane was not torn even if the spinning S-reamer contacted to the membrane. It may be due to the smooth surface of the S-reamer in which bone chips were supposed to remain in the reservoir of the head of the reamer.

After verifying the membrane was not perforated, a synthetic bone graft material was used such as CalPore® (βTCP 60% + HA 40%) in this case. 0.2-0.3 cc of bone particles were pushed inside using a condenser until reached to enough height (Fig. 3E). At this moment a bone spreader was applied in order to spread graft material into the sinus cavity properly below the Schneiderian membrane (Fig. 3F). Spreading was repeated after adding bone. When the bone grafting was performed, two 5x11.5mm implants (SinusQuick®, Neobiotec Co., Korea) were placed with insertion torque up to 35Ncm. The sufficient initial stability may result from the inferior cortical fixation due to proper size of the hole made by the S-reamer. Three days later, post-operation CT scan and panorama were taken. Panoramic view of CT scan showed adequate bone filled around fixtures (Fig. 3G). In one month after surgery, final prosthesis was delivered since it was regarded as initial stability was achieved (Fig. 3H).

Case 2

A 46 year old male patient visited at a private dental clinic in Seoul Korea. His chief problem was pain on right upper side. Right first premolar had an abscess which was extracted. Subsequently radiographic image was obtained (Fig. 4A). Panorama radiographic finding was examined. He had only anterior teeth left on the upper jaw. Both left and right maxillary reconstruction was planned with implant supported prosthesis thorough sinus lift procedure. The remaining bone height in the right side sinus area was 6-7mm and left side was 1-3mm. In terms of the remaining bone height, right side was performed with a crestal approach using the S-reamer while left side was assessed with a conventional lateral window approach at the same day.

In the right side, sinus inferior wall was prepared to make 3 proper holes using the S-reamer without tearing the sinus membrane. After verifying the intact membrane, 4x10mm, 5x7mm, 5x7mm and 5x8.5mm implant (SinusQuick®, Neobiotech Co., Korea) from right first premolar to secondary molar were placed without bone graft. Implants were inserted

into the sinus up to 1-1.5mm and all implants earned initial stability ranging approximately 35-45Ncm. Left side was treated with conventional lateral window approach. Four 4x13mm implants were placed simultaneously. Postoperation panorama view was taken (Fig.4B). Restoration was finished at fourteen days after implant installation (Fig. 4C). No complications have been reported.

Besides these two cases, eight patients had implant surgery with sinus lift procedure using S-reamer simultaneously at Seoul National University Bundang Hospital. Fourteen implants were placed with help of Sreamer in order to increase apico-occlusal bone dimension (Table 1). Four implants did not require additional bone support. Approximately initial remained bone level were various from 4.4 to 10mm. As a result, 8mm to 12mm length of implants were installed according to site preparation including internal sinus augmentation. One of the post-operative radiographic image demonstrated that about 3-3.5 mm grafted material was detected on the apex of implant fixture (Fig. 5A and B). There were no post operative complications reported.

Discussion

Implant insertion in the posterior region of the maxilla is a challenging procedure. The reduced bone quantity and low bone quality are limiting factors. Although Summer's osteotome method is considered less invasive than lateral window approach, post-operative problems was existed once in a while. Besides simple complications, a recent report mentioned that it had been associated with the provocation of benign paroxysmal positional vertigo (BPPV)[3]. These authors also warned that the trauma induced by percussion with surgical hammer, along with hypertension of neck during operation, could displace otoliths by BPPV[3].

In 2006 Ferrigno et al, pointed that from the patient aspect, implant site preparation is more comfortable when performed with spiral drills than with continuous malleting[4]. This kind of opinions has been supported by other studies. For instance, Fugazzotto described the use of a calibrated trephine bur in the first step in the procedure, mentioning that this method is less traumatic and disconcerting to the patient compared to repeated malleting[5, 6].

On the other hand, summer's osteotome technique may not achieve inferior cortical fixation from inferior border of sinus floor because it breaks the cortical bone broadly. Compared with malleting method, this osteotome technique can mostly obtain true meaning of inferior cortical fixation by preparing proper size of hole matching to the size of an implant placed. Taken into another concern, Strietzel et al, mentioned that indication for the use of osteotome technique should be considered critically with respect to the bone quality: bone quality class 1 or 2 is not suitable for this kind of implant bed preparation via compressive packing method[7].

In 2003, Wallace and Froum published a review article on implant survival rate related to sinus augmentation[8]. They proposed a 93.5 % overall survival rate of implants with conventional Osteotome techniques. Interestingly it was noted that the higher survival rate of localized management of sinus floor and crestal core elevation which was 96.9% and 98.3 respectively[8].

According to recent meta-analysis for survival rate of implant with osteotome technique, the combined data revealed survival probability of 98% until loading and 99% after 56 month of loading[9]. Other systemic review and meta-analysis study reported that the outcome of dental implantation using the osteotome technique in terms of implant survival seems to be similar to that of implants placed by means of the conventional implantation technique[10]. It concluded that survival and success rate were 95.7% and 96% after 24months and 36 month respectively[10].

Conclusion

This report showed that implant placement following drilling osteotome technique was less invasive than conventional malleting osteotome. The prognosis of implant using drilling osteotome technique is estimated to be at least as same as the published data of implants placed by conventional malleting osteotome method. The newly designed "S- reamer osteotome technique" can be used as a predictable alternative treatment modality as compared with "malleting osteotome technique"as well as external lateral window technique.

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Table 1

case	Age/sex	Site (Rt/Lt)	Site	Residual bone level#	S-reamer Yes/No	Implant-type, Implant length
1	26/F	Lt	1st PM	9mm	Yes	Implantium †, 10mm
2	54/M	Rt	2nd PM	9.6mm	Yes	Implantium, 12mm
		Lt	1st M	10mm	Yes	Implantium, 12mm
			1st M	8mm	Yes	Implantium, 12mm
			2nd M	8.5mm	Yes	Implantium, 12mm
3	47/M	Lt	1st M	4.5mm	Yes	Osstem GS§, 10mm
4	56/M	Lt	1st PM	9mm	Yes	Implantium, 10mm
			1st M	6mm	Yes	Implantium, 8mm
5	58/M	Lt	2nd PM	9.5mm	Yes	Implantium, 10mm
			1st M	6mm	Yes	Implantium, 10mm
			2nd M	6mm	Yes	Implantium, 8mm
6	57/M	Lt	2nd PM	9.5mm	Yes	Osstem GS 11.5mm
7	46/F	Rt	1st M	6mm	Yes	Tiunite¶, 10mm
8	44/M	Lt	1st M	4.4mm	Yes	Implantium, 8mm

Approximate value based on panoramic radiographic image
† implantium®, Dentium, Seoul, Korea
§ Osstem GS®, Osstem Implant system, Seoul, Korea
¶ Tiunite®, Nobel Biocare, Gothenburg, Sweden.

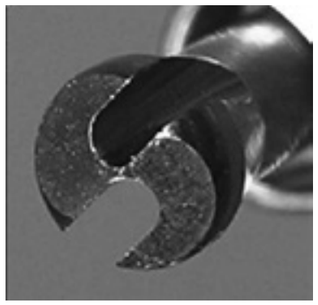

Fig. 1. A. and B. S-reamer tip was designed like letter 'S'to protect tearing of membrane through keeping bone chip around tip while spinning.

Fig. 1. B.

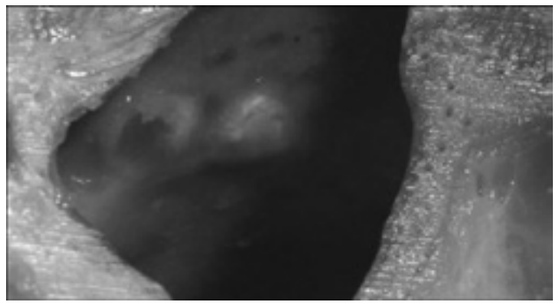

Fig. 2. It reveled that moving drill did not tear the sinus membrane even it was pushing over the border of inner sinus wall.

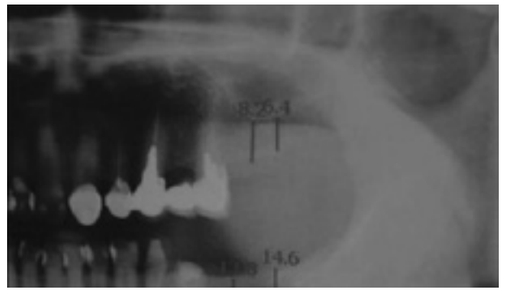

Fig. 3. A. 63- year old female patient. Preoperative radiographic image explained that 8.2mm and 6.4mm of apico-occlusal dimension of alveolar bone was remained at left first and secondary axillary molar respectively.

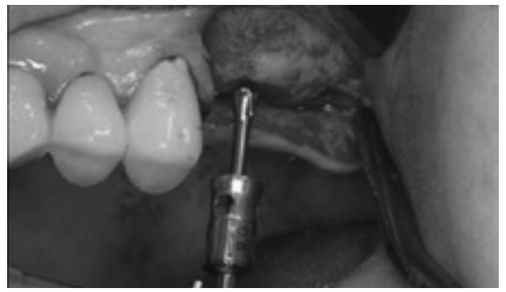

Fig. 3. B and C. Drilling was performed until stoppe® toughed the alveolar bone crest. Changing shorter stopper, drilling on the crestal bone underneath of sinus floor was repeated.

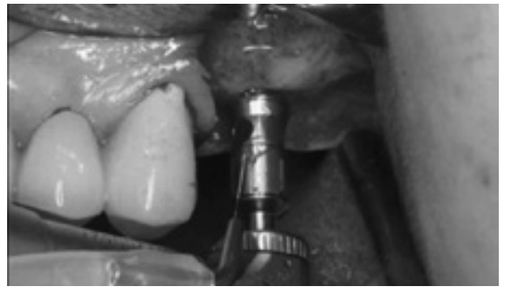

Fig. 3. C.

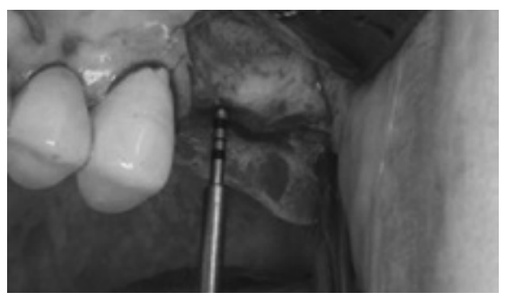

Fig. 3. D. To check any perforation, Depth gauge was inserted carefully and measured the remnant bone height precisely.

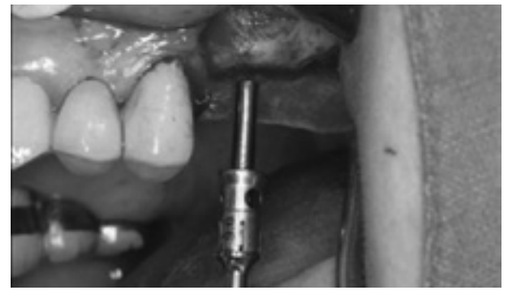

Fig. 3. E. A condenser was used connecting with stopper until reached to enough height.

Fig. 3. F. A bone spreader was applied in order to spread graft material into the sinus cavity properly below the Schneiderian membrane.

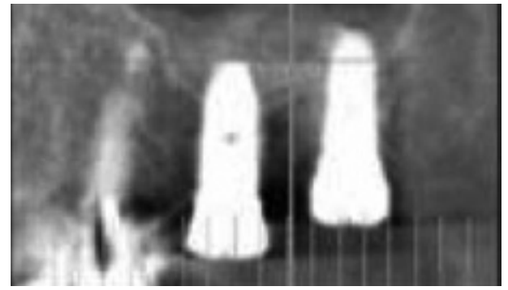

Fig. 3. G. Three days after surgery, post-operation CT scan and panorama was taken. In the Panoramic view of CT scan, adequate amount of bone was filled around fixtures.

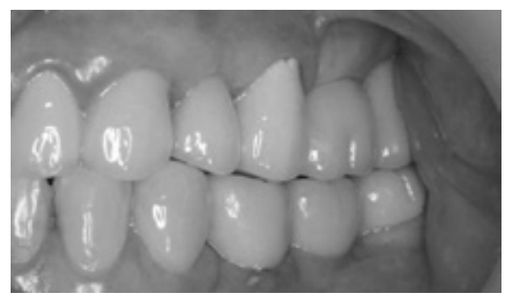

Fig. 3. H. In one month after surgery, final prosthesis was delivered since it was regarded as initial stability was achieved for immediate loading.

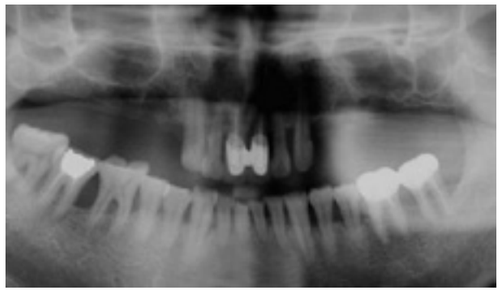

Fig. 4. A. A 46 year old male patient visited at a private dental clinic. His chief problem was pain on right upper side previously. Right first premolar had an abscess which was extracted. Subsequently radiographic image was obtained which revealed that he lost all premolar and molar on both side of upper jaw.

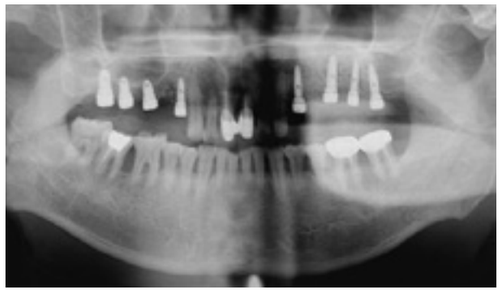

Fig.4. B. 10mm, 7mm, 7mm and 8.5mm length implant were chosen from right first premolar to secondary molar. Alveolar bone defect was grafted with synthetic bone material on distal of right first premolar.
Left side was finished with conventional lateral approach sinus lift and all 13mm implant installation.

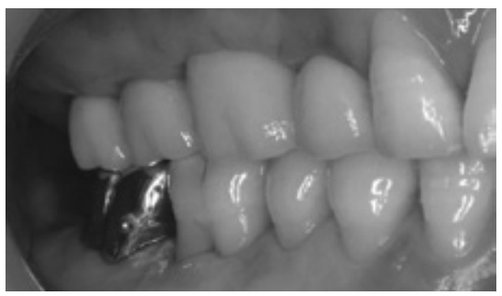

Fig.4. C. Final restoration was delivered at two weeks after surgery.

Fig. 5. A and B. One of the post-operative radiographic image demonstrated that about 3-3.5mm grafted material was detected on the apex of implant fixture. Radio-opaque bone graft material was Osteon® (Dentium, Korea).

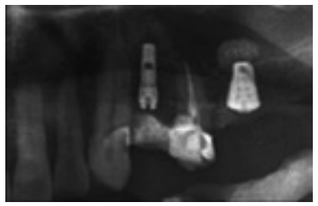

Fig. 5. B.

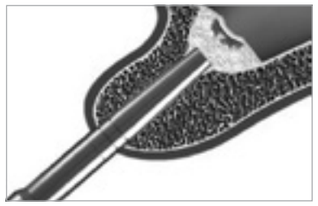

Fig. 6. A and B. Summer's osteotome technique can not achieve a bi-cortification from inferior border of sinus floor because inner cortical lining bone was broken broadly. Compared with malleting method, this drilling osteotome acquired true meaning of bi-cortification.

Fig. 6. B.

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A novel trephine design for sinus lift lateral approach: Case report

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Abstract

Various techniques are described in the literature, either by crestal or lateral approach. Sinus augmentation has a high percentage of success, but presents a number of intraoperative and postoperative complications. The most frequent complication is the Schneiderian membrane perforation with a percentage of perforations between 11% and 56% according to authors. The aim of this study is to describe another membrane approach technique for the sinus lateral wall osteotomy that minimizes the risk of Schneiderian membrane perforation. We present a case of a 50 year old patient attended the University Dental Clinic (UDC) of International University of Catalonia for implant and crown treatment due to the loss of a right maxillary first molar. To insert an implant in position 1.6 a computerized tomography (CT) was requested to determine with greater accuracy the quantity of residual crestal bone. It showed a height of 5 mm and width of 8 mm. The lateral osteotomy was performed with a (SLA KIT® -Neobiotech) trephine mounted in the same implant handpiece with which the field for the implant and the implant itself were prepared. It can be concluded that in the case described, the use of trephine drills of the SLA system mounted in a handpiece allows better access to lateral approach due to its perpendicular position relative to the sinus wall minimizing the membrane perforation risk.

Key words:

Sinus lift, lateral approach, membrane perforation, trephine drills, dental implant.

Introduction

The sinus lift technique was introduced by Tatum in 1975 and published by Boyne & James in 1980 (1). This pre-prosthetic surgery allows bone augmentation in the posterior zone of atrophic maxilla in pneumatized sinus cases for implant surgery at the same time as, or after osseointegration of sinusal graft material.

Various techniques are described in the literature, either by crestal or lateral approach. The lateral approach is to perform an osteotomy in the lateral sinus wall opening a bone window that allows access to lift the Schneiderian membrane and to place the graft material. Sinus augmentation has a high percentage of success, but presents a number of intraoperative complications (membrane perforation, fracture of the residual alveolar ridge, obstruction of the maxillary ostium, hemorrhage, and damage to adjacent dentition), early postoperative complications (hemorrhage, wound dehiscences, acute infection, exposure of barrier membrane, graft infection, graft loss and dental implants failure) and late postoperative complications (graft loss, implant loss or failure, implant migration, oroantral fistula, chronic pain, chronic sinus disease, chronic infection) (2,3). The most frequent complication is the Schneiderian membrane perforation with a percentage of perforations between 11% and 56% according to authors. The Schneiderian membrane is composed of periosteum covered by respiratory epithelium, which is thin, friable and easy to perforate. The window design, the presence of maxillary sinus septa, sinus floor irregularities and a residual ridge of 3 mm or less, increase the risk of perforation (4,5). Wallace et al. (6) describe that in most cases, perforation occurs during the use of rotary instruments for sinus wall osteotomy, before lifting the membrane. His study, showed 30% perforations with the use of rotary instruments and a drill, while with the use of piezoelectrics there were only 7% perforations. According to results, Stübinger et al. (7) who compare the ultrasonic bone cutting with burs for surgical approach for sinus lift and bone blocks graft, conclude that ultrasonic use preserves adjacent soft tissues structures. Later, Blus et al. (8) in 2008 refers to 3.8% perforations, 2 out of 53 membranes that were perforated during the sinus approach with the application of ultrasonics. The membrane perforation can lead to graft material loss, graft material dispersion leading to bacterial contamination and postoperative infection (9).

The aim of this study is to describe another membrane approach technique for the sinus lateral wall osteotomy that minimizes the risk of Schneiderian membrane perforation using the surgical instruments from a SLA KIT –Yield® (Neobiotech) mounted in a dental implant handpiece, and to assess the advantages and disadvantages offered by the system.

Clinical Case

We present a case of a 50 year old patient attended the University Dental Clinic (UDC) of International University of Catalonia for implant and crown treatment due to the loss of a right maxillary first molar. A clinical history was completed, an intraoral examination made, and extraoral and intraoral registers (study cast, frontal and lateral pictures in maxim intercuspidation, excursives movements and panoramic radiography) were performed at the first visit. The patient did not have any medical nor surgical contraindication to maxillary subantral augmentation. In a radiographic test we observed a right maxillary sinus pneumatized with a low bone height. To insert an implant in position 1.6 a computerized tomography (CT) was requested to determine with greater accuracy the quantity of residual crestal bone. It showed a height of 5 mm and width of 8 mm (Fig. 1).

We carried out a sinus lift and the implant insertion in position 1.6 at the same time to minimize the number of operations on the patient.

Access to the membrane approach was effected using the SLA KIT –Yield® (Neobiotech) for sinus lift lateral approach access. This kit has a guide drill to start the window design and obtain the correct position so avoiding slips, then the SL Reamer and/or C Reamer drills are used. The drills have diameters of 4.5 mm, 5.5 mm and 6.5 mm. The LS Reamer drills have a height of 2 mm and 3.5 mm and the C Reamer drills have heights of 1.5 mm and 3 mm. After setting the position with a guide drill the LS Reamer drill is used to collect bone chips during osteotomy of the lateral window of the sinus or the C Reamer drill that allows the safe osteotomy of the lateral window. The drill diameter and height is determined depending on each case. The contact surface of the reamer drill allows the osteotomy without the risk of perforating the Schneiderian membrane sinus.

A sterile surgical area was prepared. Surgical procedure was under a local anesthetic nerve block in the right upper maxilla, and infiltrative anesthesia in palatal zone at palatal foramen level. A crestal incision was made and a distal vertical discharge. A mucoperiosteal flap was lifted and a maxillary alveolar process was revealed. The osteotomy was performed at a height of 7 mm above the crestal margin with a trephine mounted in the same implant handpiece with which the field for the implant and the implant itself were prepared. Osteotomy milling was at 2000 rpm with external irrigation, perpendicular to the sinus wall up to the sinusal membrane. The contact area of trephine drill permits contact with the membrane without causing perforation (Fig. 2).

The lateral bone window was removed with a periosteal elevator and the membrane lifted with lift instruments from the SLA KIT. After the insertion of the sinus graft and implant in 1.6 position, the lateral window wall was repositioned and the surgical incision area was sutured with a monofilament suture 4/0. To prevent early postoperative complications of sinus augmentation, antibiotics and analgesics were prescribed and the patient was given information on postoperative care. The suture was removed one week after surgery. After 7 months a panoramic radiography image was obtained (Fig. 3).

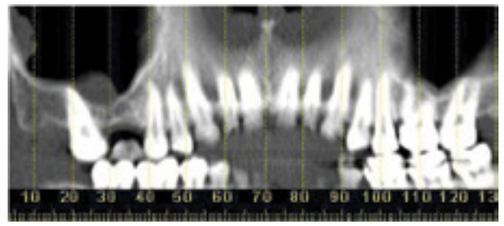

Fig. 1. Panoramic projection in the CT of surgical zone.

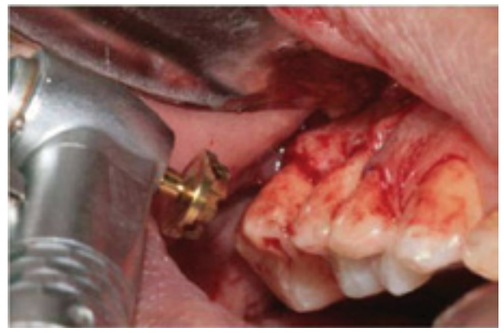

Fig. 2. Lateral osteotomy.

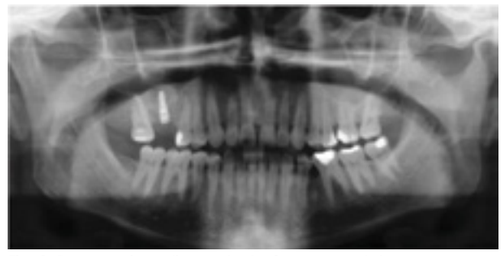

Fig. 3. Panoramic radiography before second stage.

Discussion

As the membrane integrity is important it is essential to produce a cavity which will limit the amount of sinus graft material inserted into the zone so improving implant survival and reducing complications.

Ardekian et al. (4) assess the incidence of membrane perforations, complications, and successful treatment. They did not find significant differences between implant survival for implants inserted in a grafted sinus where there was a membrane perforation and sinus with the membrane intact. However, Proussaefs et al. (9) found fewer implant survivals for implants installed in a grafted sinus with membrane perforation. Subsequently agreeing with this author, Hernández-Alfaro et al. (10) studied the prevalence of surgical complications and described an action protocol relating to the perforation size. These authors describe in their results a lower implant survival rate for implants installed in grafted sinus when there was a membrane perforation influenced also by perforation size. These results coincided with the results reported by Viña-Almunia et al. (11) who concluded that the survival of implants diminishes when they are placed in sinus lifts with a perforated membrane.

There are different options described in the literature for preparing the lateral window, such as conventional osteotomy using rotating instruments (round burrs), trephines, piezosurgery and/or lasers.

Romanos (12) describes a different technique for window preparation for sinus lift procedure. A round burr is used to prepare the osteotomy with continuous saline solution irrigation. Before the sinus mucosa is visible through the maxillary bone at the osteotomy site, a mallet and a dental mirror holder is used to tap in one blow in a perpendicular direction to the lateral bony wall, in the middle of the window. The author was not able to observe any perforation of the sinus floor mucosa using this technique in the 56 cases described. However, Sohn et al. (13) published a study where erbium, chromium, yttrium–scandium–gallium–garnet (Er, Cr:YSGG) laser and various laser systems were used for 12 sinus bone grafts in ten patients. The efficiency of the laser was evaluated according to the osteotomy time and the rate of sinus membrane perforation. The author describes a perforation ratio of 33.3% and all the implants placed immediately were successful.

In 2002, Emtiaz et al. (14) published the same surgical procedure using trephines (Implant Innovations®, Inc., Ibérica, SL, Barcelona, Spain) although reference is made to the need for caution during the lateral osteotomy due to the membrane perforation risk using a trephine.

The trephine used in this situation (SLA KIT –Yield® Neobiotech), presents differences from conventional trephine used. The contact surface of the new trephine has a curved periphery and a bone-maintaining area contacting surface. The bone maintaining area includes a first inside wall oriented in a drilling direction higher than a second inside wall with a drilling surface exposed in the drilling direction preventing sinus membrane damage when the head of drill contacts the membrane. The described technique in this article presents a number of advantages such as reduced surgical time, a small and accurate access for sinus lift for a single implant and lower risk of perforation of the sinus membrane. Due to the technique of performing osteotomy with a trephine mounted in the same handpiece used later for implant surgery, the use of auxiliary different handpieces or piezoelectric equipment was eliminated, so reducing the surgical cost.

It can be concluded that in the case described, the use of trephine drills of the SLA system mounted in a handpiece allows better access to lateral approach due to its perpendicular position relative to the sinus wall. The shape of the contact area of the drills minimizes the sinus membrane perforation risk during osteotomy. Lateral approach for sinus lifts by this technique did not present any complications in the documented case. This method provides greater confidence and security for the clinician at the time of the lateral osteotomy, and reduces the surgical time of this phase.

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Sinus Bone Grafting Technique Using Special Reamers and Microelevators

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When residual bone height is insufficient in the maxillary posterior area, the maxillary sinus elevation and implant placement with lateral approach are oftentimes used. However, the risk of sinus membrane perforation, or tearing, is high for this procedure. This article introduces a technique that uses a special reamer and a microelevator to minimize sinus membrane injury.

KEY WORDS

maxillary sinus elevation, microelevator, reamer, sinus membrane injury

Sinus bone grafting is a procedure that is commonly performed in maxillary molar areas with insufficient bone volume, and it shows good clinical outcomes. However, sinus membrane perforation is the most common complication during sinus bone grafting, and it may occur during the formation of the lateral window.[1,2] Here, we introduce a special technique for performing successful sinus bone grafting that minimizes the risk of injuring the maxillary mucosa through the use of a special reamer and a microelevator.

TECHNIQUE

Sinus bone grafting using the sinus lateral approach (SLA) instrument (Neobiotech, Seoul, South Korea) was performed in a 62-year-old male patient. The right maxillary second molar was extracted, a flap was lifted, and the maxillary bone was exposed. Using a C-reamer (diameter, 6.5 mm and length, 3.0 mm), a lateral round window was formed in the first and second molar area, removed, and stored. The lateral window of the second premolar areawas removed using the identical method. Nonetheless, the bone wall was thick, and thus, a bone window was formed by the additional use of the LS reamer. The sinus membrane was elevated through the use of a microelevator, bone graft materials were filled, and the removed bone window was repositioned. During the procedure, perforation of the maxillarymucosa did not occur, and successful sinus bone grafting outcomes were obtained (Figs. 1–5).

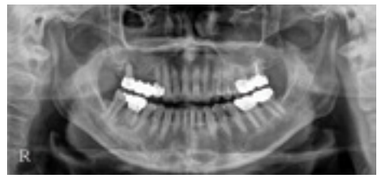

Fig. 1. Panoramic radiograph of the initial diagnosis. Sinus bone grafting was planned after extraction of the maxillary right second molar, followed by the placement of implants after 4 months.

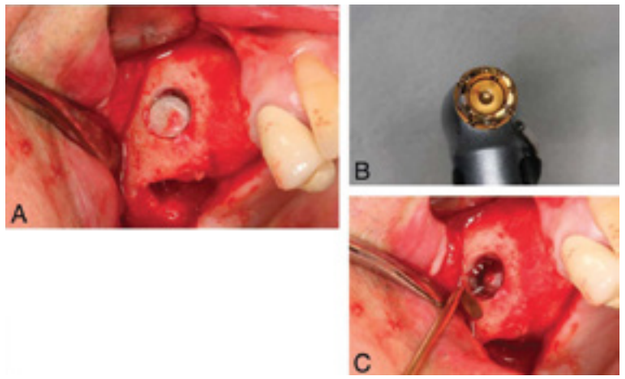

Fig. 2. Formation of a lateral window using a C-reamer. **A**, Appearance after the formation of a lateral hole in the second molar area using a C-reamer. **B**, A C-reamer of 6.5 mm in diameter and 3 mm in length. **C**, After the removal of the lateral window, the sinus membrane was elevated using a microelevator.

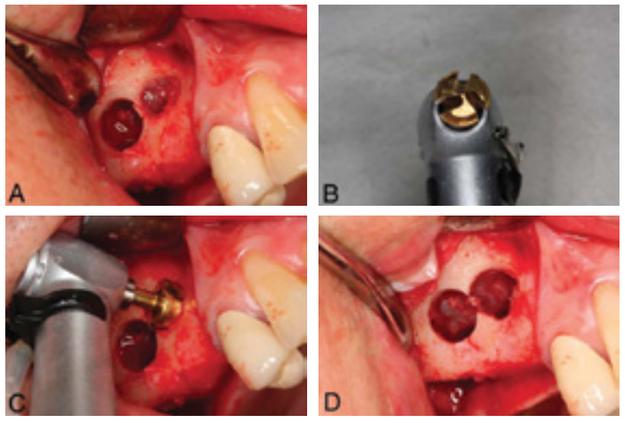

Fig. 3. Formation of a lateral window using a LS reamer. **A**, A lateral hole was formed using a C-reamer. Nonetheless, the bone wall was very thick, and thus, it could not be removed completely. **B**, A LS reamer of 6.5 mm in diameter and 3.5 mm in length. **C**, Complete formation of the lateral window using the LS-reamer. **D**, Two lateral holes were formed, and the sinus membrane was elevated using a microelevator.

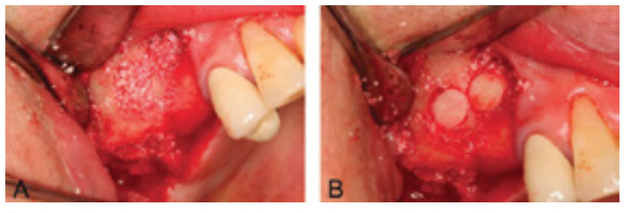

Fig. 4. A, Filled bone graft materials. **B**, After repositioning of the previously removed lateral window bone.

DISCUSSION

The incidence of perforation of the maxillary mucosa has been reported with various rates ranging from 14% to 56%.[1–3] The height of the residual bones, a large edentulous area, the septum, the thickness of the maxillary lateral wall, the thickness of the maxillary mucosa, the presence of cystic lesions in the maxillary sinus, and previous allergy involving the maxillary sinus have been reported as factors increasing the risk for perforation. In addition, sinus membrane injury occurs during the process of lateral window formation via the use of surgical burs and/or drills in many cases.[2,4–6] It has been reported that perforation of the maxillary mucosa adversely affected the prognosis of sinus bone grafts and dental implants.[3,7] However, Oh and Kraut[8] suggested that perforation of the Schneiderian membrane does not cause negative long-term effects on sinus bone grafts and dental implants. Regardless of the controversies in the potential effect of membrane perforation on postoperative complications and implant

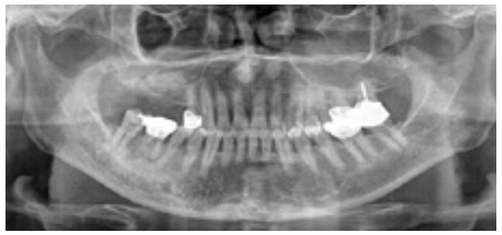

Fig. 5. Postsurgical panoramic radiograph. Successful bone graft outcomes without tearing of the sinus membrane were obtained.

failure, this potential for an intraoperative complication absolutely increases the surgical difficulty and lengthens surgical time. Therefore, it is preferable to prevent the occurrence of a membrane perforation.[4]

To minimize perforation during the generation of the lateral window, various techniques and instruments have been recently developed and applied frequently in clinical practice. Wallace et al[9] have reported that the perforation rate with piezosurgery was lower than with traditional rotator instrumentation during the formation of the maxillary lateral window. Sohn et al[10] have reported that a bony window osteotomy could be performed in 2 to 7 minutes through the use of erbium and a chromium:yttrium-scandiumgallium-garnet laser. Nonetheless, in cases with a thick lateral wall of the maxillary sinus, it may take too long to form a bony window using a laser, piezoelectric device, or the like.

Herein, the SLA instrument was used to remove the bone wall safely without injuring the maxillary mucosa by the application of the reamer principle. The SLA kit is a tool that connects a special reamer to the contra-angle and forms a lateral window safely without injuring the membrane, even in the absence of stoppers, by rotating the tool at 1500 to 2000 rotations per minute. Thirty-seven cases of sinus bone grafting were performed using the SLA instrument from September 2008 to December 2009 in the Seoul National University Bundang Hospital. Perforation of the maxillary mucosa occurred in 3 cases, and a perforation rate of 8.2% was determined for the procedure. The perforation area was smaller than 2 mm and was minor, and the bone graft proceeded without special treatment. Our cases showed an 8.2% perforation rate,which was relatively high compared with the rates reported in Wallace et al (7%),[9] Blus et al (3.8%),[11] and Toscano et al (3.6%),[12] who used piezosurgery. However, the perforations in these 3 studies occurred not when a bony windowwas formed but when sinus mucosal elevations were conducted. The reasons for the perforation are believed to be due toaverythinmucosa, the septum,and the surgeon's carelessness. As such, particular attention is neededwhen performing sinus membrane elevation after bony window formation.

The advantages of lateral window formation through the application of the C-reamer and LS-reamer of the SLA kit are as follows.

1. Because a smallwindow is formed, the formation of a minimal flap is possible, the risk of arterial bleeding is minimized, and postsurgical swelling and pain may be reduced.

2. Several holes with different diameters (4–6 mm) can be formed readily without injuring the sinus membrane, and the operation time is shortened.

3. Use of the optimal microelevator fitted to the angle of approach allows the sinus membrane elevation to be performed readily and safely.

The principle of the C-reamer is similar to that of trephine drills, and it could form lateral windows via the safe formation of a bone core. However, there is a greater possibility of perforation than that associated with the LS reamer, and the selection of the appropriate length of the reamer and formation of the bony window must be done carefully. If the bony wall is thick or if a septum exists, use in conjunction with LS reamers may be safe. The LS reamer forms a lateral hole of the desired size, and during perforation of the lateral wall, it functions to protect the membrane by forming a thin bone plate between the reamer and the sinus membrane. Microelevators are instruments of a specific shape that can elevate the membrane freely (right and left, up, and down) within a small lateral hole.

CONCLUSION

A sinus bone grafting technique using special reamers and microelevators is considered to be an effective surgical method to reduce the risk of sinus membrane perforation, and it is performed easily with anticipated surgical care.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or informationmentioned in the article.

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Comparison of a Novel Trephine Drill with Conventional Rotary Instruments for Maxillary Sinus Floor Elevation

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Purpose:

The purpose of this study was to compare a newly designed trephine drill (SLA KIT, Neobiotech) with conventional rotary instruments for maxillary sinus floor elevation based on operative time, postoperative pain, and perforation rates.

Materials and Methods:

Twenty-five patients were treated with a bilateral sinus floor elevation procedure with rotary trephine and conventional instruments. One side was treated with conventional rotary instruments, while the contralateral side was treated with rotary trephine instruments, with a 2-week gap between surgeries. Operative time was measured with a chronometer in seconds as the time from soft tissue incision to primary closure of the incision with the last suture. Pain was scored on a 10-point visual analog scale at 24 hours after surgery. The presence of tears and perforations was determined by direct visualization and the Valsalva maneuver.

Results:

Twenty-five patients were included in the study. Operative time was shorter when the trephine drill was used (11.1 ± 2.4 minutes) than with conventional rotary instruments (15.1 ± 2.9 minutes). Sinus membrane perforation was observed in eight patients when conventional rotary instruments were used, while the trephine drill resulted in two sinus perforations. Mean pain scores were 2.01 ± 0.11 after using the trephine drill and 2.25 ± 0.76 when conventional rotary instruments were used. No significant difference was found in postoperative pain scores.

Conclusion:

The trephine drill technique may result in decreased perforation rates and operative time.

Key words:

drill, implant, sinus elevation, trephine

Dental implant placement is a very simple dental procedure in patients with normal bone volume and density. The standard surgical technique consists of simple preparation of the implant site and results in a success rate of almost 100%.[1,2] However, inadequate bone volume can complicate this procedure.[3] Alveolar bone resorption decreases alveolar bone height and quality.[4–8] As a result, alveolar bone may be unsatisfactory for dental implant placement.[8] Augmentation of the maxillary sinus floor, formerly called sinus elevation, is a well-documented technique and is generally accepted as a standard implant dentistry procedure to facilitate placement of dental implants in the posterior atrophic maxilla.[9–11]

The two different techniques described in the literature for sinus augmentation are the crestal and lateral approaches.[12] The crestal approach may be preferred for maxillary sinus elevation if alveolar bone remains between the alveolar crest and the maxillary sinus height is > 5 mm. If the residual alveolar bone is < 5 mm, the traditional treatment option of choice prior to implant placement is subantral augmentation. The lateral approach consists of performing an osteotomy in the lateral sinus wall, opening a bone window that allows access to the maxillary sinus membrane, and placing the graft materials into the sinus. The periosteal portion of the sinus membrane has a few elastic fibers, which makes separation a simple procedure for an experienced dentist. As a result of this surgical procedure, the lateral maxillary sinus wall is prepared and internally rotated to a horizontal position. The newly elevated sinus floor, together with the inner maxillary mucosa, will create a space that can be filled with graft material.[9,12,13]

Previous studies of sinus elevation reported rates of 10% to 60% for perforation of the sinus membrane during sinus augmentation.[14–20] In most instances, perforation occurs either while using instruments to make the window or, more frequently, when using hand instruments to gain initial access for elevation of the membrane from the sinus walls. Sinus membrane integrity can guarantee graft stability and subsequent vascularization, which leads to the maturation and mineralization of the bone graft. Membrane perforation could result in graft material loss, an increased risk of infection as a result of the communication with other sinuses, or a risk of migration of graft particles into the sinus, where they can induce polyps or other sinus diseases and postoperative infection.[14]

Today, minimally invasive surgery is preferred by oral surgeons, and ultrasonic devices are often used for this type of surgery. Piezoelectric devices are one type of ultrasonic device used for this type of surgery because they pose a much lower risk of causing visible injury to the adjacent soft tissues and many other critical structures such as nerves and vessels.[21–24]

Wallace et al[22] showed that when a piezoelectric device is used instead of rotary instrumentation, the incidence of perforations of the sinus membrane decreased from 30% to 7%. Blus et al[23] revealed that during the sinus approach with the application of piezosurgery, the perforation rate was 3.8%. Another study showed that piezoelectric devices increased operative time but did not affect the sinus membrane perforation rate.[24] All of these studies conclude that piezoelectric devices increased operative time.

Emtiaz et al[25] used trephine drills (Biomet 3i) in sinus elevation procedures; however, caution was advised for the risk of membrane perforation during the lateral osteotomy when using a trephine drill. A recently introduced trephine drill kit (SLA KIT, Neobiotech) has a special design, using a guide drill to start the window and obtain the correct position to avoid slipping, after which the other drills in the kit are

used. The drills have diameters of 4.5 mm, 5.5 mm, and 6.5 mm with heights of 2 mm and 3.5 mm. Drill diameter and height are determined depending on the case. The SLA KIT is used at high speeds (2,000 to 10,000 rpm) and with necessary irrigation. The tapered trunk of the drill is designed to control the drilling depth without the use of stoppers. Only the initial contact surface of the drill is sharp (Fig 1a). This sharpness is convenient when the drill enters the bone for the first time. The contact surface of this trephine has a curved periphery and a bonemaintaining area contacting the surface of the drill. The bone-maintaining area includes two inside walls: the first is oriented in a drilling direction higher than the second, which has a drilling surface exposed in the drilling direction. This orientation prevents sinus membrane damage when the head of the drill contacts the membrane (Fig 1b). During the operation, the reamer, filled with bone chips, protects the membrane from tearing.[26] This specially designed trephine drill has several unique features that are expected to solve various problems with the conventional lateral approach. One such problem is the difficulty in using a straight handpiece and round bur. Other challenges are arterial bleeding and rupture of the membrane.

The aim of this study was to perform sinus elevation using the surgical instruments from the SLA KIT mounted in a dental handpiece and to compare it with the same procedure done with conventional rotary instruments. Operative time, postoperative pain, and operative and postoperative rates of complications were recorded.

MATERIALS AND METHODS

Twenty-five patients (mean age 45.6 ± 6.9 years; range, 35 to 63 years; 11 women and 14 men) agreed to participate in this study. The patients, who had been referred to the Bezmialem Vakif University Department of Oral and Maxillofacial Surgery in Istanbul, required prostheses for their bilaterally edentulous posterior maxillae.

The inclusion criteria were as follows:

- Severely resorbed bilaterally maxilla (class V or VI according to Cawood and Howell27)
- Edentulism in the posterior maxilla for at least 1 year
- No history of radiotherapy in the head or neck region
- No history of previous implant surgery
- No pathology in the maxillary sinus

Patients were deemed ineligible for this study if any of the following criteria were met:

- Poor dental hygiene habits
- Presence of acute infection requiring antibiotics at the time of screening
- Presence of acute or chronic sinus pathology
- History of sinus augmentation in either maxillary sinus
- Known allergies to metal alloys
- History of alcohol or drug abuse within the previous 2 years
- Heavy smoking habit (10 or more cigarettes per day)
- Compromised general health

In all patients, fixed partial prostheses on each side supported by two to three implants were planned. Informed consent to participate in this study was obtained in writing from all patients. Panoramic radiographs were obtained and lateral cephalometric analyses were performed to assess the height of the maxillary alveolar bone and the dimensions of the maxillary sinus. The radiographs were also screened for sinus pathology. The mean vertical height of the alveolar bone on the panoramic radiograph between the top of the alveolar crest and the sinus floor was 3.2 ± 2.4 mm (range, 1.5 to 5.5 mm), indicating a need for preimplantation reconstructive surgery in all cases.

All patients were treated with a bilateral sinus floor elevation procedure using both trephine rotary instruments and conventional rotary instruments (Figs 2a and 2b). Through random assignment by opening envelopes preoperatively, one side was treated with conventional rotary instruments (the control group), and the other side was treated 2 weeks later with trephine rotary instruments (the test group)—or the opposite, ie, test treatment followed by control treatment—for within-patient comparisons of postoperative pain. The surgeon did not know which was the control side and which was the test side until opening the envelope just prior to surgery.

The following variables were analyzed for each patient:

- Operative time. This was measured in seconds with a digital chronometer by one investigator who was blinded to the treatment and comprised the time from soft tissue inci-

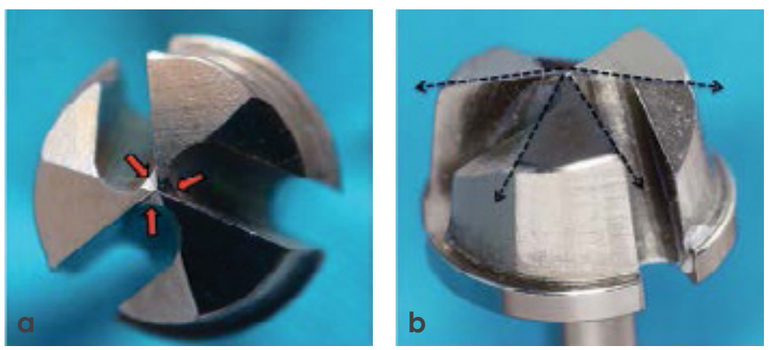

Fig 1 Specially designed trephine drill.

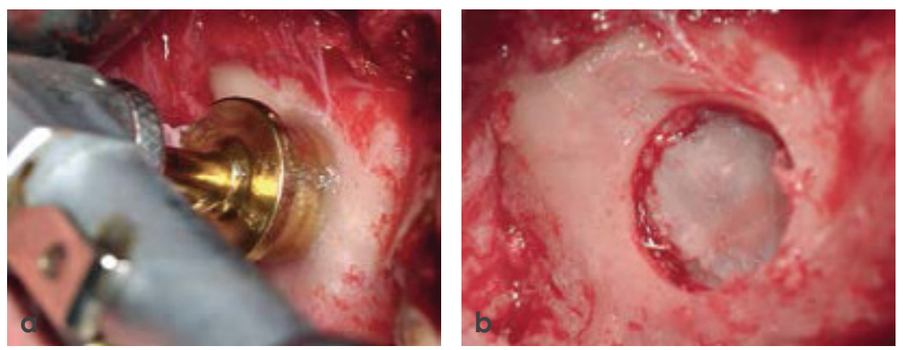

Fig 2a SLA KIT trephine drill application for lateral window osteotomy.

Fig 2b Access to the maxillary sinus without sinus membrane perforation.

sion to primary closure of the incision with the last suture.

- Postoperative pain. Pain was scored with a 10-point visual analog scale (VAS) at 24 hours after surgery.
- Operative and postoperative complications. This included membrane tears or perforations, which were repaired by applying collagen membranes.

The maxillae of all patients were reconstructed with allogeneic bone grafts (SteriGraft, Bone Bank Allografts) under local anesthesia. In all cases, because the height of the maxillary bone was < 5 mm, a two-stage bilateral procedure was performed (stage-one surgery: bone grafting; stage-two surgery: placement of implants). All surgeries were performed by the same surgeon.

A collagen membrane (Bio-Gide, Geistlich) was used to cover the facial sinus wall surface of grafted sites. The mucoperiosteal flap was replaced, and wound closure was performed using 3.0 silk nonresorbable suture material (Doğsan).

After surgery, the patients received 1,000 mg amoxicillin and 550 mg naproxen sodium orally for 5 days (two times a day) and used an aqueous 0.2% chlorhexidine mouth rinse (1 minute, three times daily) for 1 week. An ice pack was applied to the surgical area for at least 30 minutes postsurgery. After a healing period of 3 to 4 months, stage-two surgery was performed under local anesthesia. Because the bone volume was sufficient in all cases, nonsubmerged dental implants (neo CMI, Neobiotech) with adequate primary stability could be placed (a total of 123 implants, 60 on the right and 63 on the left; mean: 4.9 implants per patient). Three months after implant placement, prostheses were inserted.

All patients were clinically evaluated 1, 3, 6, and 12 weeks after surgery. Furthermore, patients were followed up at 1 year after functional loading.

A t test for statistical analysis and a linear regression analysis for analysis of time were used. A P value of < .05 was considered significant.

RESULTS

Healing was uneventful in all 25 patients, and all underwent the planned implant placement and received a functioning implant-supported prosthesis. Adequate bone was created through all 50 maxillary sinus elevation procedures that were performed.

Operative time was significantly shorter when using the trephine drill (11.1 ± 2.4 minutes) than when using conventional rotary instruments (15.1 ± 2.9 minutes) (P < .001).

Tears and perforations were detected by direct visualization and the Valsalva maneuver. When the conventional rotary instruments were used, eight sinus membrane perforations occurred. In contrast, when the trephine drill was used, only two perforations occurred (P < .001). Membrane perforations were repaired with collagen membranes, and implants were inserted as usual at the grafted sites.

Mean pain scores on the VAS were 2.01 ± 0.11 after using the trephine drill and 2.25 ± 0.76 when conventional rotary instruments were used (P > .005).

In all, 123 implants were placed and primary stability was achieved in all cases. The implants were placed an average of 12.6 weeks (range, 10 to 16 weeks) postaugmentation. Healing was uneventful, and all patients received the planned implants and prostheses. Implant survival 1 year after functional loading was 100%.

DISCUSSION

Successful sinus elevation depends greatly on the patient's physical condition. The position of sinus floor convolutions, presence of septa, transient mucosa swelling, and a narrow sinus may be a contraindication for sinus floor elevation. Absolute contraindications are maxillary sinus tumors and destructive previous sinus surgery such as the Caldwell-Luc operation.13 The lateral sinus wall is usually a thin bone plate that is easily penetrated by rotating or sharp instruments. The fragile sinus membrane plays an important role in the containment of bone grafts applied to the sinus cavity. The process of preparing the window and elevating it, together with preparation of the sinus mucosa, may cause a mucosal tear. When these perforations are not too large, they will usually fold together when the trap window is turned inward and upward and can be glued with a fibrin sealant or covered with a resorbable collagen membrane. If the perforation is too large, the procedure will be aborted.[16–20]

Although sinus augmentation has a high rate of success, it may result in a number of intraoperative complications, which include sinus membrane perforation, obstruction of the maxillary ostium, hemorrhage, fracture of the residual alveolar ridge, and damage to teeth while preparing the window. Early postoperative complications include hemorrhage, wound dehiscence, acute infection, exposure of the barrier membrane, graft infection, graft loss, and dental implant failure. Late postoperative complications include graft loss, implant loss or failure, implant migration, oroantral fistula, chronic pain, sinusitis, and chronic infection. However, the most frequent complication is sinus membrane perforation.[11,13] This complication could decrease implant success rates and cause chronic maxillary sinusitis.[15,28]

Because the bony thickness of lateral maxillary sinus walls averages only 0.91 mm, and the adjacent sinus membrane averages 0.15 mm in thickness, the traditional use of high-speed rotating instruments for the preparation of lateral sinus antrostomies requires precision and attention to detail.[29] With conventional rotary instruments, the risk of membrane perforation is high (11% to 56%, depending on the surgeon's experience).[30,31] In their study, Nkenke et al[31] noted that the presence of microtears and perforations cannot be adequately determined with the Valsalva maneuver and may require the use of an endoscope.

Trephine drills are usually used for collecting autogenous bone blocks; however, the SLA trephine drills used in this study are special. The advantages of the SLA KIT are small window formation (the formation of a minimal flap is possible, the risk of arterial bleeding is minimized, and postsurgical swelling and pain may be reduced); the ability to form several windows with different diameters (4 to 6 mm) without injuring the sinus membrane; and shortened surgical time.[32] In this study, it was observed that using an SLA trephine drill in sinus elevation procedures decreased the membrane perforation rate versus the use of conventional rotary instruments (P < .001).

Piezosurgery is an elegant bone-cutting modality with a rapidly increasing number of indications in various surgical areas. The main advantages of piezosurgery include soft tissue protection, optimal visibility in the surgical field, decreased blood loss, decreases in vibration and noise, increased comfort for the patient, and protection of tooth structures. An additional benefit of the piezoelectric unit was the lack of arterial lacerations.[33] Intraosseous arterial branches have been found in 100% of cadaver specimens and 52% of computed tomography studies.[34,35] The discrepancy in the prevalence of arterial encounters in prior anatomic studies of the maxillary sinus might

be explained by the average location of the intraosseous arterial branch, which ranges from 16 to 19 mm from the alveolar crest.[35] Therefore, if the superior aspect of the lateral antrostomy is less than 16 mm from the alveolar crest, the artery will not be encountered. SLA drills decrease injuries to the sinus floor during membrane elevation, which may lead to a decrease in injury to the soft tissue and arteries.

The only reported limitation of piezosurgery is operative time, which was significantly longer than when using conventional rotary instruments. These data are in agreement with previous studies.[33,36,37] From a clinical perspective, the difference in surgical time between both operative procedures is negligible; however, in areas with a higher bone structure or thickness, an osteotomy via piezoelectric surgery could take up to five times longer than conventional rotary instruments.[33] In this study, SLA trephine drills reduced operative time compared to conventional rotary instruments ($P < .001$).

Some studies showed that using piezosurgery in sinus elevation procedures decreases postoperative discomfort.[24,38] Moreover, in an in vivo experimental model, the wound-healing response was evaluated following osteotomy with piezosurgery and diamond or carbide burs. The results, while acknowledging the small sample size, indicated a more favorable osseous response with piezosurgery when compared with diamond or carbide burs.[39] In this study, it was found that, compared to carbide burs, using trephine drills in sinus elevation procedures decreases postsurgical pain. This difference was not significant, possibly because of the small sample.

CONCLUSION

This study compared SLA KIT trephine drills to conventional rotary instrumentation with the described technique in sinus elevation procedures. Advantages of the SLA drills include reduced surgical time and lower risk for perforation of the sinus membrane. In addition, SLA drills are much less expensive than piezoelectric devices, and they perform sinus elevation more quickly than conventional rotary instruments. No difference was found in postoperative pain scores. Further studies are needed to compare piezoelectric devices and SLA trephine drill techniques in sinus elevation procedures.

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The authors reported no conflicts of interest related to this study.

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Sinus Membrane Elevation by the Crestal Approach Using a Novel Drilling System

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Purpose:

The purpose of this study was to evaluate the clinical outcomes of patients undergoing sinus membrane elevation by a minimally invasive crestal approach using a novel drilling system.

Materials and Methods:

From May 2008 to November 2009, 21 implants were placed in 19 patients (10 men and 9 women) ranging from 23 to 69 years of age (average of 49.5 years). Implants were placed in maxillary premolar and molar areas that demonstrated insufficient residual bone quality; maxillary sinus membrane elevation was performed using a crestal approach with the sinus crestal approach kit (Neobiotech, Seoul, Korea).

Results:

There was no sinus perforation or osseointegration failure. The implant survival rate was 100%. The postsurgical, augmented volume of the alveolar height ranged from 2 to 9.2 mm (average of 5.81 ± 2.06 mm). Six months after maxillary sinus elevation, the bone reduction volume ranged from 0.06 to 1.42 mm (average of 0.6 ± 0.38mm). At final F/U, the amount of bone-height reduction ranged from 0.06 to 2.60 mm (average of 0.82 ± 0.63 mm).

Conclusion:

Sinus membrane elevation by the crestal approach using special reamers is advantageous because of the noticeable reduction in the risk of perforation and the ability to perform the surgery rapidly. (Implant Dent 2017;26:351–356)

Key words:

sinus floor augmentation, crestal approach, reamer

The cortical bone of the maxillary molar area is thin, with type 3 or 4 underlying cancellous bone, making the initial fixation of implants difficult in many cases. In addition, the maxillary sinus undergoes pneumatization after extraction, and the residual bone undergoes vertical and horizontal resorption. Consequently, available bone height is diminished; therefore, placement of the implant is difficult. To resolve such problems, sinus membrane elevation, bone grafting, vertical ridge augmentation, and other surgical procedures have been applied. Sinus membrane elevation is classified as follows: (1) a lateral window opening procedure, which allows for the formation of a bony window in the lateral wall, elevates the Schneiderian membrane and becomes filled with bone graft materials; (2) an osteotome technique proposed by Summers that involves the elevation of the sinus membrane by an intentional osteotomy of the sinus floor using the crestal route. The crestal approach is a simple procedure that is associated with fewer complications and has advantages over the lateral approach.[1] A wide array of modifications of the osteotome and/or drilling techniques has been reported in the literature.[2–5]

The purpose of this study was to evaluate the clinical outcomes of patients undergoing a sinus membrane elevation by the crestal approach using a uniquely designed drilling system.

MATERIALS AND METHODS

Approval from the institutional review board (IRB), Seoul National University Bundang Hospital (approval number: B-1007-105-105) was obtained before the initiation of the study. The studysubjectspresentedwith amaxillary molar area that had insufficient residual bone volume. Sinus membrane elevation by the crestal approach using the sinus crestal approach (SCA) kit (Neobiotech) was performed before implant placement; these procedures took place between May 2008 and November 2009. In this study, surgery was performed using the uniquely designed S-reamer. The S-reamer has been given the name because the blade shape of the drill is S-shaped and it is a special drill for sinus surgery. The S-reamer can be used for effective bone removal with high rotation speeds of 800 to 1200 rpm. In addition, it is designed that bone chip protects the tip of the S-reamer, so even if it touches the sinus membrane directly, the sinus membrane will not be torn, and it can safely be preserved when the perforation of the side or septum is performed.

Inclusion Criteria

1. Cases involving one oral and maxillofacial surgeon performing the operation
2. Cases having a residual bone height, from the alveolar crest to the sinus floor, of less than 8 mm
3. Cases in which a bone graft was performed

The medical records and radiographs of the patients were analyzed. In all, 21 implants were placed in 19 patients (10men and 9 women). The age of the patients ranged from 23 to 69 years (average of 49.5 years). Five patients presented with systemic diseases; among these 5 patients, 2 had more than 2 systemic diseases. Systemic diseases included hypertension, diabetes, heart disease, and thyroid disease, all of which were well controlled by medication, and 2 patients were smokers.

Intraoperative and postoperative complications were examined, and the augmented height of the alveolar bone was evaluated on presurgical and postsurgical panoramic radiographs.

The preoperative height of the remaining alveolar bone from the crest to the sinus floor was measured; subsequently, on the basis of the panoramic radiograph taken immediately after the operation, the length from the alveolar crest of each implant to the topmost portion of the sinus bone graft was measured to evaluate the augmented height. Based on the length of the placed implants, each magnification rate was considered and evaluated. The panoramic radiograph taken 6 months after the bone graft and finallyF/Uwas used tomeasure the resorption height of the graft material. For radiographic measurements, an IMPAXsystem (Agfa-Gevaert Group, Mortsel, Belgium) was used (Figs. 1 and 2).

The periapical radiograph taken 6 months after prosthetic function and at final F/U was compared with the radiograph taken immediately after implant placement tomeasure the amount of bone resorption. The length of the implants was used to calculate the magnification rate of the periapical radiograph to evaluate the resorption height. The average resorption height on the mesial and distal sides was calculated to determine the resorption height of the alveolar crest.

Surgical Procedure

Using panoramic radiographs, the height of the residual bones was measured, and the hole was drilled to a depth that was 1 mm shorter than the measured implant length. Next, using the S-reamer, which had been equipped with a stopper thatwas 1mmlonger than the initial drill, the inferior wall of the maxillary sinus was perforated. The Sreamer has multiple drill stops and various diameters. After the maxillary floor was perforated, the residual bone heightwas assessed using a depth gauge. The lack of perforation was confirmed by instructing the patient to blow out of his or her mouth while the nose was blocked. If the sinus

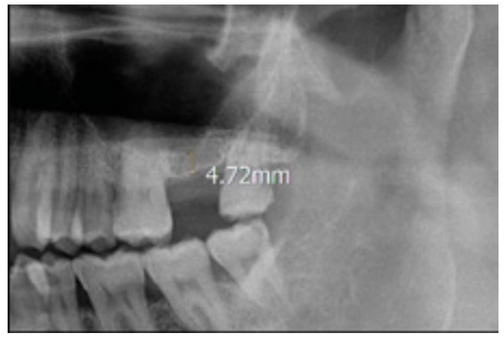

Fig. 1. Measurement of alveolar bone height. The preoperative height of the remaining alveolar bone from the crest to the sinus floor was measured.

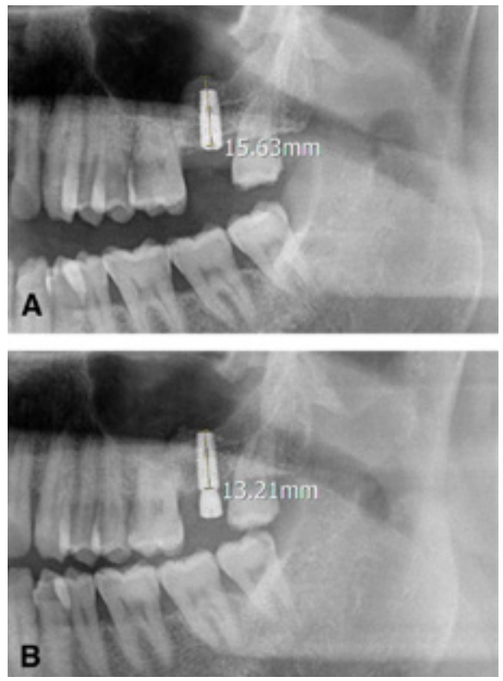

Fig. 2. Measurement of bone height for the evaluation of grafted material. **A**, Panoramic image taken immediately after surgery. The bone height was measured from the first implant thread to the highest border of the graft material. Measurements were performed for buccal and lingual sites. The average of the 2 measured values was calculated using the magnification to determine the actual height. **B**, Panoramic postsurgical view (6 months). The same formula was used to calculate the bone height at the sinus.

membrane was not perforated, bone grafting was performed while elevating the maxillary sinus membrane with a bone carrier and a bone condenser. In general, a 1-mm elevation of the sinus membrane allowed for 0.1-cc of bone graft materials to fill the space. The bone graft materials were spread to the lateral side using a bone spreader, and additional bone graft materials were applied. After the completion of the maxillary sinus membrane elevation, implants with appropriate diameters and lengths were placed in the area. Approximately 4 to 6 months after implant placement, the second surgery and prosthetic treatments were performed (Fig. 3).

RESULTS

The mean follow-up observation period was 45.4 months after surgery. The average healing period after the first surgery was 4.4months, and the average loading period after final prosthetic delivery was 39.2 months. Of the 21 implants, 15 were placed using submerged procedures, and 6 were placed using nonsubmerged procedures (Table 1). In all cases, bone graft materials were filled with a bone condenser and were moved laterally with a spreader. This technique is similar to a bone-added osteotome sinus floor elevation.[6] The types of bone graft materials used were as follows: autogenous bone harvested from the oral cavity, allogenic bone (Orthoblast II; Integra Lifesciences Corporation, Irvine, CA, ICB; Rocky Mountain Tissue Bank, Aurora, CO), xenogenic bone (Biocera; Osscotec, Seoul, Korea, BioOss; Geistlich Pharm AG, Wolhusen, Switzerland), and synthetic bone (MBCP; Biomatlante Sarl, Vigneux de Bretagne, France). The bone graft materials were used alone or in combination. In total, 7 implants were restored with a partial fixed prosthesis, and 14 were restored with a single crown.

There were no maxillary sinus membrane perforations and osseointegration failures.Mild symptoms of local infection developed after surgery in 1 patient; these symptoms were managed with antibiotics as well as incision and drainage (I & D). One patient showed acute maxillary sinusitis 5 months after surgery, and this condition was resolved over time with an empirical antibiotic treatment and I & D. Because of crestal bone loss, implant thread exposure occurred on 2 implants of 2 patients at the second surgery. In these cases, we connected a healing abutment and cleansed the implant thread with hydrogen peroxide and chlorhexidine solution. After that, we covered the bone graft material and closed the wound (Table 2).

Twenty-one implants were analyzed radiographically. The presurgical height of the residual bones ranged from 4 to 7.8 mm (average of 6.2 mm) (Table 3). The postsurgical height of the residual bones ranged from 8 to 16.2 mm (average of 12.0) (Table 4). The augmented volume of the alveolar bone height after surgery ranged from 2 to 9.2mm(average of 5.81±2.06 mm) (Table 5). The height of the graft materials was evaluated by calculating the difference between the height of the grafted bones immediately after maxillary sinus elevation and 6 months after panoramic radiographs. In the 6 months after the operation, the height of the graft materials was evaluated in 15 implants. The measurement range for the reduction in volume of the bone graft ranged from 0.06 to 1.42 mm. The average reduction in volume of the grafted bones was 0.6±0.38mm(Table 6). Six months after loading, the loss of crestal bone was evaluated, and an average marginal bone loss of 0.32 ± 0.49 mm was observed. At final follow-up, the average reduction of the bone has slightly increased to 0.82 ± 0.63 mm and the amount of reduced bone height ranged from 0.06 to 2.60 mm. The average crestal bone resorption was also found to increase to 0.52 ± 0.49 mm at final follow-up.

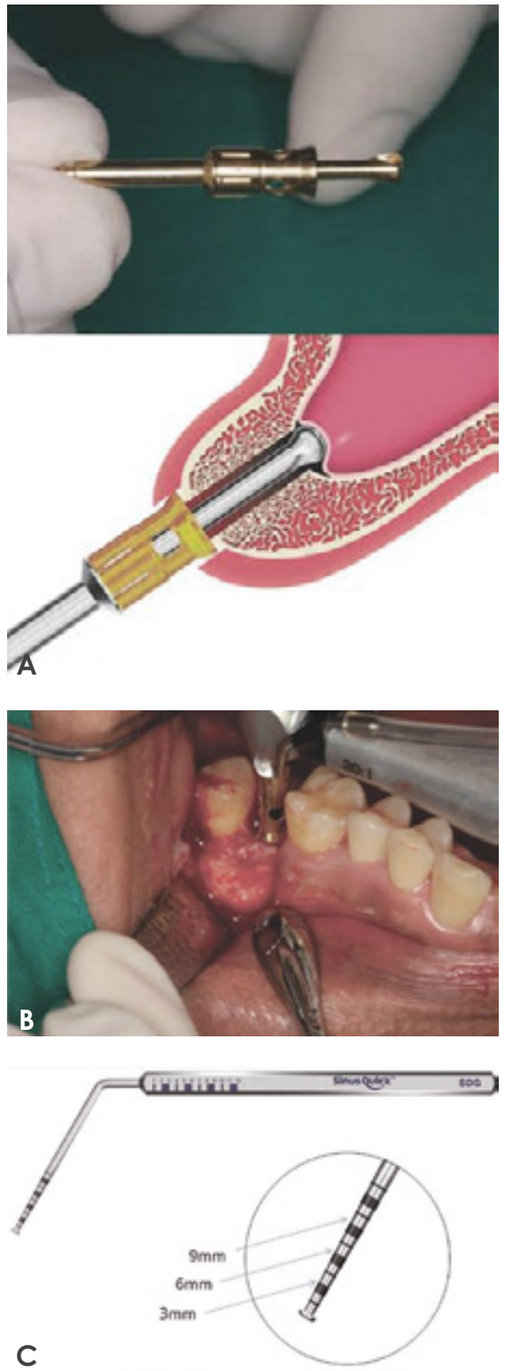

Fig. 3. Clinical view of the surgical procedure. **A** and **B**, Drilling was performed until the stopper contacted the alveolar bone crest. **C**, The depth gauge was inserted carefully, and the alveolar bone height was measured precisely. **D**, A bone condenser with a stopper was used to fill with the graft material. **E**, A bone spreader with a stopper was used for lateral spreading of the graft material.

DISCUSSION

The success of implant placement in the maxillary molar area is typically dependent on the available bone height and the bone quality. However, there is often insufficient bone volume in the maxillary molar area because of the pneumatization of the maxillary sinus, resorption of residual bone after tooth extraction, periodontitis, and the use of removable dentures. To overcome these problems, numerous surgical procedures have been developed. Among these procedures, the osteotome technique was proposed by Summer[1] in 1994. Lalo et al[3] proposed a method that used osteotomes and drills with a stop that reduced the perforation of the Schneiderian membrane. Tilotta et al[5] described a procedure that used osteotomes equipped with a trephine bur and stopper. Nonetheless, in procedures that use osteotomes, the initial stability of the implant may be lost because of the perforation of the maxillary sinus membrane or the formation of an excessive bony hole in the implant placement area. The initial stabilization can only be obtained from the residual alveolar bone; therefore, the required residual bone height of at least 5 mm is a limitation of this method. In addition, this procedure is mainly used on type III or type IV soft bones; if the osteotome procedure is applied forcefully to hard bones, compression necrosis or cortical bone fractures may develop. Additional risks include postsurgical headaches and inner ear injuries. In addition, during all stages of the procedure, it is difficult to obtain clear visualization of the surgical field. Therefore, the procedure depends greatly on the skill of the surgeon.[6–9]

Various procedures and instruments have been developed to overcome the shortcomings of the osteotome technique. When the maxillary sinus mucosa is elevated using the osteotome and mallet, pressure may be concentrated at one point and damage may occur. Consequently, controlled hydrostatic sinus elevation was introduced to maintain uniform pressure on all the portions of the elevated maxillary sinus mucosa. By applying a uniform pressure to all contact surfaces using water pressure, the Schneiderian membrane can be safely elevated.[10] In addition, Chen and Cha[11] published the hydraulic sinus condensing procedure, and the procedure they reported is the one in which the cortical bone is punctured using a high-speed bur and the maxillary sinus mucosa is immediately elevated by the cooling water supplied to the handpiece. However, the possibility of sinus perforation due to the highspeed bur, the use of nonsterile water, and the difficulty of mucosal elevation due to low pressure may be problems. In this regard, the hydrodynamic piezoelectric internal sinus elevation method has also been introduced. It is the procedure in which noninvasive cortical bone removal is performed using ultrasonic piezoelectric microvibration generated by the piezoelectric device, and then, the maxillary sinus mucosa is elevated through the water pressure by sterile saline injected from the same device.[12,13] Moreover, maxillary mucosal elevation procedures using a balloon have been published, and they have been described as the antral membrane balloon elevation (AMBE) or similarly as the minimal invasive AMBE.[14,15] Park and Kim[16] reported a case of successfully performing membrane elevation using the sinus balloon and implant placement.

However, the maxillary sinus elevation procedure using the SCA kit is faster and more convenient as drilling methods are used; the risk for perforation of the maxillary sinus membrane can be reduced by using reamers and other instruments that are specifically made for this procedure. In addition, the conventional malleting process used in the osteotome technique is not required. Therefore, complications, such as head echoes, consequent pain, and other side effects, can be reduced. In addition, the use of the drilling system enables the easy formation of an implant bed; this formation can even occur in areas where the sinus septum is present or in areas with a hard bony quality.

In this study, the average augmentation effects were 5.81 ± 2.06 mm. This finding is comparable to findings reported in other studies that demonstrate bone augmentation effects of 2 to 7 mm using the crestal approach. A total of 13 of 21 implants gained more than 12 mm of bone height. The length of the longest implant that was used in this study was 12 mm. The volume stability of augmented bone was also evaluated in this study. The average loss of bone height in grafted site was 0.6 ± 0.38 mm after 6 months and 0.82 ± 0.63 mm at final F/U (45.4 months after surgery in average). Only 0.22 mm of further bone resorption was observed. Compared with the 5.81-mm gain, the amount of augmented bone loss and the volume stability observed in this study seems to be clinically acceptable. Leblebicioglu et al7 conducted a radiographic evaluation of dental implants placed using an osteotome technique. The mesial and distal alveolar bone gain after 6 months of healing was 3.9 ± 1.2 mm and 2.9 ± 1.2 mm. They reported a 97.3% success rate after 25 months of loading. Toffler[17] reported osteotome-mediated sinus floor elevation; the mean elevated amount in the area of implant placement using an osteotome was 3.8 mm. After the average loading period of 27.9 months, the implant success rate was reported to be

Table 1. Length and Diameter of Implant

Implant Length (mm)	Number	Diameter (mm)	Number
8–8.5	6	3.4–3.8	1
10–11.5	13	4–4.3	4
12	2	4.5–4.8	8
		5–5.3	8
Total	21		21

Fifteen implants were placed using submerged procedures, and 6 were placed using nonsubmerged procedures.

Table 2. Postoperative Complication Distribution

Complication	N (Patient)
Local infection	1
Thread exposure	2
Acute maxillary sinusitis	1
Total	4

Table 3. Preoperative Bone Height

Bone Height Before Surgery (mm)	Number
4–5.9	4
6–7.9	17
Total	21

The average presurgical height of the residual bones was 6.2 mm.

Table 4. Postoperative Bone Height

Bone Height After Surgery (mm)	Number
8–9.9	3
10–11.9	5
12–13.9	9
14–15.9	3
>16	1
Total	21

The average postsurgical height of the residual bones was 12.0 mm.

Table 5. Quantity of Sinus Elevation

Quantity of Elevation (mm)	Number
2–3.9	3
4–5.9	8
6–7.9	6
8–9.9	4
Total	21

The average augmented volume is 5.81 6 2.06 mm.

Table 6. Reduction of Grafted Bone Heights After 6 Months

Change of Bone Length (mm)	Number
< 0.3	3
0.3–0.49	3
0.5–0.79	6
0.8–1	1
1–1.49	2
Total	15

The average reduction in volume of the grafted bones was 0.6 6 0.38 mm.

93.5%. However, a residual bone height of 5 mm or greater had a 94.7% success rate. With a residual bone height of 4 mm or less, the survival rate dropped to 73.3%. It has been reported that after the performance of a maxillary sinus bone graft using a lateral approach, the bone graft materials are absorbed by 0.34 mm after 6 months and by 1.22 mm after 3 years. When bone graft materials with or without a reduced ratio of autogenous bone are used, they are stably maintained in the maxillary sinus for an extended time.[18] The performance of a maxillary sinus bone graft using the crestal approach shows an implant success rate of approximately 97%, and the grafted bones are stably maintained.[6,19] In this study, the height of the graft materials was evaluated. After 6 months, the height of the grafted bones was reduced by an average of 0.6 ± 0.36 mm. During the follow-up period of 45.4 months, there were no implant failures. A survival rate of 100% was obtained.

Nkenke et al[20] examined the quality of bone augmentation in the placement area and the number of perforations in the maxillary sinus membrane after maxillary sinus membrane elevation; they reported that the amount of maxillary sinus elevation using osteotome procedures should be limited to an average of 3.0 ± 0.8 mm to prevent perforation. As demonstrated in the literature, so-called closed sinus elevation with bone grafting using osteotomes is very appropriate for bone augmentation within 5 mm.[17,21] In this study, there were no perforations in the maxillary sinus membrane. During surgery, it is important to assess the presence or absence of perforation in the maxillary sinus membrane by instructing the patient to blow out of his or her mouth while closing the nose (Valsalvamaneuver). If a perforation is detected, the surgery should be terminated and attempted again after a healing period of approximately 4 weeks. Alternately, a lateral window technique should be performed to assess the perforation area, administering the appropriate treatments and continuing the surgery. The drilling procedure used herein noticeably reduced the risk for the perforation of the maxillary sinus membrane.Nonetheless, if the bone graft materials are filled or if the sinusmembrane undergoes an excessive elevation, the risk for perforation increases. Therefore, similar to osteotome techniques, it is safer to use the procedure to elevate the maxillary sinus membrane by 3 to 5 mm in cases that presentmore than 5mmof residual alveolar bone. In cases that demonstrate a residual alveolar bone height of less than 4 mm, a forceful elevation will increase the risk for perforation. In addition, if the height of the residual alveolar bone is inadequate, a sufficient healing period should be allowed, even in the case of a successful procedure.[22]

Limitations of this retrospective study include the lack of standardization in research conditions because of short-term follow-up periods and the use of a variety of bone graft materials. The utilization of panoramic radiographs to perform preoperative and postoperative bony height assessments is vague from its 2-dimensional limitation perspective. A cone beam computed tomography would have been ideal to obtain these measurements 3-dimensionally.

CONCLUSION

The sinus elevation of average 5.81 mm was obtained through crestal drilling with a uniquely designed Sreamer, and sinusmembrane perforation or failure of osseointegration did not occur. Sinus membrane elevation by the crestal approach using a novel drilling technique (uniquely designed S-reamer) is advantageous because of the noticeable reduction in perforation risk and the ability to perform the surgery rapidly.

DISCLOSURE

The authors claim to have no financial interest, directly or indirectly, in any company or product mentioned in this article.

APPROVAL

Approval from the IRB, Seoul National University Bundang Hospital (approval number: B-1007-105-105) was obtained before the initiation of the study.

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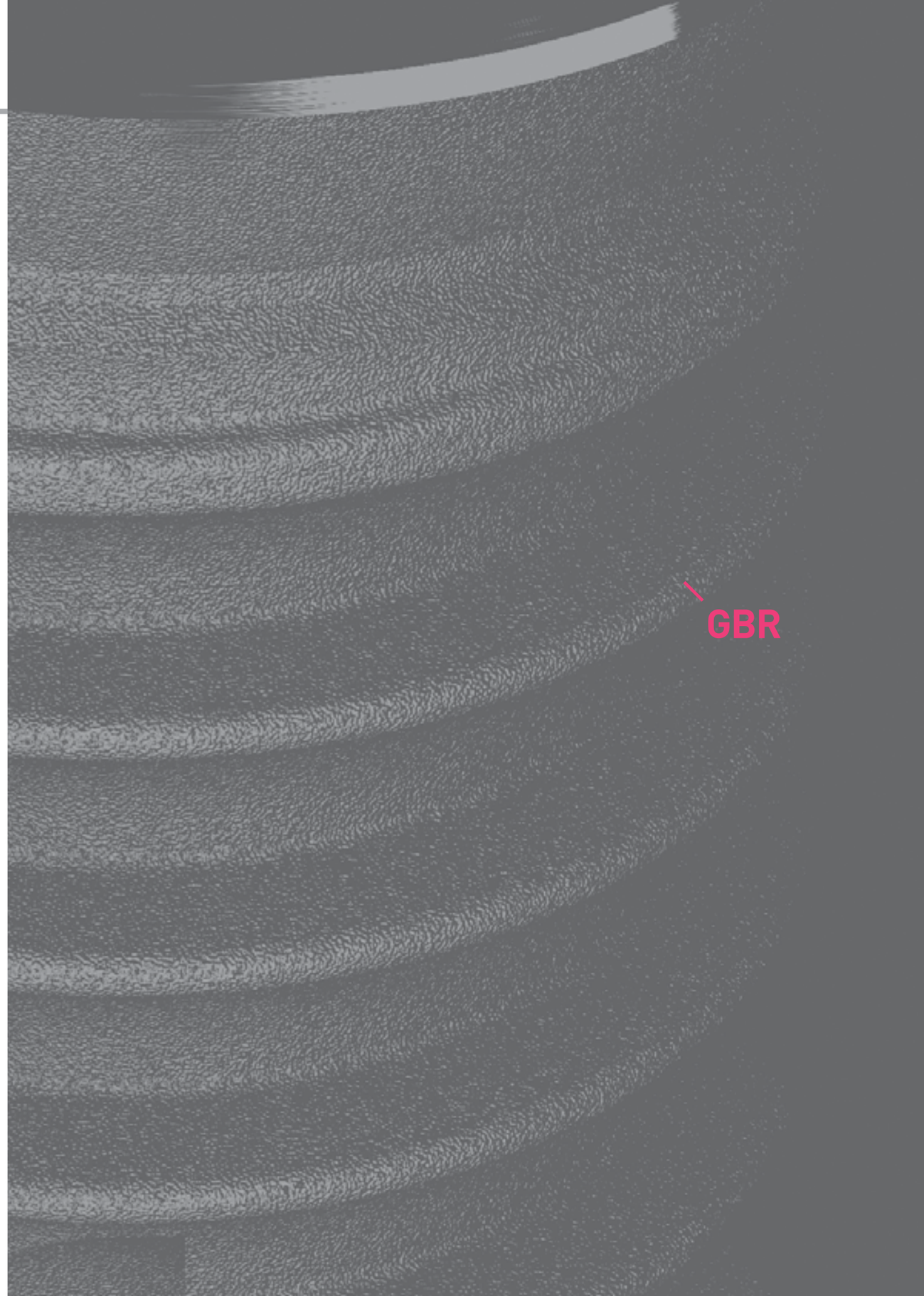

The effects of ErhBMP-2-/EGCG-coated BCP bone substitute on dehiscence around dental implants in dogs

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OBJECTIVES:

The purpose was to evaluate the effect of Escherichia coli-derived recombinant human bone morphogenetic protein-2 (ErhBMP-2)-/epigallocatechin-3-gallate (EGCG)-coated biphasic calcium phosphate (BCP) and titanium barrier membrane on dehiscence defects in dogs.

MATERIALS AND METHODS:

In five mongrel dogs, the dehiscence bony defects around dental implants were surgically created and in total three implants were placed at edentulous ridge of which teeth had been extracted 12 weeks before. For the control group, BCP was applied to the dehiscence defect. For experimental groups, ErhBMP-2-coated BCP and ErhBMP-2-/EGCGcoated BCP were applied. The newly designed titanium barrier membrane was used to apply all the defects. The defects were evaluated histologically and histometrically after 12 weeks. The comparative statistics of the groups were obtained through Kruskal–Wallis test.

RESULTS:

In bone-to-implant contact (BIC), bone density (BD), bone regeneration height (BRH), and bone mineralization apposition rate (BMAR), differences among groups were not found. ErhBMP-2/EGCG group appeared to have higher value. In fluorescence analysis, bone remodeling around graft material was more active in the ErhBMP-2/EGCG group.

CONCLUSION:

Within the limit of this study, it is reasonable to assume that BMP-2-/EGCG-coated biphasic BCP and the newly designed titanium membrane were more beneficial in dehiscence defect healing with increased bone remodeling.

Keywords:

GBR; biphasic calcium phosphate; dehiscence defect; epigallocatechin-3-gallate; ErhBMP-2; titanium barrier membrane

Introduction

The success rate of guided bone regeneration (GBR) procedure is diversely reported from 79% to 100%, and it has been greatly affected by barrier membranes and graft materials (Hammerle et al, 2002). Membrane induces selective cell proliferation and maintains space for new bone to be regenerated (Rosen and Reynolds, 2001). Nonresorbable membrane like titanium mesh is superior to resorbable ones in maintaining the space and in keeping a low incidence of degradation by immune reaction (Hammerle et al, 2002). However, when nonresorbable membranes are clinically used for GBR procedure, additional surgery for membrane removal is needed. In addition, when the membrane is exposed, infection and inflammatory reaction might jeopardize the defect even worse than without GBR.

Graft material not only retains the space but also prevents the formation of empty space under the membrane and consequently contributes to the formation and stabilization of the blood clot. In addition, it could reduce the fine movement of the membrane and promotes the formation of new bone (Jovanovic and Nevins, 1995). Biphasic calcium phosphate (BCP) is one of alloplastic bone substitutes, which consists of hydroxyapatite (HA) and b-tricalcium phosphate (TCP), and has a similar structure with human bone. As the ratio of b-TCP gets higher, the resorption rate becomes higher accordingly, whereas as the ratio of HA gets higher, the resorption rate becomes lower accordingly as well. It is revealed that the overall resorption rate is regulated according to their proper ratio. Thus, BCP bone substitute consisting of HA and b-TCP in the ratio of 7:3 was used to maximize the osteoconductive effect since this ratio showed good results in previous studies (Bae et al, 2010; Kim et al, 2011b).

Many surface treatments have been tested to improve osteoinductive effect on BCP (Zhu et al, 2009). Rh-BMP is a growth factor, which is osteoinductive and also differentiates mesenchymal stem cell into osteoblastic cells to increase new bone formation (Jung et al, 2003). As watersoluble osteoinductive proteins such as BMP diffuse rapidly when applied to the transplant area directly, a carrier system is needed to make it work on the local spot continuously (Jung et al, 2011). Collagen has been used clinically and experimentally as a BMP carrier and has made a good result in new bone formation (Kim et al, 2011a). However, it has failed to provide sufficient space for bone regeneration when applied to the large bony defect (Jung et al, 2011). Therefore, BCP could be considered as a better carrier than collagen (Kim et al, 2011a). The method of putting a carrier into the solution diluted with osteoinductive protein presents a difficulty in manipulating the flow and in keeping the accurate concentration (Park et al, 2011). For these reasons, BCP coated with rhBMP-2 could be better than BCP moistened with diluted rhBMP-2.

Escherichia coli-derived recombinant human bone morphogenetic protein-2 (ErhBMP-2) was made to overcome difficulties in making rhBMP-2. A new production method in which BMP gene is inserted into Escherichia coli (E. coli) was introduced, so that BMP can be obtained much more easily with a cheaper cost (Vallejo et al, 2002). ErhBMP-2 showed more adipose tissue in bone matrix and bone formations than CrhBMP-2. In the previous study by Kim et al (2011a), more bone formation was shown in BCP group that was coated with ErhBMP-2 than the group with no surface treatment.

Of various osteoinductive agents, epigallocatechin-3-gallate (EGCG) reduces the fat content in the blood and enhances the immune reaction as well as has a therapeutic efficacy on several diseases including vascular diseases, diabetes, allergy, cancer, and obesity (Chacko et

al, 2010). It was shown that such effects were mainly originated from the green tea extract's antioxidant effect and the removal effect on the active oxygen (Shen et al, 2011). EGCG, one of the compounds in green tea extract, is known to prevent bone resorption by inducing the apoptotic cell depth of osteoclast and inhibition of osteoclast formation. Green tea's extract blocks the activity of NF-κB and inhibits the generation of IL-1ß. Consequently, it blocks the formation of the osteoclast and inhibits bone resorption (Nakamura et al, 2010). Recently, it was also reported that EGCG enhances bone formation by suppressing T3-stimulated synthesis of osteocalcin, which is a determinant of bone formation (Kato et al, 2011). If such effects of green tea extract are applied to the defect site of implant by being coated to BCP together with ErhBMP-2, more beneficial effects will surely be obtained.

The purpose of this study was to examine the osteogenic potential of BCP coated with low-concentrate ErhBMP-2 and epigallocatechin-3-gallate (EGCG) and to evaluate the healing aspect and the newly designed titanium barrier membrane with a histological manner in dehiscence defects in dogs.

Materials and methods

Animals and experimental groups

In this study, five mongrel dogs (weighing approximately 30 kg) were used. For prestudy preparation, scaling and plaque control were performed for periodontal health. After treatments, they were fed with liquid foods to prevent masticatory trauma during healing. All experiments were approved by the Animal Care and Use Committee, Yonsei Medical Center, Seoul, Korea (no. 2010-0362).

All of the surgical treatments were carried out under anesthesia. Atropine (0.04 mg kg^{-1}: Kwangmyung Pharmaceutical Ind. Co. Ltd., Seoul, Korea) was injected by intravenous administration, and xylazine (2 mg kg^{-1}: Rompun, Bayer Korea Co., Seoul, Korea) and ketamine (10 mg kg^{-1}: Ketara, Yuhan Co., Seoul, Korea) were injected by intramuscular administration. During the treatment, intubation was implemented, and then, inhalation anesthesia (Gerolan, Choongwae Pharmaceutical Co., Seoul, Korea) was carried out. Additional local anesthesia with 2% lidocaine (1:80 000 epinephrine, lidocaine HCl, Yuhan Co., Seoul, Korea) was added on surgical sites. Laboratory animals were monitored by electrocardiogram during operation.

Twelve weeks after the extraction of four teeth (P2, P3, P4, and M1) on the left mandible, crestal incision was conducted to elevate a full thickness flap. Three bone defects were formed for groups 1, 2, and 3, respectively, at interval of 11 mm around the buccal sites of alveolar bone. Enough intervals were positioned to prevent interaction among adjacent implants. Those defects were equally formed 4 mm width, 5 mm height, irrigating them with enough saline. The defects were informed through probing.

A total of 15 hydroxyapatite-coated implants (3.5 9 10 mm; Neo CMI Implant Neobiotech, Seoul, Korea) were used. For control group, BCP (OSTEON, Dentium, Seoul, Korea) was applied to the dehiscence defect. It is synthetic bone graft material with similar pore system to human cancellous bone, particle size of 0.5–1.0 mm, hydroxyapatite 70%, and b-TCP 30%. For experimental group 1, ErhBMP-2 (0.05 mg ml^{-1})-coated BCP was applied. For the experimental group 2, BCP coated with EGCG 5 mg ml^{-1} (purity 97.5–102.5%; Sigma, St Louis, MO, USA) and ErhBMP-2 0.05 mg ml^{-1} (Cowellmedi®, Busan, Korea) was used (Table 1). Each defect site was grafted with corresponding bone substitute and covered with titanium mesh membrane (CTi-mem®, Neobiotech, Seoul, Korea). This membrane was newly designed for the customized titanium membrane. It can provide various sizes of membrane, which are suitable for treatment use and can bend the membrane for attaching on that location. After completing GBR, it can easily be removed without additional flap surgery (Figure 1).

Table 1 Experimental design

	Bone graft materials	Healing time (weeks)	N (=implant)
Group 1	BCP	12	5
Group 2	ErhBMP-2-coated BCP	12	5
Group 3	EGCG-/ErhBMP-2-coated BCP	12	5

BCP, biphasic calcium phosphate; ErhBMP-2, Escherichia coli-derived recombinant human bone morphogenetic protein-2; EGCG, epigallocatechin-3-gallate.

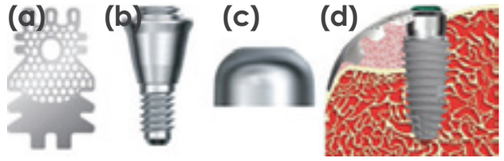

Figure 1 The newly designed titanium membrane and accessories design used in the study. (a) Membrane (b) screw (c) cap (d) schematic drawing describing the installation of titanium membrane

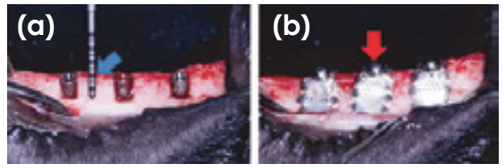

Figure 2 Clinical views of the dental implantation and bone graft. (a) Buccal view after implant placement. Those defects were equally formed with 4 mm width, 5 mm height. The defects were informed through probing (blue arrow). (b) Titanium membrane application after implant placement. It can effectively apply and cover the guided bone graft sites (red arrow)

Each group was treated with bone graft materials and membranes after implantation and randomly allocated for reducing differences of the sites. Membranes were fixed by fixing screws (IS CTi Spacer, Neobiotech) and caps (CTi Cover Cap, Neobiotech) (Figure 2). Before closing the wounds, all residual bone particles were removed with physiological saline, which rinsed all the defect sites. Then, periosteal releasing incisions were conducted and vertical mattress suture was used for primary closing with 4-0 Monosyn (glyconate absorbable monofilament, BBraun, Aesculap, PA, USA). The same experienced operator performed all surgical procedures. Suture materials were removed after 2 weeks.

Preparation of BCP coated with low-concentrate ErhBMP-2 and EGCG

Surface coating process of bone graft material can be classified into three stages. First step was 3-aminopropyltriethoxysilane (APTES) (Sigma) to combine the OH- of HA with silane coupling agent. The second step was to combine N-succinimidyl-3-maleimidopropionate (SMP) (Sigma), which is a bifunctional crosslinker, with amino radicals. The last step was to combine EGCG and ErhBMP-2 with SMP. The graft material that had completed the coating procedure was lyophilized. The graft material was frozen in temperature to –45°. It was kept for 3 h at that temperature. Then, it went through primary drying and was kept for 2 h in the pressure chamber at 7–10 mTorr. Secondary drying was performed from –20 to 20°C. For sterilization of bone graft material, gas sterilization was performed at low concentration for a long time with ethylene oxide.

Fluorescence analysis

Fluorescence expression agents were injected in specimen for observation under a fluorescent microscope. Oxy-TC (oxytetracycline HCl; yellow; Pfizer, Seoul, Korea; 20 mg kg^{-1}; iv) was injected 3 days after implantation, calcein green (calcein green, Sigma; 20 mg kg^{-1}; iv) 4 weeks later, oxytetracycline HCl 8 weeks later, and Alizarin red S (Alizarin red S; Junsei Chemical, Tokyo, Japan; 20 mg kg^{-1}; iv) was injected 3 days before sacrifice.

Topographic localization of the new bone formation and remodeling activity was analyzed in 2, 4, 8, and 12 weeks. Their fluorescence microscopic image (DM LB, Leica, Wetzlar, Germany) was taken at the wave range of 543–617 nm (red filter) and 515–560 nm (green filter).

Necropsy and tissue collection

After healing time of 12 weeks, thiopental was excessively injected to euthanize the animals. The oral tissues including an implant were sectioned, and it was fixed with 10% neutral buffered formalin (pH 7.0) for 2 weeks. After that, it was dehydrated by ethanol and embedded in methylmethacrylate (Technovit 720VLC., HeraeusKulzer, Dormagen, Germany).

Determination of bony change in the dehiscence defects

The specimen was cut along the center axis of the implant and into bucco-lingual plane by a cutting system (Exakt 300, Kulzer, Norderstedt, Germany). The central section of each specimen was cut 15 μm in thickness by a microgrinding system (Exakt, Apparatebau, Norderstedt, Germany). The sectioned specimens were dyed with hematoxylin and eosin (H&E). Dyed specimens were histologically analyzed under an optical microscope (Leica DM 2500, Leica Microsystems, Wetzlar, Germany). And then, Image Pro Plus 4.5 program (Media Cybermetics Inc, Bethesda, MD, USA) and SPOT (SPOT ver. 4.1, Diagnostic instrument Inc., Sterling heights, MI) were used to implement computerassisted histometric measurement.

The following parameters were histologically evaluated (Figure 3).

1. Defect height: half of implant length
2. Bone-to-implant contact (BIC): percentage regenerated from bone-to-implant contact

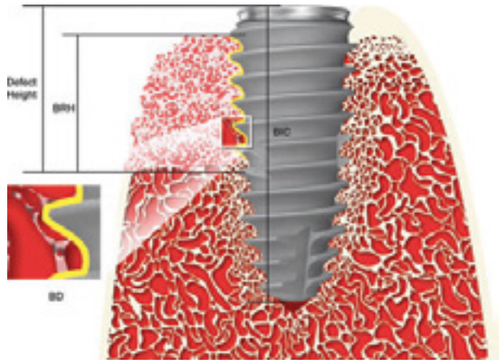

Figure 3 Schematic drawing describing measurement of the guided bone regeneration with defect height, BIC, BD, and BRH

3. Bone density (BD): percentage of mineralized bone at the base of defect in the same square (1 × 1 mm)
4. Bone regeneration height (BRH): linear distance from the defect base to top of the regenerate bone
5. Bone mineral apposition rate (BMAR): bone mineral apposition rate from the implant surface to 150 μm region

Statistical analysis

All data were expressed as means ± standard deviation. Data obtained from histological analysis were processed by SAS 9.2. Because of the limited number of implants, nonparametric analysis was implemented. The comparative statistics of groups were obtained through Kruskal–Wallis test.

Results

The clinical healing patterns in all samples were progressed without any singularity. However, membrane was exposed in some implants. No edema and acute inflammation response such as redness were seen around the exposed membrane. Therefore, removal procedure of membrane was not carried out additionally.

Histological effects of ErhBMP-2/EGCG

The shape of the alveolar bone varied according to each dog, so different shapes of new bones were formed on the buccal defect side. The shape of the bone which formed in the buccal side was affected by membrane exposure. Thick connective tissue formed under the membrane and the upper side of the new bone was collapsed where the membrane was exposed. In addition, many of the inflammatory cells infiltrated under the membrane and buccal grafting material was lost. It had an effect on the osseointegration of the lingual bone side (Figures 4 and 5).

In each specimen out of the groups, the bone grafting materials did not remain. After checking the specimens, they were regrouped and compared among groups in which the bone grafting materials still remained.

When comparing BIC among groups having the bone grafting materials, the higher BIC was shown in order of the ErhBMP-2 group, the ErhBMP-2/EGCG group, and lastly the BCP group. There were no significant differences. However, when the control group (BCP) and the experimental group (ErhBMP-2, ErhBMP-2/EGCG) were compared, the experimental group showed significantly higher value in BIC ($\alpha = 0.05$). The bone density increased in the order of the BCP group, the ErhBMP-2 group, and then the ErhBMP-2/EGCG group. But these differences did not reach statistical significance. All three groups showed over 4 mm of bone regeneration height. But there were no statistically significant differences in BRH (Table 2).

Analysis of bone mineral apposition rate

Throughout fluorescence analysis, the active bone forming area was observed and the bone mineral apposition rate was measured. Seen through the green filter (515–560 nm wave length), calcein green emitted green, and under the red filter (450–490 nm wavelength), alizarin red S emitted red.

The green emitting region showed the bone formation at 4 weeks, and the red emitting region showed the bone formation at 12 weeks (Figure 6). In the 4-week period, a bright fluorescence color appeared in the space between bone defect base and graft material; in the 12-week period, a bright fluorescence color appeared at the boundary of bone grafting material and the interface of implant. Like the 4 weeks, the 6 weeks' bright fluorescent color was observed in the space between the base of the bone defect and graft material. Comparing the 4 weeks and the 12 weeks, there were more regions of bright fluorescent color in the 4-week group.

However, when comparing the active bone forming area around the implant (from outer surface of implant to 150 μm of it), ErhBMP-2/EGCG group showed higher BMAR value in 4 and 12 weeks. There were no statistically significant differences (Figure 7, Table 3).

Discussion

Buccal bone loss often occurs due to periodontal disease or trauma. It can cause defects around the implant in the form of perforation or dehiscence, because the thin buccal bone is absorbed more rapidly compared with the lingual bone (Araujo and Lindhe, 2005). Insufficient bone volume threatens the long-term prognosis of implants (Chiapasco and Zaniboni, 2011). To overcome such problems, GBR procedure was attempted and has been successful. In previous studies, various time intervals re-

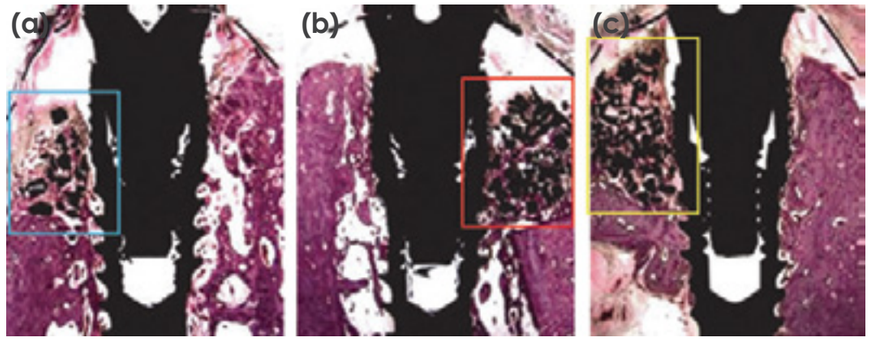

Figure 4 The representative histological images (×12.5, H&E staining) at 12 weeks. (a) BCP group. Characteristically, small particles being absorbed can be seen in the buccal side (blue box). (b) ErhBMP-2 group. The coated graft material has excellent bone formation ability (red box). (c) ErhBMP-2/ EGCG group. The buccal bone shows superior bone formation and bone-to-implant contact from the base to the top of implant (yellow box). It also shows the absorption of the graft material

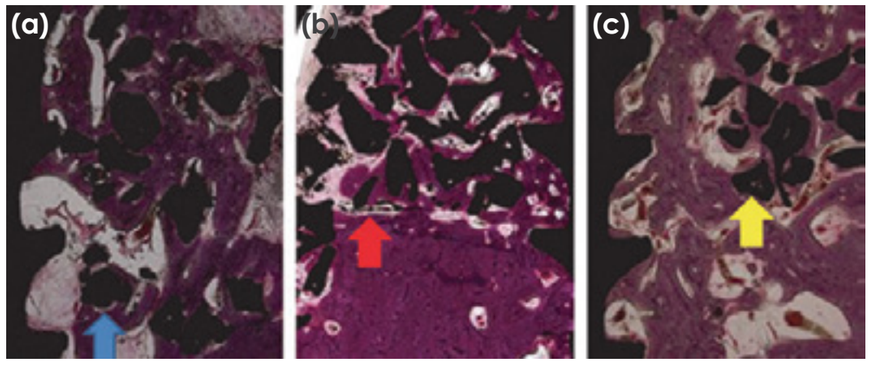

Figure 5 The high-resolution images (950, H&E staining). (a) BCP group. The margin of grafting materials became smooth (blue arrow). (b) ErhBMP-2 group. There is a clear boundary between the new bone and the defect (red arrow). (c) ErhBMP-2/EGCG group. Unlike the BMP group, vague boundary was shown between the defect and the new bone (yellow arrow)

Table 2 Mean values ± s.d. of bone-to-implant contact (%), bone density (%), and bone regeneration height (mm) after 12-week healing period (n = 4 dogs)

	DH	BIC	BD	BRH
BCP	4963.45 ± 33.50	35.39 ± 7.40	25.37 ± 14.31	4.48 ± 0.56
ErhBMP-2	4971.87 ± 23.47	58.68 ± 16.47	36.63 ± 10.9	4.23 ± 0.64
ErhBMP-2/EGCG	4953.01 ± 33.02	50.25 ± 12.39	37.71 ± 20.08	4.86 ± 0.10

DH, defect height; BIC, bone-to-implant contact; BD, bone density (%); BRH, bone regeneration height; BCP, biphasic calcium phosphate; ErhBMP-2, Escherichia coli-derived recombinant human bone morphogenetic protein-2; EGCG, epigallocatechin-3-gallate.

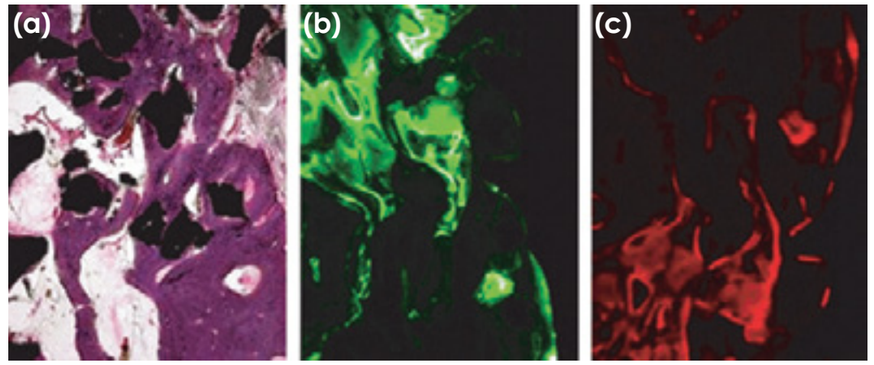

Figure 6 Fluorescence microscopic images. (a) Histological findings in the same region. (b) green emitting region (4 weeks): bright fluorescence color appeared at the space between bone defect base and graft material. (c) Red emitting region (12 weeks): bright fluorescence color appeared at the boundary of bone grafting material and the interface of implant

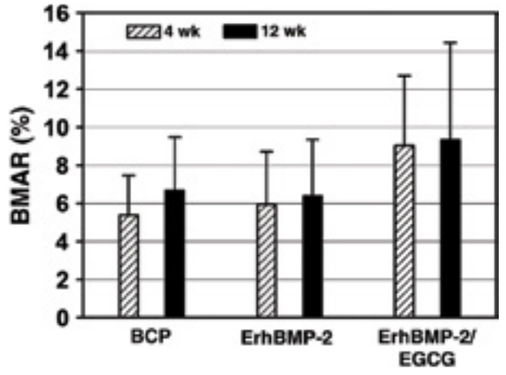

Figure 7 Graph with BMAR (%). ErhBMP-2/EGCG group showed higher BMAR value in 4 weeks and the 12 weeks. There were no statistically significant differences

Table 3 Mean and standard deviation of BMAR in the 4 and 12 weeks

Group	BMAR in 4 weeks (%)	BMAR in 12 weeks (%)
BCP	5.39 ± 2.09	6.68 ± 2.82
ErhBMP-2	5.95 ± 2.76	6.38 ± 2.98
ErhBMP-2/EGCG	9.03 ± 3.67	9.35 ± 5.09

BMAR, bone mineral apposition rate; BCP, biphasic calcium phosphate; ErhBMP-2, Escherichia coli-derived recombinant human bone morphogenetic protein-2; EGCG, epigallocatechin-3-gallate.

quired for the healing of the defect in each animal model were tried (Caton, 1997). Compared with a human bone, bone remodeling period is shorter in dogs. Six weeks, 12 weeks, and 17 weeks are needed for bone remodeling in rabbits, dogs, and human, respectively (Roberts et al, 1987). Therefore, in this experiment, for sufficient healing in dogs, the experimental time was set at 12 weeks.

In this experiment, BCP was coated with ErhBMP-2 and EGCG. However, a highly concentrated BMP could bring the adverse effects such as cyst-like bone formation, ectopic bone formation, and soft tissue swelling (Smucker et al, 2006; Wong et al, 2008). Therefore, if possible, the application of a low-concentrated BMP in clinics is recommended. The concentration of EGCG (25 μM) was chosen from previous studies, which showed good bone formations, and for ErhBMP-2, a low concentration of 0.05 mg ml^{-1} was selected to avoid the adverse effect from a high-concentration rhBMP-2 while producing an optimum effect (Wikesjö et al, 1999; Boyne et al, 2005). Dehiscence defect was treated using BCP coated with a combination of low-concentration ErhBMP-2 and EGCG, and osteogenic potential was evaluated at 12 weeks after implantation.

The newly designed titanium membrane was fixed with screws and caps to minimize fine movement. The fixing screw of the membrane not only prevents minute movement but also induces tight contact between the bone and the membrane. Therefore, bone formation is enhanced by preventing adipose tissues and connective tissues from growing it into the space under the membrane. This titanium membrane would affect the comparisons of bone graft materials in this study because the stability of the non-resorbable membrane was sufficient to maintain the bone graft, which resulted in gaining of large amount of bone graft materials. This could be why BMP site showed similar bone regeneration compared with control sites in this experiment.

However, the structure of screws and caps, which protrude over the bone surface as much as 3 mm, makes primary closure of the soft tissue difficult. To minimize the tension remaining inside the soft tissues, a sufficient releasing incision was made. But there was membrane exposure and loss of bone grafting material in many specimens. In previous animal experiments, wound dehiscence and membrane exposure were often reported in GBR procedures. In this study, the specimen with exposed membrane formed thick soft tissues under the membrane and most of bone grafting material was lost, and such cases were excluded from the histometric analysis.

It is known that EGCG improves osteoblastic activity, suppresses osteoclastic activity, and influences bone metabolism. In addition, it can also enhance vascular endothelial growth factor-mediated mechanism (Chen et al, 2005; Vali et al, 2007; Luo et al, 2012). Therefore, in this experiment, ErhBMP-2/EGCG group showed a high measured value in bone-to-implant contact (BIC), bone density (BD), bone regeneration height (BRH), and bone mineral apposition rate (BMAR). In fluorescence analysis, the bone mineral apposition pattern was compared for various periods. In the 4-week group, a bright fluorescent color appeared at the space between bone defect base and bone grafting material; in the 12-week group, a bright fluorescent color appeared at the boundary of the bone grafting material and the interface of implant. When the 4-week group is compared with the 12-week group, more area shows fluorescent color in the 4-week group. It showed that bone formation was more active in the 4-week group. In the 12-week group, the resorption of grafting material was more active than new bone formation. Continuous bone remodeling around the implant was still seen at 12 weeks. Osteogenic potential was compared to confirm the combination effect of low-concentration ErhBMP-2 and EGCG by histological analysis, fluorescence analysis, and histometric analysis (BIC, BV, and BRH). The surface modification of BCP with low-concentration BMP and EGCG showed better results than other groups. Consequently, ErhBMP-2/EGCG group was more effective in enhancing the osteogenic potential around dental implants.

Until now, the studies on EGCG have been made mostly in vitro, while in vivo studies are rare. Additional study is needed to evaluate the proper concentration, releasing kinetics, and the synergy effect when it is used together with ErhBMP-2 and EGCG in vivo. It was hard to obtain statistically significant data between the experimental groups. But BMP-2-/EGCG-coated BCP showed more active tendency of bone healing in this experimental design.

Conclusion

In this study, osteogenic potential was compared to confirm the effectiveness of the combination of Escherichia coli-derived recombinant human bone morphogenetic protein-2 (ErhBMP-2)/epigallocatechin-3-gallate (EGCG) by histological analysis, fluorescence analysis, and histometric analysis. The results were obtained as follows. But significant difference was not found.

1. When comparing among the three groups, ErhBMP-2/EGCG group appeared to have higher value in bone-to-implant contact (BIC), bone density (BD), bone regeneration height (BRH), and bone mineralization apposition rate (BMAR).
2. In fluorescence analysis, bone remodeling around graft material and implant was more active in the ErhBMP-2/EGCG group.

Consequently, within the limit of this study, it is reasonable to assume that BMP-2-/EGCG-coated biphasic calcium phosphate (BCP) and the newly designed titanium barrier membrane were more beneficial in dehiscence defect healing with increased bone remodeling.

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Conflict of interest

The authors declare no conflict of interest.

Author contributions

Y-S Shin, J-Y Seo, and H-S Moon performed the experiments, analyzed the data, and wrote the manuscript. Y-S Shin and H-S Moon contributed equally to this study. J-H Kim and Y-B Park revised the manuscript. S-H Oh gave conceptual advice. S-T Kim designed the study and analyzed the data and supervised.

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Volumetric comparison of three different innovative bone collecting debices for autogenous bone grafts

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OBJECTIVES:

The aim of this study was to evaluate the clinical relevance of three different bone collecting devices in a volumetric comparison.

METHOD AND MATERIALS:

Bone harvesting for the collection of bone particles was performed on bovine mandibles. Three different types of bone collecting devices (Tests 1, 2, and 3) were used. Ten drilling sites in each group were prepared and bone particles were collected. Bone particles were sieved twice in sieves with 500 µm and 1,000 µm openings. The bone particles were divided into three groups: < 500 µm (SP), 500–1,000 µm (MP), and >1,000 µm (LP). Total wet volume, fractional wet volume, fractional dry volume, and weight were measured. The shape of the dried particles was examined using a microscope.

RESULTS:

All particles in all three groups had a wood shaving-like appearance. With Test 1 and Test 2, LP were the most common (0.510 ± 0.064 mL, 0.430 ± 0.067 mL), and in Test 3, MP was the most common (0.112 ± 0.019 mL). Among the SP and MP, the wet volume of Test 3 was significantly greater than those of Tests 1 and 2 ($P < .001$). However, among the LP, the wet volume sequentially increased from Test 1, to Test 2, and Test 3 ($P < .001$). The proportion of dry volume was similar to that of wet volume.

CONCLUSION:

Three innovative bone collecting devices could collect comparable amounts of bone particles to commercially available bone graft materials. (Quintessence Int 2015;46:807–815; doi: 10.3290/j.qi.a34458)

Key words:

autogenous bone graft, bone collector, oral implantology, particle size

Implantation is a successful procedure in dental rehabilitation. This procedure often requires guided bone regeneration or bone grafts when the alveolar ridge is atrophic or if implant dehiscence is present. Of the various bone graft materials, autogenous bone is considered the gold standard because of its superior biocompatibility, osteogenicity, osteoconductivity, and osteoinduction.[1,2] There are many methods to collect autogenous bone in the mouth. Autogenous bone grafts can be collected in either particulate or block form.[3-5] Autogenous bone in particulate form can be collected using hand chisels, burs, or bone collectors.[6-8] If protruded alveolar bone, such as torus and exostosis, is present around the implant site, a hand instrument such as an Ochseinbein chisel and mallet may be useful to collect the autogenous bone. These sites allow for the easy collection of autogenous bone. When the collected bone particles are grafted onto the dehiscence or fenestration bone defects of the implant site, new bone formation can be successful and stable results maintained.[9-11]

A bone scraper (Safescraper curve, Meta), which consists of a blade, body, and collection chamber, can be used to scrape cortical bone around the surgical field to place in the chamber.[8,12] A trephine bur can be used to collect bone cores at the chin or retromolar area and has the advantage of allowing for the collection of large amounts of autogenous bone core (diamete 5 to 7 mm).[13] However, additional steps are required to crush the bone core with a bone crusher or bone mill if particulate bone is necessary. There is also the possibility of damaging the nerve with excessive drilling because there is no stop. Another bone collecting device such as a bone collector is connected to the suction. Sufficient bone can be obtained without an additional surgical site.[14,15] However, this device is not appropriate to use in the maxilla where there is not enough cortical bone. Although contamination is another limitation of this method, preoperative chlorhexidine mouth rinse for 1 minute showed good results, without infection.[16] Anitua et al[17] suggested a novel drilling procedure for collecting autogenous bone during implant site preparation procedures. They drilled at low speed (20 to 80 rpm) without irrigation, which was useful when a small amount of bone was needed, and had the advantage that no additional surgical site was necessary. However, the authors did not report on the amount of bone debris.

There have been many efforts to collect autogenous bone more easily and faster. Several innovative devices for collecting autogenous bone are available. These devices have been designed to collect more bone debris than implant drills. The aim of this study was to evaluate the clinical relevance of three different bone collecting devices in a volumetric comparison.

METHOD AND MATERIALS

Description of three bone collecting devices

Three different types of currently available bone collecting devices were used in the present study. They have been designed to collect autogenous bone particles using a rotating drilling system. They are recommended for use at low speed (200 to 300 rpm). They have stops to prevent overdrilling to the nerve, and also to collect bone particles.

- Test 1: Auto Chip Maker, Neobiotech. This is a straight, cylindrical device with an empty center. It has two flutes and a 15-mm plastic cap that extends to the tip end. The role of the plastic cap is not only to collect the bone particles during the drilling, but also to function as a 4-mm stop. The device has a protruded point at the tip of the drill to allow for initial drilling stability on the cortical bone.
- Test 2: AutoBone Collector, Osstem Implant. This is a twist drill that has two flutes and a 10-mm metal cap that extends to 4 mm below the tip end. It has a protruded point on the front portion of the drill to help stabilize the initial drilling.
- Test 3: Dentium Harvest Drill, Dentium. This is also a twist drill that has two flutes, and a 16-mm metal cap that extends to 4 mm below the tip end. It was designed to be used without a stop during implant site preparation for harvesting autogenous bone.

The diameters of Tests 1, 2, and 3 were 5.0 mm, 5.0 mm, and 4.4 mm respectively. The description of each device and the protocol suggested by the manufacturers is summarized in Table 1.

In vitro experiment

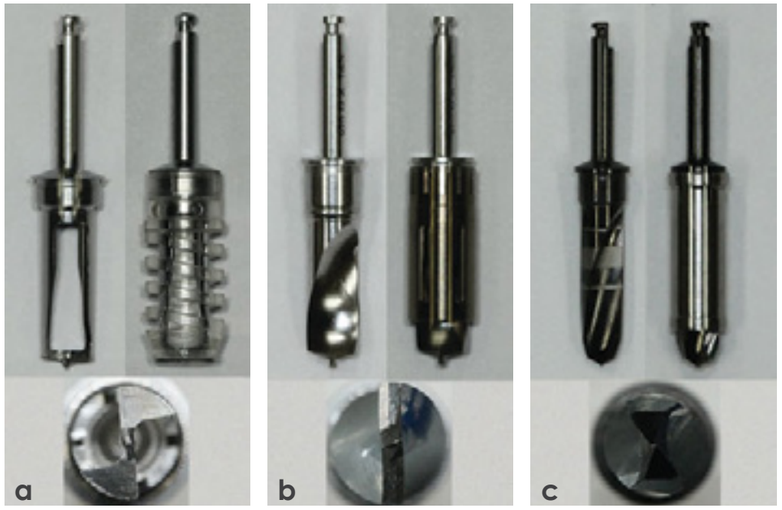
The experimental protocol was designed by modifying a previously described in vitro experiment for bone collection.[6,18] Briefly, bone harvesting for the collection of bone particles was performed on bovine mandibles. Frozen mandible bone was left for 3 hours at room temperature for thawing. The periosteum was removed with periosteal elevators to expose the cortical bone. Three different types of bone collecting devices were used (Fig 1).

Ten drilling sites in each group were prepared using the implant engine (Surgic XT Plus, NSK) under irrigation. All drilling sites were prepared on bovine mandible body (Fig 2). The drilling speed was 300 rpm in Tests 1 and 2, and 200 rpm in Test 3, according to the manufacturers' instructions. Bone particles were collected in a small bowl after drilling with the devices. Particles around the preparation holes were also collected with thorough saline irrigation. The bone particles were packed into a 1-mL syringe to measure the total wet volume. The bone particles were then sieved using sieves (Chunggye) with 500-μm and 1,000-μm openings. The bone particles were divided into three groups:

- < 500 μm (small particles; SP)

Table 1 Characteristics of the three innovative bone collecting devices and the manufacturers' protocols

	Shape	Flute number	Diameter (mm)	Length (mm)	Speed (rpm)	Torque (N·cm)
Test 1	Straight and hollow	2	5.0	14 (stop 4 mm)	300	10
Test 2	Twist	2	5.0	14 (stop 4 mm)	300	10
Test 3	Twist	2	4.4	20 (stop 4 mm)	200	50



Figs 1a to 1c The three types of autogenous bone collecting devices used in the present study: (a) Test 1 (Auto Chip Maker, Neobiotech); (b) Test 2 (AutoBone Collector, Osstem Implant); (c) Test 3 (Harvest Drill, Dentium).

- 500 – 1,000 µm (medium particles; MP)
- > 1,000 µm (large particles; LP).

Each group was packed into a 1-mL syringe and the fractional wet volume was measured. After drying for 24 hours at room temperature, the fractional dry volume was measured. In addition, the total dry volume and weight were measured. A JW-1 electronic-scale (Acom) was used for measuring dry weight. Three more drilling sites in each group were prepared to evaluate the size distribution of particles.

Microscopic analysis

The shape and size of the dried particles were examined using an Olympus BX51 fluorescence microscope and an illuminator (DLS-100HD, Daeshin I Tech). Digital images were captured by Olympus software (DP Controller v2.1.1.231). The size distribution of particles was also evaluated using digital images.

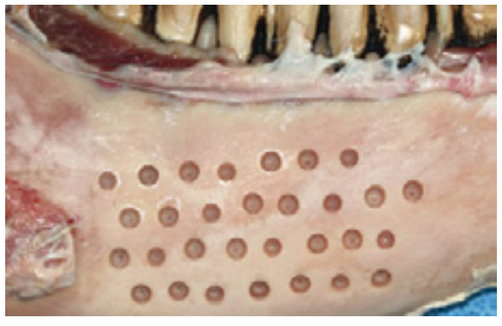
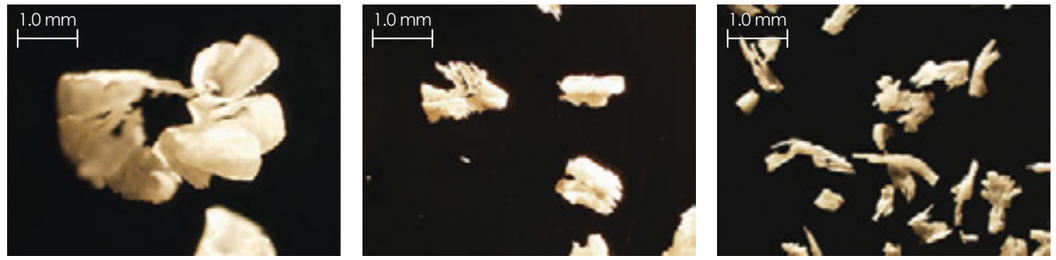


Fig 2 Drilling sites in the bovine mandible.

Statistical analysis

Statistical analysis was performed using a computer program (SPSS v17.0). Nonparametric tests were used. Intergroup and intragroup comparisons of the properties of the collected bone particles were statistically evaluated using the Kruskal-Wallis test followed by the Mann-Whitney test. A P value of < .05 was considered statistically significant.



Figs 3a to 3c Microscopic views of bone particles from Test 1 (original magnification ×20): (a) large particles (LP); (b) medium particles (MP); and (c) small particles (SP).

RESULTS

Microscopic analysis

Particles were shown to have a wood shaving-like appearance in all three groups. However, this characteristic feature was more clearly found with increasing particle size, especially in LP. SP seemed to be the crushed fragments from MP and LP. Among the three kinds of bone collecting devices, the particles from Test 3 had less pronounced wood-shaving shape compared to the bone from Tests 1 and 2. No specific difference in shape between the particles from the three devices was found within each size (LP, MP, or SP; Fig 3).

Quantitative analysis

Table 2 and Fig 4 show the wet volume among the three groups. Drilling time was less than 15 seconds in all groups. The total wet volumes of Tests 1 and 2 were greater than that of Test 3 ($P < .001$). Among bone particles that were LP, the wet volume of Tests 1, 2, and 3 significantly and sequentially increased ($P < .001$). However, among the bone particles that were SP and MP, the wet volume of Test 3 was significantly greater than that of Tests 1 and 2 ($P < .001$). In the intragroup comparison of wet volume, the particle proportion in Tests 1 and 2 showed a similar pattern; most of the wet volume was LP followed by MP and SP. However, MP made up the greatest proportion of the bone particles in Test 3 (Fig 4). The number of particles of clinically useful size (> 500 µm) showed a similar pattern. Most of the wet volume was LP followed by MP and SP (Table 2).

Table 3 and Fig 5 show the dry volume among the three groups. The proportion of dry volume was similar to that of wet volume. Table 4 shows the intragroup comparison of total dry weight. The total dry weight of Test 1 was significantly more than for Test 3 ($P < .001$), but not than Test 2 ($P = .052$). Both the wet volume and the dry volume in Test 1 were significantly greater than in Tests 2 and 3.

Figures 6 and 7 show the size distribution of particles among the three groups. SP was the most common in all test groups, and in particular SP accounted for more than 50% in Test 3. LP was the most common in Test 1.

DISCUSSION

In the present study, the amount and the size distribution of autogenous bone particles were evaluated when three types of innovative bone collecting devices were used. The result was comparable to other studies on bone graft particle size. Many studies on graft particle size

Table 2 Wet volume (mL) of the bone particles collected from the three different bone collecting devices (mean ± standard deviation)

Particle size	Test 1	Test 2	Test 3	P value
Total	0.531 ± 0.060	0.491 ± 0.049*	0.237 ± 0.043	< .001
< 500 µm (SP)	0.007 ± 0.008	0.017 ± 0.009	0.063 ± 0.018	< .001
500–1,000 µm (MP)	0.034 ± 0.012	0.053 ± 0.022	0.112 ± 0.019	< .001
> 1,000 µm (LP)	0.510 ± 0.064	0.430 ± 0.067	0.021 ± 0.016	< .001
≥ 500 µm (MP + LP)	0.544 ± 0.062	0.483 ± 0.053	0.133 ± 0.026	< .001
P value	< .001	< .001	.001	

* There were no significant differences between Tests 1 and 2 (P = .088).

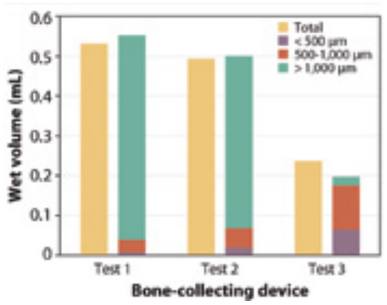


Fig 4 The measurement of wet volume (mL) of the bone particles from the three bone collecting devices.

Table 3 Dry volume (mL) of the bone particles collected from the three different bone collecting devices (mean ± standard deviation)

Particle size	Test 1	Test 2	Test 3	P value
Total	0.468 ± 0.081	0.406 ± 0.079*	0.119 ± 0.032	< .001
< 500 µm (SP)	0.006 ± 0.002	0.010 ± 0.006	0.044 ± 0.018	< .001
500–1,000 µm (MP)	0.040 ± 0.041	0.037 ± 0.013†	0.083 ± 0.024	< .001
> 1,000 µm (LP)	0.511 ± 0.080	0.415 ± 0.075	0.012 ± 0.004	< .001
≥ 500 µm (MP + LP)	0.551 ± 0.085	0.452 ± 0.081	0.094 ± 0.023	< .001
P value	< .001	< .001	.001	

*No significant differences between Tests 1 and 2 (P = .096).

†No significant differences between Tests 1 and 2 (P = .445).

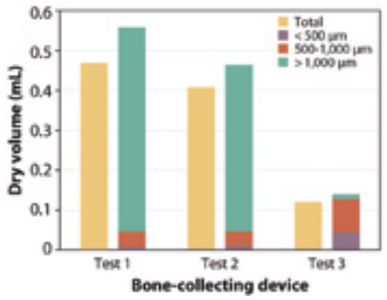
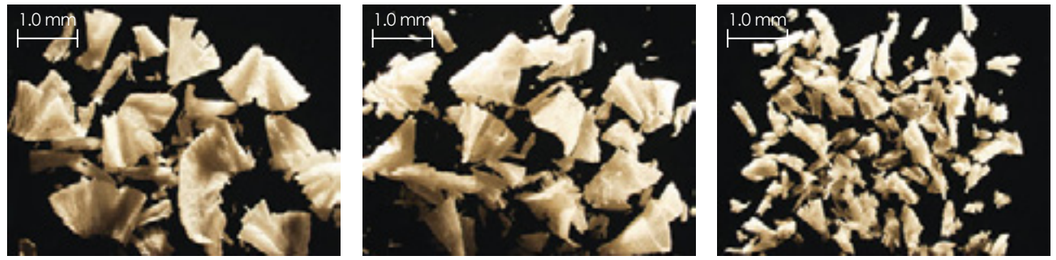


Fig 5 The measurement of dry volume (mL) of the bone particles from the three bone collecting devices.

Table 4 Total dry weight (mg) of bone particles collected from the three different bone collecting devices (mean ± standard deviation)

Particle size	Test 1	Test 2	Test 3	P value
Total dry weight	0.099 ± 0.020	0.082 ± 0.009*	0.046 ± 0.011	< .001

* No significant differences between Tests 1 and 2 (P = .052).



Figs 6a to 6c Microscopic views of bone particles (original magnification ×12.5): (a) Test 1; (b) Test 2; (c) Test 3.

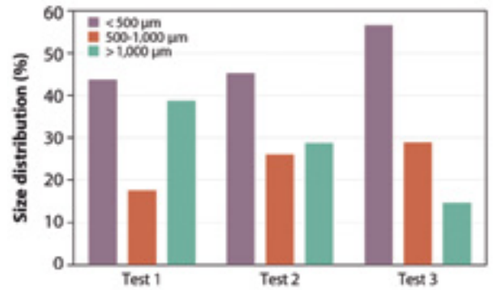


Fig 7 The size distribution of bone particles from three bone collecting devices.

have been reported. Small particles showed more rapid resorption, greater surface area, and enhanced osteogenesis compared with large particles.[19-22] Many studies have suggested particles of various size for grafting and bone regeneration.[20,23,24] Decalcified freezedried bone allografts (DFDBAs) ranging from 250 to 420µm showed better bone induction than DFDBA ranging from 1,000 to 2,000 µm.[25] However, other researchers have shown that bone particles ranging from 500 to 1,000 µm result in more new bone formation than larger particles after 4 weeks.[22,26-28] Based on these data, two types of particle-sized bone graft materials are available on the market: 250 to 1,000 µm, or > 1,000 µm.

Bone particles collected during implant site preparation have been studied. Characteristics of mesenchymal stem cells were found in stromal cells from bone chips during implant osteotomy.[29] The authors isolated human alveolar bone derived stromal cells from the bone chips. These cells were positive for early mesenchymal stem cell markers such as STRO-1 and CD146. The quality of the bone particle can be influenced by the drilling speed, drilling time, and the drill's shape. Jeong et al[18] studied the effect of implant drilling speed on the composition of the particles collected during site preparation with the Brånemark system drill. They used 1,500 rpm and 800 rpm speeds during the collection of the bone particles in the bovine mandible. The drilling speed did not affect the total volume and weight of the bone debris. However, drilling at 800 rpm produced a larger percentage of large particles (> 500 µm) than drilling at 1,500 rpm. In the present study, the amount of LP was greater in Tests 1 and 2 (300 rpm) than in Test 3 (200 rpm). Park et al[6] studied the effect of implant drill design on particle size and found that tapered- and stepped-shaped drills produced smaller bone particles than parallel- or tapered-shaped drills. They also reported that the group in which osteotomy was performed at 2,000 rpm had significantly more large particles (> 500 µm) than the group with osteotomy performed at 1,000 rpm. The authors suggested that other factors such as drill geometry had a larger influence on bone particle size than drilling speed. In their study, the parallel twisted drill was a more favorable design for collecting larger bone particles and a greater collectable quantity of bone than the tapered stepped-shaped drill. They also reported that drills with a large web and narrow flute produced more small particles and a lower amount of bone particles. In the present study, Test 3 collected fewer bone particles than Tests 1 and 2. The difference in drill design could explain this result. In clinical situations, Test 3 without using the stop during implant site preparation could collect acceptable amounts of bone particles without an additional donor site.

The donor site could be another factor affecting particle properties (Table 5). In the present study, the donor site was bovine mandible body with cortical bone thickness of approximately 5 mm. Because all three devices were mounted with a 4-mm stop, all collected bone particles were cortical bone. The cortical bone thickness in the human mandible is usually less than 4

Table 5 Measurement of bone thickness in the human mandible

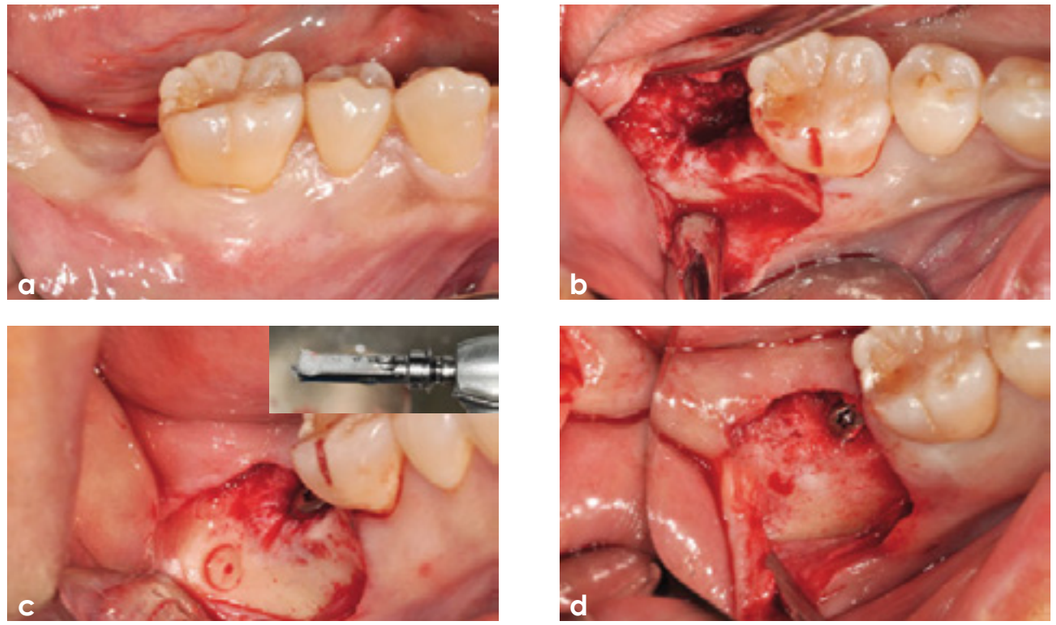
Study	Study design	Measurement	Measuring site		Value (mm)	Notes
Al-Jandan et al[30]	CBCT	Cortical bone thickness	Mandibular 1st molar		2.5 (1.6–3.5)	Root apex
			Mandibular 2nd molar		3.18 (2–5.25)	
Leong et al[31]	Cadaver (Boley gauge caliper)	Cortical bone thickness	Mandibular 1st molar		2.76 ± 0.62	NA
			Mandibular 2nd molar		2.81 ± 0.67	
			Mandibular 3rd molar		2.53 ± 0.65	
			Total		2.70 ± 0.15	
Park et al[32]	Cadaver sectioning and scanning	Cortical and cancellous bone thickness	Mandibular symphysis	Cortical bone	1.32–2.43	5 mm below the root apex: the internal margin of the inferior border of the mandible
				Cancellous bone	3.30–6.75	
Yates et al[33]	Cadaver	Cortico-cancellous bone thickness	Mandibular ramus		5.12 (4.69–5.60)	NA
			Mandibular symphysis		7.82 (7.37–8.30)	

* No significant differences between Tests 1 and 2 (P = .052).

mm.[30-33] Al-Jandan et al[30] evaluated the cortical bone thickness of the mandible using CBCT and reported that the mean thickness at the apex of the mandibular second molar was 3.18 mm. The labial cortical plate of the mid-mandibular symphyseal region was 1.26 to 2.31 mm thick and became thicker from the superior to the inferior region. In one cadaver study, the buccal bone of the mandibular molar area was 2.61 to 2.87 mm thick.[31] The amount of bone could have been smaller if cancellous bone had been collected along with the cortical bone in a clinical situation.

Several authors have recommended that an appropriate particle size is 250 to 1,000 µm.[20,22,24,25] In the present study, there were 0.544 mL, 0.483 mL, and 0.133 mL of > 500 µm-sized particles in Tests 1, 2, and 3, respectively. Savant et al[34] collected 0.195 mL of wet bone particles using a bone collector during single implant site preparation. Kainulainen et al[35] collected 0.09 to 0.12 mL of bone for a Straumann implant site preparation while Young et al[15] collected 0.054 g of bone for a Frialit-2 implant site. The volumes of bone particles collected during the present three types of implant drilling procedures were less than 0.13 mL in bovine rib bone (unpublished results). Although the devices used in the present study need additional surgical sites, the amount of collected bone was much larger than in other studies using implant drills. For clinically useful sizes (> 500 µm), Tests 1 and 2 collected 0.544 mL and 0.483 mL at one drilling, respectively. Because commercial bone graft material is usually approximately 0.5 mL or 1.0 mL, one or two uses of these devices could collect autogenous bone particles equivalent to commercially available bone graft materials (Fig 8). In addition, these devices allow safety by using a stop, and are free from the salivary contamination that is found with aspiration-collecting technique devices.

In clinical situations, many factors would differ from the conditions in the present study. First, the study used bovine mandible cortical bone. As previously described, cortical bone thickness is different in humans. In clinical situations, less bone could be collected in cases of thin cortical bone. Second, all collected particles had a wood shaving-like appearance. If large-sized particles are compressed during bone collecting or grafting, they could be broken into smallsized particles, which would decrease the volume of particles. Third, it is not easy to collect SP because most SP would be lost during saline irrigation.



Figs 8a to 8d Clinical picture of autogenous bone collection using Test 1. (a) Preoperative view. There is soft tissue depression at the position of the mandibular right second premolar. (b) After flap reflection, the alveolar socket is not fully filled with new bone. (c) Autogenous bone was collected from the mandibular buccal shelf using Test 1 (diameter 4 mm; inset). (d) Three months later cortical bone had almost been regenerated with new bone (circle).

CONCLUSION

In this in vitro study, three different types of autogenous bone harvesting drills were compared with regards to the characteristics of the bone particle collected. Three innovative bone collecting devices could collect sufficient amounts of bone particle to use clinically, and enough to provide an alternative to the use of commercially available bone graft materials.

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Peri-implantitis

Surgical Treatment of Severe Peri-Implantitis Using a Round Titanium Brush for Implant Surface Decontamination : A Case Report With Clinical Reentry

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The most common cause of peri-implantitis is the accumulation of plaque and the formation of a biofilm on the implant surface. Terminating the development of the disease requires the biofilm to be removed from the implant surface. This paper describes 2 cases of severe peri-implantitis lesions treated through surgical approaches. Complete mechanical debridement with a round titanium brush was mainly performed to detoxify and modify the affected implant surface. A regenerative approach was then performed. In both cases, the surgical procedure was effective in arresting the peri-implantitis, and clinical reentry revealed uneventful healing of the existing bone defect. No further radiographic bone loss was observed over the 2-year follow-up period. This technique has the advantage of effective cleaning the contaminated implant surface, producing positive clinical and radiological results. However, further studies involving more cases are necessary to verify the reliability and validity of this technique.

Key words:

debridement, dental implant, peri-implant disease, regeneration

Introduction

Peri-implantitis is an irreversible inflammatory disease that affects both the soft and hard tissues of a dental implant; if left untreated, it will result in implant failure in most instances.[1,2] There have been wide variations in the previously reported prevalence rates of peri-implantitis, due to the use of different study designs and limited patient populations.[3,4] In a recent systematic review, Derks et al.[5] found that peri-implantitis was present at 14–30% of implant sites.

The most common cause of peri-implantitis is the accumulation of dental plaque and formation of a bacterial biofilm on the implant surface.[6–8] Terminating the development of the disease requires removing the bacterial biofilm from the implant surface. Various conservative and surgical therapies have been introduced for decontaminating the implant surface.[9–13]

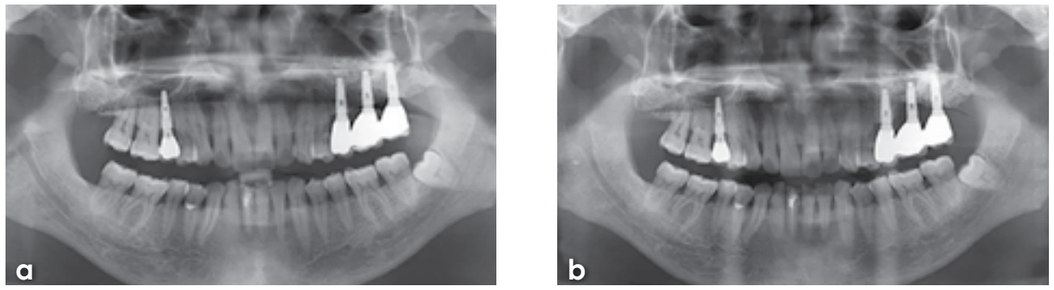


FIGURE 1. (a) Panoramic view after delivering the prosthesis in 2006. (b) Seven years later, reoperative radiograph showing a severe vertical peri-implant defect around the implant positioned at the maxillary left first molar.

Although conservative therapies that include the use of metallic curettes with an adjunct of local or systematic antibiotics, and laser and ultrasonic devices have been effective in removing the bacterial biofilm from the surface of an implant, difficulties with access and visibility impeded the thorough debridement in cases with moderate or severe infection.[14]

Surgical approaches are commonly more appropriate and suitable for the thorough decontamination of moderate or severe peri-implantitis. Several decontamination protocols have been presented in the literature. In a prospective human study, Roos-Jansa°ker et al.[15] reported that bone fill using a bone substitute with or without a resorbable collagen membrane could arrest disease progress for 3 years after decontamination. In an ongoing randomized clinical trial, Wohlfahrt et al.[16] described a regenerative protocol incorporating open-flap debridement of the implant surface, decontamination using 24% EDTA gel, grafting with

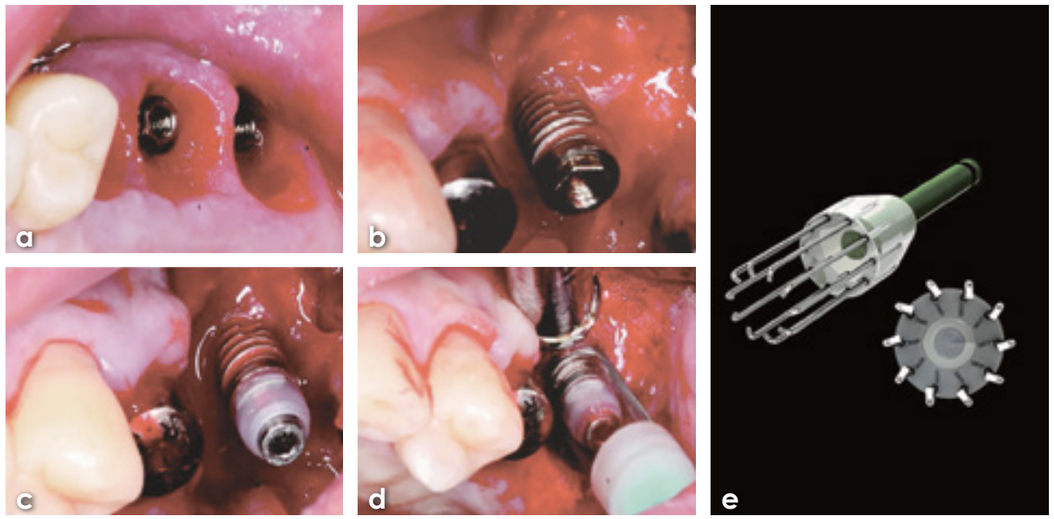


FIGURE 2. (a) Intraoral view after removing the prosthesis. (b) After opening the flap, a large vertical defect without buccolingual bony walls was seen. (c) A protective cap was attached to protect the implant platform. (d) A round titanium brush with titanium alloy bristles (RBrush) was used to decontaminate the implant surface at a rotation speed of about 8000 rpm for 30 sec per thread. (e) Three-dimensional view of the R-Brush instrument.

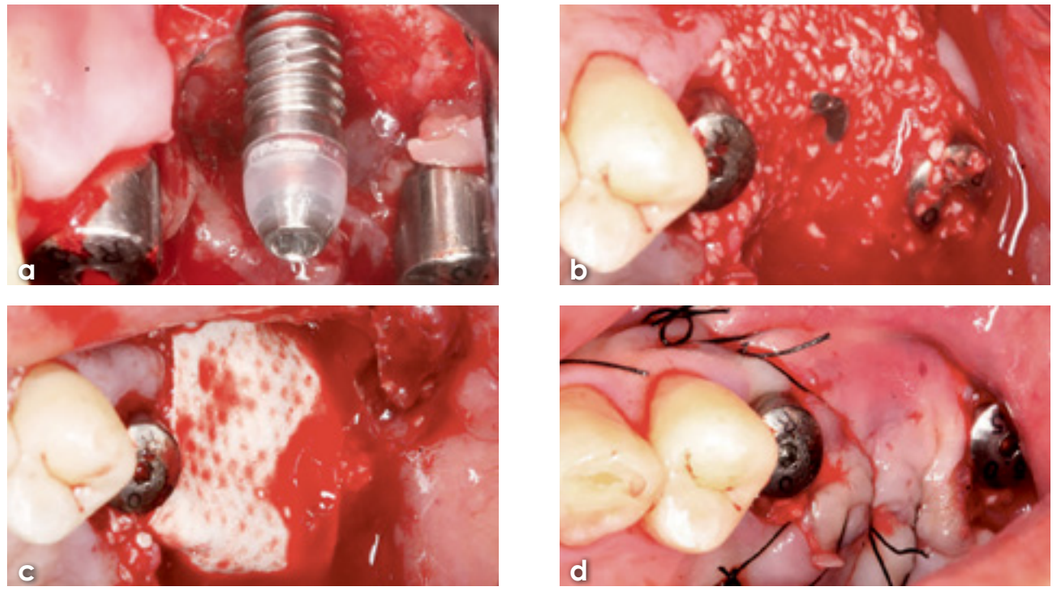


FIGURE 3. (a) The implant surface looked smooth and clean after debridement with the R-Brush. The original rough surface was removed and created by a new surface. (b) The bone defect area was filled with freeze-dried allograft bone. (c) The grafting material was covered by a protective collagen membrane. (d) Primary wound closure was achieved using interrupted sutures.

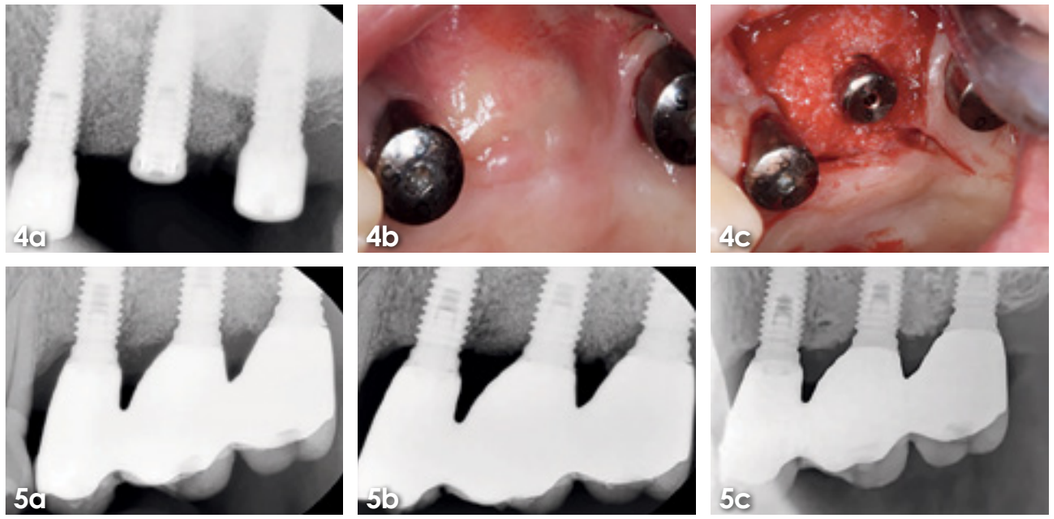
porous titanium granules, and resubmersion of the implant, proving effective during a 12-month follow-up period. However, there is currently limited evidence of the effective of these surgical procedures.[17]

A round titanium brush comprising titanium alloy bristles (R-Brush, NeoBiotech, Seoul, Korea) was recently developed for detoxifying and modifying an implant surface contaminated with severe peri-implantitis. The instrument can be used for bone defects of class Ie (circular bone resorption while under maintaining the buccal and lingual bone) or class II (supracrestal defect).[18] The R-Brush for treating peri-implantitis was found to be easier, faster, and more effective than any other conventional instrument.

The purpose of the present case report was to describe the surgical procedure for treating severe peri-implantitis with a regenerative approach, focusing on decontamination of the implant surface using the R-Brush.

CASE 1

A 52-year-old male patient was referred to a local clinic in March 2014. His chief compliant was a dull aching pain from an implant in the maxillary posterior region. The patient initially received implant treatment in July 2006. Three externalconnection implants were placed and then fixed using a screw-retained prosthetic restoration from the maxillary left second premolar through to the maxillary left second molar (Figure 1a). All 3 implants had a diameter and length of 4.0 and 13 mm, respectively. The patient had a bone density of D3[19] at the implant positions. The 3 fixtures were inserted with good primary stability: implant stability quotients of 40, 60, and 55. However, the patient had not been followed up after the pros-



FIGURES 4 AND 5. FIGURE 4. (a) Periapical radiograph obtained at 5 months after surgery. (b) Clinical view at 5 months after surgery. (c) Clinical view at reentry showing the formation of solid bone in the original bone defect. **FIGURE 5.** (a) Periapical radiograph obtained at 6 months showing that the bone density had increased. (b) Periapical radiograph obtained at 12 months, showing a stable alveolar bone height without any bone resorption. (c) Periapical radiograph obtained 2 years after surgery. No further radiographic bone loss was observed.

thetic restorations were delivered. The implant had been in function at least for 7 years. Clinically, no swelling, purulence, or mobility was recorded in any of the implants, but a probing depth of 10.0 mm was found in the implant positioned at the maxillary left first molar. A radiographic examination showed a crater defect at this implant position (Figure 1b). No bone loss was observed in the 2 neighboring implants.

Surgical procedure

To access the bone defect and allow mechanical debridement of the infected implant surface, the 3-unit prosthesis was removed (Figure 2a). Surgery was performed under local anesthesia (1:100 000 epinephrine), and a mucoperiosteal flap was reflected buccally in the implant positioned at the maxillary left first molar. The 8 threads of the fixture were exposed by removing a large formation of granulation tissue (Figure 2b), and then a protective cap was attached over the implant platform (Figure 2c). An R-Brush connected to a low-speed handpiece was used at a rotation speed of about 8000 rpm for 30 sec per thread to not only eliminate the old implant surface but create a new rough surface. Thorough irrigation with physiological sterile saline from a monojet syringe was also applied during preparation for diluting the microbial species in the defect and reducing the heat generated by metal friction (Figure 2d and e).

It took about 4 minutes to treat the 8 exposed threads with the R-Brush. The treated surface was thoroughly examined with a magnifying glass to detect any untreated area (Figure 3a). After a final rinsing, a cover screw was placed and the defect was grafted with freeze-dried allograft (Regenoss, Cellumed, Seoul, Korea), and a resorbable collagen membrane (Genoss, Seoul, Korea) was placed over the grafting material to protect it from penetration by the surrounding soft tissue cells. To achieve primary wound closure, the flap was repositioned with a vertical releasing incision and sutured with a 4-0 monofilament suture material (REXLON Supramid, SM Eng, Busan, Korea; Figure 3b through d). The patient received antibiotic therapy (500 mg of amoxicillin 3 times daily) for 7 days. The patient was also advised not to brush the surgical site and to rinse with 0.12% chlorhexidine solution for 2 weeks to prevent postsurgical infection caused by plaque accumulation.

RESULTS

The sutures were removed 14 days after the surgery. The implant remained without a prosthetic restoration for a 5-month healing period. Maintenance was performed at 3, 6, and 12 months. The patient did not report complaint or discomfort. At a 5-month check-up, a clinical examination revealed uneventful healing of the surgical site (Figure 4b). At reentry 5 months after the treatment, although a part of 1 thread was exposed on the buccal aspect of the implant, solid abundant bone was regener-

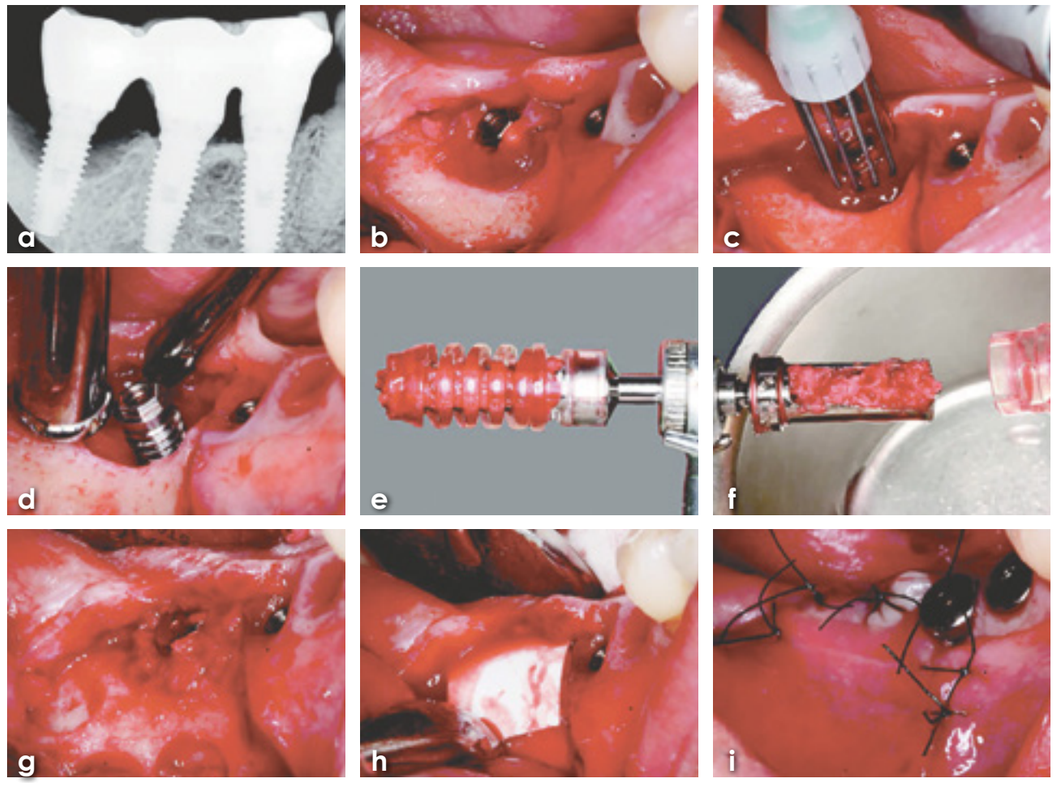


FIGURE 6. (a) Preoperative radiograph showing a crater defect around the implant positioned at the mandibular right second molar. (b) Granulation tissue around the implant was removed after opening the flap. (c) Debridement of the implant surface using the R-Brush. (d) View after debridement. (e) Utilization of a bone harvesting drill to harvest autogenous chip bone. (f) Autogeous chip bone harvested from the buccal shelf area of the second and third molars of the mandibular body. (g) Harvested autogenous bone was grafted into the defect. (h) The grafting material was covered by a resorbable collagen membrane. (i) Primary closure with interrupted sutures.

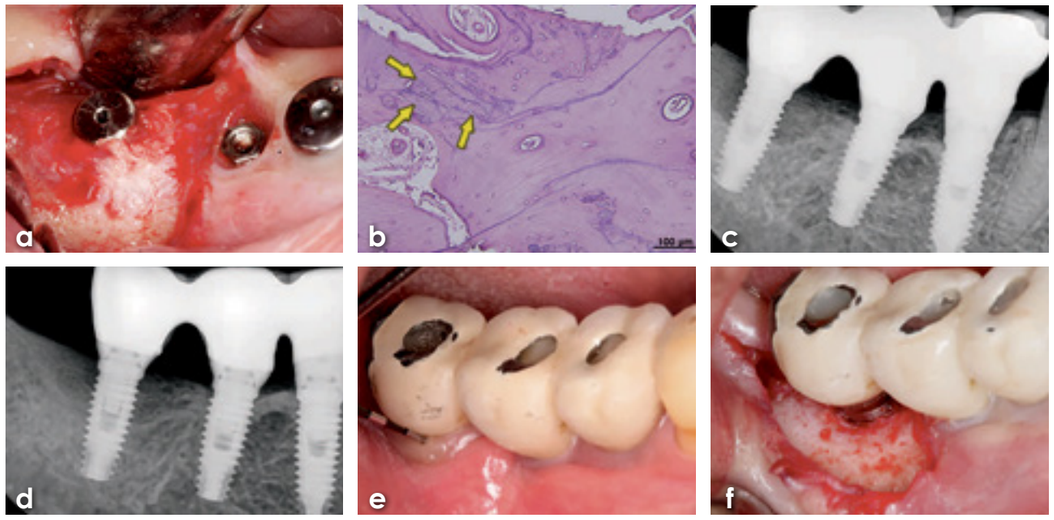


FIGURE 7. (a) Clinical view at reentry after surgery showing solid and newly formed bone over the cover screw. (b) Biopsy sample obtained from the grafted site (hematoxylin and eosin stain,320). The large piece of compact bone showed the new bone attached to the grafted autogenous bone (yellow arrows). This lesion was competent with favorable bony remodeling. (c) Periapical radiograph after the uncovering procedure and delivery of the prosthesis. (d) Periapical radiograph obtained at 24 months after the debridement surgery. (e) At the 24-month follow-up there was a probing depth of 3 mm on the buccal aspect. (f) The newly formed bone around the implant remained stable at the 24-month reentry.

ated, and a periapical radiograph showed that the boundary between the graft and the existing bone was unclear (Figure 4a and c). The final prosthetic restoration was placed again at 5 months after the bone graft surgery. Figure 5a through c show the periapical views at 6, 12, and 24 months after surgery, respectively, indicating that the bone density increased gradually and that no further bone resorption was observed mesially and distally for 2 years.

CASE 2

A 54-year-old male patient presented at a local clinic in January 2014. His chief complaint was food impaction at an implant in the mandibular posterior region. The 3 implants had been inserted 7 years previously in another clinic. A radiographic examination showed a crater defect at the implant positioned at the mandibular right second molar (Figure 6a). Clinically, the implant was stable, but there was a probing depth of 7.0 mm with gingival redness and swelling observed.

Surgical procedure

Surgical treatment was applied, comprising reflection of a mucoperiosteal flap, removal of granulation tissue, debridement with an R-Brush, and irrigation with saline (Figure 6 through d). After these surgical steps, a 6-mm–diameter bone harvesting drill (ACM, Auto Chip Maker, NeoBiotech) with a rotation speed of 50–70 rpm was used without saline irrigation to harvest fresh, bloody autogenous bone chips from the cortical bone of the adjacent buccal shelf area (Figure 6e and f). After drilling 3 times, approximately 1 cc of autogenous bone chips was collected, and bone was subsequently grafted into the defect, which was covered by a resorbable collagen membrane (CollaGuide, Bioland, Cheonan, Korea) and mucoperiosteal flap in stepwise fashion. Primary wound closure was achieved with interrupted sutures (Figure 6g through i). After the surgery, the patient received antibiotic therapy for 7 days and was informed about important postoperative protocols.

RESULTS

Uncovery surgery was performed 3 months after the debridement surgery. A clinical examination revealed entire regeneration of the defect site. D2-like cortical bone was detected, and bone grown over the cover screw was harvested as a biopsy sample (Figure 7a). Histological results revealed the deposition of new bone onto the grafted autogenous bone (Figure 7b). The prosthetic restoration was delivered immediately after the uncovery procedure (Figure 7c). The patient was followed up at 3, 6, 12, and 24 months postoperatively, and a gradual increase of radiographic bone density was observed. Figure 7d shows a periapical view at 24 months after surgery. A clinical examination performed at the 24-month follow-up revealed a probing depth of 3 mm on the buccal aspect (Figure 7e). An additional re-entry revealed that the well-matured regenerated bone around the implant had remained stable, and no bone loss and no soft tissue engagement between the implant surface and the bone was detected (Figure 7f).

DISCUSSION

The current treatment methods for peri-implantitis are based on the methods used to treat natural teeth with periodontal disease.[20] Several surgical approaches are used to treat periimplantitis. However, although these methods are universally applied, there is still no strong consensus or recognized treatment method for completely eradicating peri-implantitis.[21] The present case study applied mechanical decontamination combined with sterile saline to treat the contaminated surface of implants, with the results indicating that utilization of an RBrush was highly effective at removing dental plaque and biofilm from the implant surface. Furthermore, this technique has been developed to eliminate the contaminated original rough surface and create a new rough surface. Figure 8a through c show the difference of the surfaces between beforeand-after treatments with the R-Brush. It has been confirmed that open debridement may result in re-osseointegration, and this integration is more pronounced on rougher implant surface.[22] To date, there is no literature describing the treatment of severe peri-implantitis using such

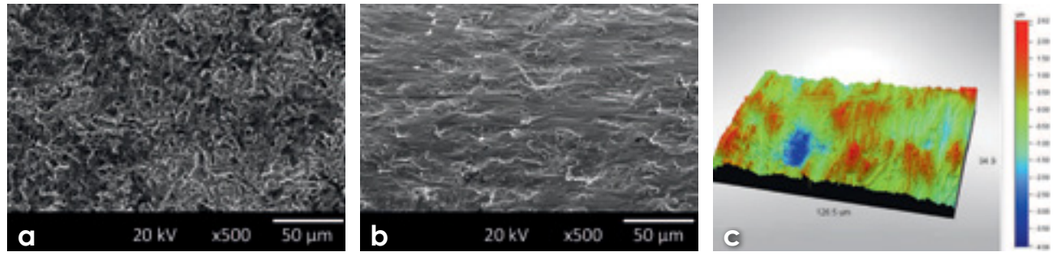


FIGURE 8. (a) SEM image before R-Brushing (magnification, 3500). (b) SEM image after R-Brushing (magnification, 3500). (c) 3D surface display after R-Brushing.

a protocol. However, due to the small number of cases considered, the efficacy of the described method needs further investigation in animal studies or other clinical trials, ideally leading to a predictable and reliable method of treating peri-implantitis and an understanding its effects on the healing process.

Several studies have shown that re-osseointegration can occur on surfaces previously contaminated by dental plaque and surrounded by a bone defect. The results obtained in the present case study were consistent with these previous studies.[22–24] However, in those studies, induced peri-implantitis artificially in animal models and the partial implant surface was exposed in the oral environment for a period of time, with the bone defect produced mechanically by a drill when preparing the implant sites. It should be noted that the microbial species populating the implant surface could differ from those for an implant located in the human oral environment.

In the present case study, after debridement with an R-Brush, a regenerative approach was applied with autogenous bone or allograft bone. In such circumstances, the geometry of the bone defect critically affects the clinical outcome.[25] A bone defect characterized by circular bone resorption with the buccal and lingual bone plates preserved has provided a more predictable and effective outcome following the regenerative approach. In this second case, the bone defects were all craterlike defects with preserved circular bone plates. The patients were followed up at 3, 6, 12, and 24 months. Periapical radiographs revealed that the alveolar bone height was stable, and no bone resorption could be observed mesially and distally. However, in the first case in this study, the defect was quite large, and there was no bony wall buccolingually. Surprisingly, this case showed an acceptable vertical bone augmentation (6 mm) and 2-year maintenance without further bone loss and any peri-implant radiolucency. This means that re-osseointegration might be obtained in the grafted implant surface. This result shows that re-osseointegration could be established if the contaminated surface is totally detoxified and decontaminated.

The aim of implantoplasty is to produce a smooth and polished implant surface, thereby reducing the amount of dental plaque that attaches to it as well as remove the implant threads, providing a less attractive environment to bacteria.[14,26] However, the obvious disadvantage of this technique is that any further re-osseointegration is considered unpredictable. In contrast to implantoplasty, decontamination with an R-Brush can produce a well-distributed and rough surface, and moreover preserve the implant threads; this makes the success of the regenerative approach more predictable. Another advantage of this technique is that decontamination with an R-Brush not only reduces chair time for the clinician but also reduces muscle fatigue in the patient associated with prolonged opening of the mouth.

The release of titanium particles from implant fixtures placed onto the peri-implant bone during preparation of the implant bed has been reported. The number of particles were correlated with the roughness of the implant and its topographical configuration.[27,28] Previous studies have shown that the released titanium particle debris is mainly concentrated at the crestal parts of the bone in contrast to apical areas. Debris amounts reaching 0.2–3.0 mg may induce peri-implant osteolysis, which manifests as early marginal bone loss around the implant.[27,29] In an animal study, Schliephake et al.[30] reported that loose particles attached to the surface of the bone could be pressed into the bone microenvironment and that intense rinsing of the implant site would still not remove all titanium particles from the bone surface. In the present study, contaminated implant surfaces were debrided using an R-brush and, after thorough irrigation, a regenerative approach was applied with autogenous or allograft bone. No bone loss was observed during a 2-year follow-up period. Thus, the direct effect of particle debris on peri-implant bone has not been clearly defined. In this case, mechanical debridement plus saline irrigation appears to have been useful in reducing titanium concentration so that reosseointegration was possibly achieved and no bone loss occurred in the early phase. However, further investigation of the titanium particles deposited on the periimplant bone after debridement may contribute to the recognition of a biological effect.

CONCLUSION

The results obtained in the present 2 cases emphasize the importance of mechanical decontamination by eliminating the contaminated surface and creating a new rough surface for a regenerative approach in the treatment of severe periimplantitis. This technique has the advantages of effective cleaning of the contaminated implant surface and producing positive clinical and radiological results during the 2-year follow-up period. However, further studies are necessary to verify the reliability and validity of this technique.

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NOTE

The authors report no conflicts of interest.

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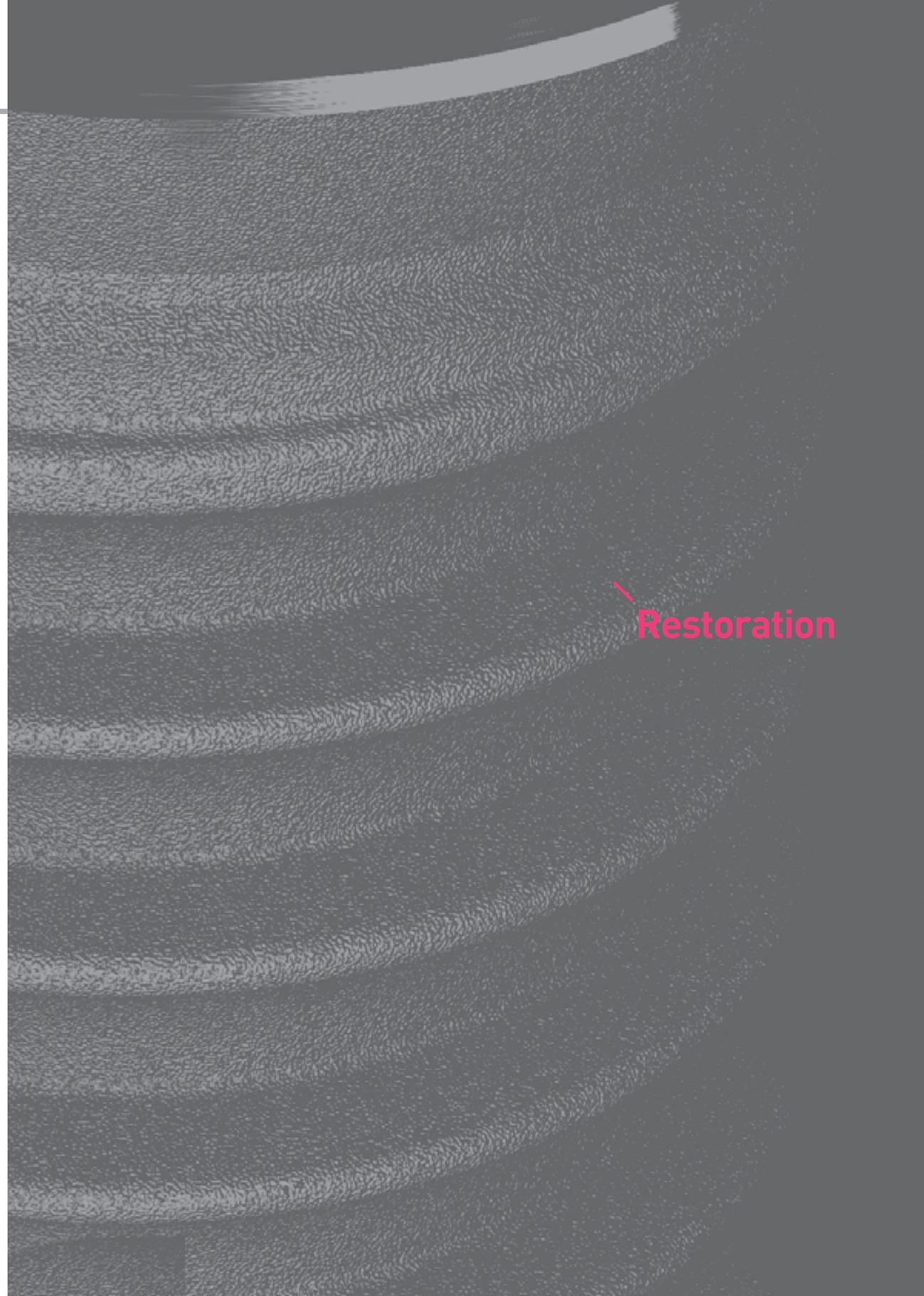

A Newly Designed Screw- and Cement-Retained Prosthesis and Its Abutments

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The degree of misfit between a prosthesis and its supporting implants is a major concern in screw-retained prostheses because it can lead to screw loosening or mechanical failure of implant components. On the other hand, the difficulty of removing subgingival excess cement and the irretrievability of the superstructure are major drawbacks to cement-retained prostheses. A newly designed screw- and cement-retained prosthesis (SCRP) may solve these problems with its passivity, retrievability, and ease in the complete removal of excess cement, giving it the advantages of both screw-retained and cement-retained prostheses. This prosthetic system is mainly composed of a cement-retained framework with screw holes on the occlusal surface and specially designed cementable abutments for multiunit prostheses. The principle and structure of the SCRP system is described in this article.

One of the key factors for the long-term success of implant treatment is the passivity of fit between the superstructure and the implants.[1] However, in a clinical situation, it is almost impossible to achieve a completely passive fit of the prosthetic framework to the implant abutments, especially in multiple splinted implant restorations.[2] For retention, implant-supported fixed prostheses can be either screw- or cement-retained. One advantage of the cement-retained approach is the ability to compensate for minor discrepancies between the superstructure and the abutment by filling the space with cement.[3] While the screw-retained approach requires a high degree of precision, a cement-retained prosthesis can obtain a passive fit with relatively simple clinical and laboratory procedures. Despite these benefits of cement-retained implant prostheses, their disadvantages include irretrievability, the difficulty of removing the cement surplus in the subgingival sulcus, and a lack of retention with a short abutment in areas with insufficient interocclusal space.[3]

Previous studies have attempted to overcome these problems with single- and multiunit fixed implant restorations. The KAL technique by Voitik[4] and a technique for multiunit implant-supported prostheses by Jiménez and Torroba[5] compensate for the misfit of the superstructure by using cements for fixation of the framework to obtain a passive fit of the prosthesis. In addition, Rajan and Gunaseelan[6] introduced a retrievable cement- and screw-retained implant-supported crown, but this approach is limited to single-tooth replacement.

The present article introduces a new method for fabricating a screw- and cement-retained multiunit implant-supported prosthesis to overcome the disadvantages of both types of prostheses.

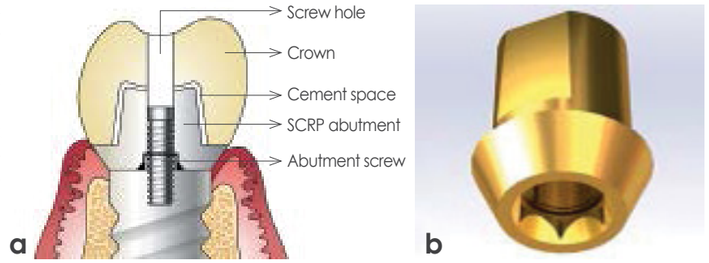

Fig 1 The components of the SCRP system. (a) SCRP is composed of specially designed abutments (SCRP abutments) and a cement-retained prosthesis with the screw holes on the occlusal surfaces. (b) This abutment has both hex and nonhex configurations, which satisfies two functions, repositioning of abutment and retrievability of SCRP.

Fig 2 Retrieved SCRP prosthesis. The abutment-superstructure unit can be removed from the mouth after cementation by unscrewing the abutment screws through the holes. The excess cement around the abutments and any ill-fitting crown margins can also be removed and polished extraorally.

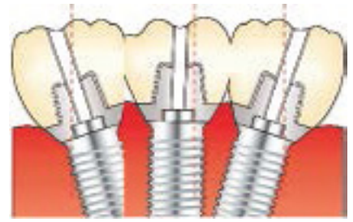

Fig 3 Conventional cementable abutments with hex connections: For conventional cementable abutments that possess a totally hex-type engagement, the prosthesis-abutment unit cannot be retrieved from the implants because of undercuts created from the hex parts of the nonparallel implants.

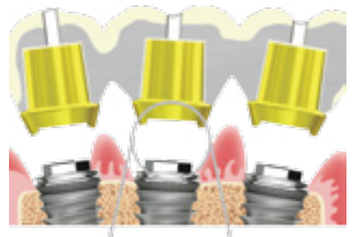

Fig 4 Schematic image of retrievable multiunit SCRP. Even for the angled implants, any multiunit SCRP can be retrieved due to the nonhex part of the abutments, which are designed to compensate for most of undercuts created from the path of insertion.

The Principle and Structure of Screw- and Cement-Retained Prostheses

A screw- and cement-retained multiunit implantsupported prosthesis (SCRP) is a new concept for an implant restorative system and incorporates the advantages of both the screw- and cement-retained approaches. The prostheses of the SCRP system have achieved not only a passive fit through using a cement, but also retrievability, if needed, through the screw holes on the occlusal surfaces. The SCRP system is composed of specially designed abutments and a cement-retained prosthesis with the screw holes on the occlusal surfaces (Fig 1). After the prepared abutments are repositioned individually by their hex part and attached to the implants, the prosthesis is cemented over the abutments with a definitive cement. The abutment-superstructure unit is removed from the mouth by unscrewing the abutment screws through the holes (Fig 2). A clinician can then remove the excess cement around the abutments and polish any ill-fitting crown margins

extraorally. The finished one-piece prosthesis is a passively fitting screwretained prosthesis.

SCRP Abutment

Conventional cementable abutments with external hex connections can be used for both single- and multiunit implant restorations when implants are placed in parallel. However, hex abutments on nonparallel implants are not retrievable because of the undercuts created between the angled implants. Nonhex abutments should be used in such cases, but they cannot be repositioned after preparation without a repositioning jig. Nonhex abutments, however, sometimes cannot be repositioned if the jig is not fit precisely or if the seating is disturbed by the surrounding gingiva.

A specially designed prepared abutment called an SCRP abutment (Fig 1) is unique in having both hex and nonhex components in one cementable abutment. The lower half of the hex portion has a nonhex figure. The upper hex (engaging) portion of the abutment is designed to allow for each prepared abutment to be reconnected to its corresponding implant without a repositioning jig in the mouth. The lower nonhex portion is designed for retrievability of the SCRP after cementing the multiunit superstructure to the abutments intraorally. Unlike conventional hex abutments, the SCRP abutments allow the entire superstructure to be retrieved even if the implants are not parallel (Figs 3 and 4). This is possible because of the special structural design of the SCRP abutment, which provides spaces to compensate for the undercuts created between the hex parts of the nonparallel implants.

The Clinical Pros and Cons of SCRP

With the SCRP system, the prosthetic superstructure is retained with any definitive resin cement, which can compensate for minor discrepancies created during fabrication processes. As a result, it is possible to achieve a passive fit even in long-span prostheses without cutting and soldering. The prosthesis of the SCRP system is retrievable after permanent cementation, so a clinician can unscrew and retighten the entire superstructure as needed for repair, maintenance, or the removal of excess cement extraorally. Furthermore, this retrievability makes it possible to use a definitive cement instead of a temporary cement. Lastly, in cases with a limited interarch distance, a longer abutment with a deep subgingival margin can be used because it can be retrieved for extraoral cleaning and repair.

As with conventional screw-retained prostheses, the presence of screw holes on the occlusal surface can affect the stable occlusion and esthetic component of the SCRP prosthesis. Since the SCRP is cement-retained, cement washout is inevitable in the long term even if a definitive cement is used. Therefore, it is critical for the success of the SCRP system to establish the maximum retention form of the abutment and select a definitive cement with a high strength.

Conclusions

The SCRP system is a new concept for an implant restorative system that can easily obtain a passive fit and retrievability. The SCRP abutment with both hex and nonhex components in one allows repositioning of the abutment and retrievability of the prosthesis. The SCRP system simplifies implant treatment procedures and eliminates the difficulty of removing excess cement.

Acknowledgments

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Literature Abstract

Does Ridge Preservation Following Tooth Extraction Improve Implant Treatment Outcomes: A Systematic Review.
Group 4: Therapeutic Concepts and Methods

This systematic review and meta-analysis (1) investigated the additional effect of alveolar ridge preservation (ARP) on implant-related outcomes in comparison with unassisted socket healing and (2) estimated the size effects according to the type of intervention for ARP. General inclusion and exclusion criteria were explained in detail. Ten randomized controlled trials (RCTs) and controlled clinical trials (CCTs) and 30 RCTs and CCTs and prospective case series were included in the study for each respective aspect of the proposed aim. The authors found that ARP procedures may decrease the need for further ridge augmentation during implant placement (pooled relative risk for further ridge augmentation was 0.150) but did not increase the feasibility of implant placement. The survival and success rates and marginal bone levels of implants placed in alveolar ridges following ARP are comparable to those of implants placed in untreated sockets. Different types of ARP intervention (GBR, socket filler, and socket seal) did not show superior impact on implant outcomes. The authors mentioned that the majority of included studies were qualified for high risk of bias.

Mardas N, Trullenque-Eriksson A, MacBeth N, Donos N. Clin Oral Implants Res 2015;26(suppl 11):180–201. References: 63.
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Effects of Implant Angulation and Impression Coping Type on the Dimensional Accuracy of Impressions

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PURPOSE:

To analyze the accuracy of impressions in relation to implant angulation and type of impression coping.

MATERIALS AND METHODS:

Three metal master models with 2 implants of 3 different angulations (parallel, mesiodistal, and buccolingual) were fabricated. Nine groups of experimental models were fabricated to duplicate the 3 master models using 3 types of impression copings: transfer, pick-up, and hybrid. The distance between the analogs for each model was measured using a video measuring system. The influence of angulation and type of impression coping was analyzed by a two-way ANOVA (P , 0.05).

RESULTS:

There were significant differences in error rates in relation to implant angulation and type of impression coping (P , 0.05). Impressions of buccolingually divergent implants with transfer copings showed statistically higher error rates than other groups (P , 0.05).

CONCLUSIONS:

Buccolingual divergence can be a variable that influences the impression accuracy of transfer copings compared with pick-up and hybrid copings. Hybrid copings demonstrate reasonable reproducibility similar to that of pick-up copings. (Implant Dent 2015;24:726–729)

Key Words:

transfer, pick-up, divergence

Accurate impression taking is one of the challenging procedures in implant dentistry because it provides the opportunity to produce an implant restoration with a passive fit,[1] which is related to the long-term success of the implant treatment.[2] The accuracy of impressions is affected by the impression material, impression technique, angulation of implants, and implant impression components.[3,4]

Most studies analyzing the effects of implant angulation on multiple-unit implant impression accuracy have used2 implants. In the majority of these studies, implant angulation significantly influenced reproducibility at 20 to 25 degrees, but no statistically significant differences were reported at 5 to 15 degrees angulations.[5–7] Most of the previous studies have modified the degree of angulation to simulate mesiodistally angulated implants, although implants with buccolingual angulations are also observed in clinical situations. Moreover, there are few studies comparing the differences of impression accuracy between mesiodistal and buccolingual divergence of the same angulation.

As for the implant impression components, most studies have analyzed the difference between 2 types of impression copings: pick-up and transfer. Although there were no consistent results, the majority of these studies demonstrated that the pick-up type seemed to have better reproducibility than the transfer type, especially where a larger number of implants were involved.[8–10] However, the transfer impression coping has also been used frequently in clinics because of its convenience of use. When sufficient space for access to use the open tray technique is not available, the transfer impression coping can be the only option for impression taking. Recently, the hybrid impression coping designed to offer the advantages of both types of impression copings, the accuracy of the pick-up and the convenience of the transfer type, was introduced. However, there are no studies investigating the reproducibility of the hybrid impression coping.

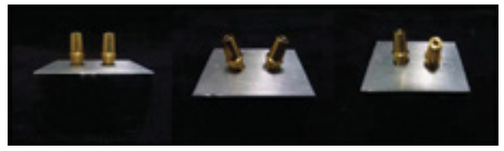


Fig 1. Three Metal master models were fabricated using the CAD-CAM system. Two implants with different angulations were installed in the master models including parallel, 15 degree mesiodistal divergence, and 15 degree buccolingual divergence.

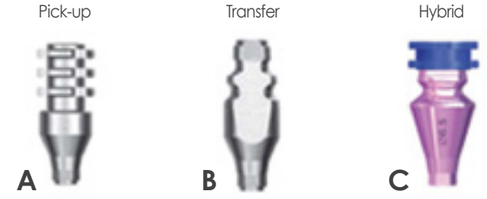


Fig 2. The 3 different types of impression copings used in this study. Hybrid coping is composed of a plastic coping that remains within the impression body, and a metal component that remains on the implant after impression taking. A, Pick-up, (B) transfer, and (C) hybrid.

The purpose of this study was to compare the accuracy of impressions in relation to the angulation between implants (parallel, mesiodistal divergence, and buccolingual divergence) and the type of impression coping (pick-up, transfer, and hybrid).

MATERIALS AND METHODS

Master Models

Three metal master models (length: 30 mm, width: 20 mm, height: 15 mm) with 2 holes of 9-mm depth at 10-mm intervals were fabricated using the Computer Aided Design-Computer Aided Manufacturing system. Three different

angulations between the holes (parallel, 15 degree mesiodistal divergence, and 15 degree buccolingual divergence) were established in each master cast (Fig. 1). Implant laboratory analogs were positioned into the holes using resin cement (G-CEM LinkAce; GC Corporation, Tokyo, Japan).

Experimental Models

Ninety experimental models were fabricated with 3 different types of impression copings including pick-up (Neobiotech Corporation, Seoul, Korea), transfer (Neobiotech Corporation), and hybrid (Pick-cap; Neobiotech Corporation) for duplicating the 3 master models with 3 different angulations between the holes (Table 1, Fig. 2). The open tray method was used for pick-up coping impressions, and the closed tray method was used for transfer and hybrid coping impressions. The impression coping was fixed to the metal master cast, and the impression was taken using light body and heavy body impression materials (Imprint III; 3M ESPE, Saint Paul,MN). After 8 minutes, for complete setting of the impression material, the impression body was separated from the master cast. The impression-coping analog assembly was then prepared on the impression body for fabricating the models as per the manufacturer's instructions. Type IV dental stone (GC Fujirock; GC Corporation, Leuven, Belgium) was poured into the impression, and the tray was separated from themodel after the setting of the stone.

Measurement of Distance

The distance between the analogs of the models was measured using a video measuring system (Optical video measuring system; Seven Ocean Technology, Dongguan city, China) following installation of the abutments on the analogs. The distance between the centers of the 2 abutments was measured, and all measurements were performed by a single trained examiner using the double blind method. The error rate was calculated using the following formula:

Distance (mastermodel) − Distance (experimental model)/Distance (master model) × 100 (%).

Table 1. The Design of the Study

Impression Coping/ Angulation	Parallel	Mesiodistal	Buccolingual
Pick-up	P-p (N = 10)	P-m (N = 10)	P-b (N = 10)
Transfer	T-p (N = 10)	T-m (N = 10)	T-b (N = 10)
Hybrid	H-p (N = 10)	H-m (N = 10)	H-b (N = 10)

Ninety experimental models were fabricated with 3 different types of impression copings including pick-up, transfer, and hybrid, for duplicating the 3 master models with 3 different angulations between the holes.

Table 2. Mean Distances Between Abutments and Their Standard Deviations

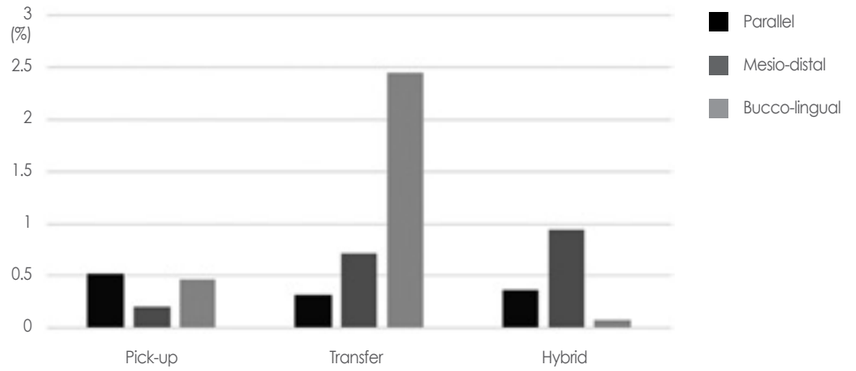
Impression Coping	Angulation	Mean Difference (mm)	Standard Deviation
Pick-up	Parallel	10.62	0.11
	Mesiodistal	15.14	0.13
	Buccolingual	11.62	0.17
Transfer	Parallel	10.61	0.13
	Mesiodistal	15.24	0.14
	Buccolingual	11.85	0.23
Hybrid	Parallel	10.61	0.12
	Mesiodistal	16.06	0.07
	Buccolingual	11.65	0.16

The error rate was calculated using following formula: Distance (master model) - Distance (experimental model)/Distance (master model) 3 100 (%).

Table 3. Mean Differences Between the Master and Experimental Models and the Error Rates

Impression Coping	Angulation	Mean Difference	Error Rate
Pick-up	Parallel	-0.034	0.52*
	Mesiodistal	0.022	0.20*
	Buccolingual	0.036	0.47*
Transfer	Parallel	-0.021	0.32*
	Mesiodistal	-0.080	0.72*
	Buccolingual	-0.188	2.45†
Hybrid	Parallel	-0.024	0.36*
	Mesiodistal	0.105	0.94*
	Buccolingual	0.006	0.08*

The error rates for the buccolingual angulation with the transfer impression coping showed statistically higher than others (P , 0.05).
*It did not show any statistically significant difference (P . 0.05).
†Stastically significant differences with other groups.



Statistical Analyses

The mean and standard deviation of the error rates were calculated for each group. The influence of the independent variables, namely angulation and type of impression coping, was analyzed by a two-way ANOVA (P , 0.05). Comparison of error rates between experimental groups was conducted by the one-way ANOVA and Tukey multiple-comparison tests (P , 0.05). All statistical analyses were carried out using SPSS for Windows (release 12.01; SPSS Inc., Chicago, IL).

RESULTS

The mean distances between the abutments and standard deviations for each group are summarized in Table 2. Mean differences between the master and experimental models are demonstrated in Table 3, and the error rates are shown in Table 3 and Figure 3. The error rate of impressions with transfer coping and buccolingual divergence (Group T-b) exceeded the International Standardization Organization standard (1.5%). The two-way ANOVA revealed that there were significant differences in error rates because of the implant angulation and type of impression coping (P , 0.05; Table 4).

When comparing the error rates to evaluate the effect of implant angulation, there were no significant differences with a change in angulation for the pick-up and hybrid types of impression copings. However, the error rates for the buccolingual angulation (Group T-b) were significantly higher than was for other angulations with transfer impression coping (Groups T-p and T-m) (P , 0.05).

As for the effect of the type of impression coping, the results demonstrated that there were no statistically significant differences between the types of impression coping with parallel and mesiodistal angulations. However, significantly higher error rates were found when the transfer coping (Group T-b) was used compared with pick-up and hybrid impression copings with a buccolingual angulation (Groups P-b and H-b) (P , 0.05).

DISCUSSION

This study examined the error rates of implant impressions at parallel, mesiodistally divergent, and buccolingually divergent implant angulations using pick-up, transfer, and hybrid types of impression copings to evaluate the effect of implant angulation and type of impression coping on the accuracy of implant impressions. Parallel and mesiodistal divergence of 15 degree had no effect on the accuracy of impressions regardless of the type of impression coping, but buccolingual divergence of 15 degree caused statistically higher error rates when the transfer type of coping was used. Hybrid copings showed reproducibility similar to that of pick-up copings, but the transfer type demonstrated relative inaccuracy, especially at 15 degree buccolingual divergence.

There were no statistical differences between the error rates of parallel and 15 degree mesiodistal divergence in this study. This result corresponds with the results of previous studies and demonstrated that a divergence below 15 degree had no effect on the accuracy of the impression.[11–13] However, buccolingual divergence of 15 degree demonstrated statistically higher error rates than parallel angulation. The difference between mesiodistal and buccolingual angulations of the same degree seemed to be induced by the difference in the direction of impression material distortion during the process of removal of the impression body. The impression material on mesiodistally angulated impression copings is distorted only in the mesiodistal direction during the process of removal of the impression body; however, the impression material on buccolingually angulated impression copings is distorted not only buccolingually but also mesiodistally because of the mesiodistal distance between the implants. Moreover, the impression tray is usually tilted in the anteroposterior direction during removal from the patient's mouth, and this tilting may cause further distortion of the impression material in buccolingually divergent impression copings, when the implant is placed in the molar area.

The error rates of pick-up and transfer copings with parallel or mesiodistally divergent angulations had no statistical differences. These results concur with the results of a number of previous studies,[14–19] although the opposite results were also demonstrated by some studies.[9,20] Some authors suggested that the number of implants involved is the variable that induces differences in the reproducibility of pickup and transfer copings.[21] Based on the results of this study, buccolingual divergence can also be suggested as a variable that influences the difference between pick-up and transfer copings.

Although pick-up copings seem to have better accuracy, they also have some disadvantages. Open trays should be used for pick-up impressions, but preparation of the open tray may make the procedure complicated. To release the retaining screw of the pick-up coping, sufficient vertical space in the mouth is necessary, and sometimes pick-up impressions may not be feasible owing to a lack of space. On the other hand, transfer copings seem to be less accurate but are easy to use and have broader indications. Hybrid impression copings were invented to combine the advantages of pick-up and transfer copings. Hybrid copings are composed of a plastic coping that remains within the impression body, and a metal component that remains on the implant after impression taking. The procedure of impression taking with hybrid copings is simple like that of transfer copings owing to the closed tray technique that is used; the accuracy of impressions of hybrid type is comparable to that of the pick-up type because the plastic coping is picked up during removal of the impression body. Although there is a possibility of an error occurring at the gap between the plastic coping and the metal component compared with the pick-up type, the results of this study demonstrated that the hybrid coping has reproducibility similar to that of a pick-up coping. Future studies that examine the reproducibility of the hybrid coping in multiple-unit implants of more than 3 numbers and at larger number of angulations may be valuable.

Table 4. Results of the Two-Way ANOVA for All Test Groups

Variations	P
Angulation	0.000*
Impression coping	0.003*
Angulation and Impression coping	0.062

The two-way ANOVA revealed that there were significant differences in error rates because of the implant angulation and type of impression coping.
*The mean difference is significant at P , 0.05.

CONCLUSIONS

1. Buccolingual divergence can be a variable that influences the differences in impression accuracy between pick-up and transfer copings; but parallel and mesiodistal divergence angulations do not induce such differences.
2. Hybrid impression copings have the convenience of use because of the closed tray technique that is used, and their reproducibility is similar to that of pick-up impression copings.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

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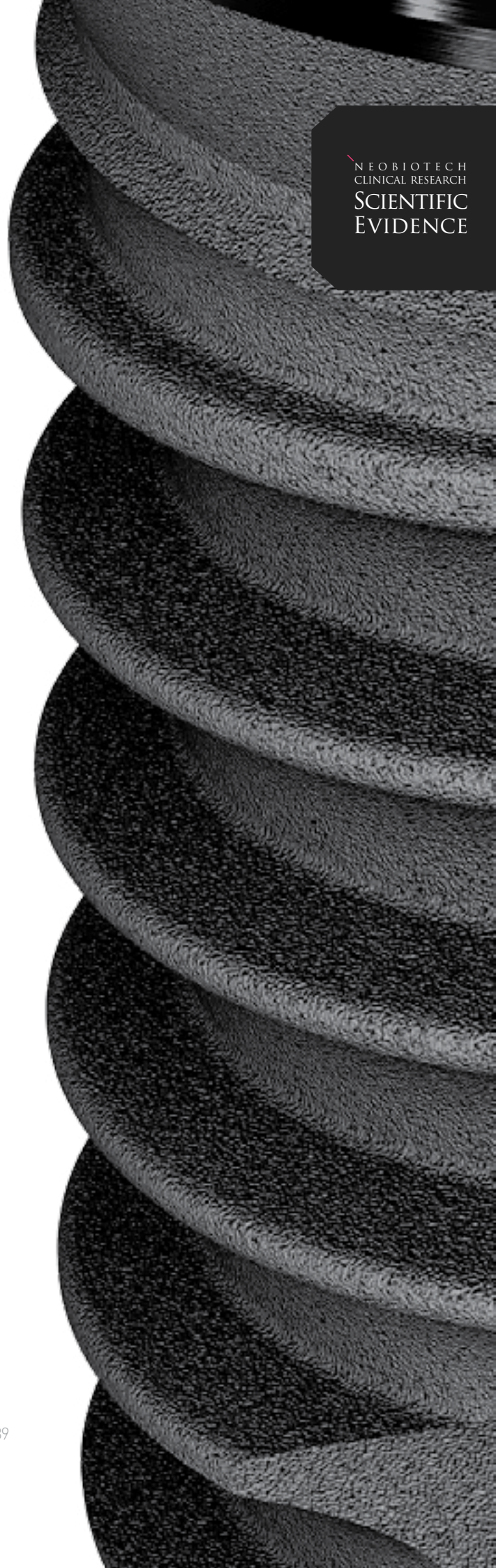

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