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Alveolar ridge augmentation using self-retaining synthetic block bone substitute in damaged extraction socket: a randomized clinical controlled study

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Graduate School

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Alveolar ridge augmentation using self-retaining synthetic block bone substitute in damaged extraction socket: a randomized clinical controlled study

Advisor Jung, Ui-Won

A Dissertation Submitted
to the Department of Dentistry
and the Committee on Graduate School
of Yonsei University in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Dental Surgery

Park, Shinyoung

June 2025

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Alveolar ridge augmentation using self-retaining synthetic block bone substitute in damaged extraction socket: a randomized clinical controlled study

This Certifies that the Dissertation of Park, Shinyoung is Approved

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감사의 글

학위 과정을 마무리하며, 그동안 따뜻한 응원과 귀한 도움을 주신 많은 분들께 진심 어린 감사를 드립니다.

먼저, 이 논문이 완성 되기까지 저를 지도해주시고 연구와 임상에서 늘 본보기가 되어 주신 정의원 교수님께 깊은 감사를 드립니다. 교수님의 아낌없는 지지와 가르침 덕분에, 이 논문을 통해 다양한 국제 무대에서 활동하고 인정받는 소중한 경험을 쌓을 수 있었습니다.

그리고 논문을 준비하면서 어려운 순간마다 많은 조언을 해주시고 논문이 완성되기까지 세심하게 도움을 주신 임현창 교수님께 깊이 감사드립니다. 또한 논문 심사와 지도를 통해 배움의 기회를 더 해주신 이중석, 최성호, 김창성, 차재국, 백정원, 박진영, 송영우, 박승현 그리고 홍인표 교수님께 감사 인사를 드립니다. 매일 치열한 일상 속에서도 함께 해준 동기들, 따뜻한 격려를 아끼지 않으셨던 선배님들, 그리고 응원해준 후배님들께도 고마움을 전합니다.

무엇보다도, 언제나 저에게 아낌없는 지지와 사랑으로 격려해주신 부모님, 따뜻한 마음을 가진 사랑하는 남편 민수, 사랑스러운 든든한 동생 현영이, 그리고 넘치는 사랑으로 기도해주신 외할머니, 친할머니, 친할아버지, 시부모님께도 진심으로 감사드립니다.

끝으로, 언제나 저를 사랑해주시고 은혜로 이끌어주시는 하나님께 감사를 드리며, 저에게 항상 “박-박사” 라고 응원해주신 하늘에 계신 외할아버지께도 감사의 마음을 전합니다.

그동안 받은 사랑과 배움을 마음에 깊이 새기며, 앞으로 더 좋은 모습으로 보답할 수 있도록 노력하겠습니다.

2025년 6월
저자 박신영

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ABSTRACT

Alveolar ridge augmentation using self-retaining synthetic block bone substitute in damaged extraction socket: a randomized clinical controlled study

Background: After tooth extraction, the alveolar bone surrounding extraction socket undergoes remodeling processes including physiological resorption. Especially, larger dimensional decrease with a higher variability is anticipated in a damaged extracted socket. In order to minimize the dimension of alveolar ridge resorption after extraction, alveolar ridge augmentation (ARA) has been introduced. Due to particulate bone's lack of stability and inadequate volume maintenance at the coronal level during wound closure, block bone grafting has been purposed as an alternative method. Block bone has been proven to have better mechanical properties and volume stability compared to particulate bone. This study aims to compare the dimensional stability of a self-retaining synthetic block bone (srBB) and synthetic bone particles (SBP) for ARA in damaged extraction sockets.

Materials and Methods: ARA was randomly performed in two centers on 57 participants presenting damaged extraction socket in a non- molar tooth: (i) srBB and collagen membrane (srBB group, n = 29) or (ii) SBP and collagen membrane (SBP group, n = 28). Cone beam computed tomography (CBCT) was performed immediately after ARA (baseline, T0) and at 6 months (T1). T0 and T1 CBCTs were superimposed, and horizontal widths (H0–H5), vertical heights and volume changes were assessed using t-test. In addition, patient reported outcome measures (PROMs), frequency of additional augmentation at time of implant placement, implant survival rate and peri-implant clinical and radiographic parameters were also compared.

Results: Due to wound dehiscence, srBB was removed in 10 patients. The change in horizontal width at the most coronal level (H0) was significantly lower for srBB compared to SBP (srBB: 0.8 ± 1.0 mm; SBP: 1.9 ± 2.2 mm, $p < 0.05$). However, no

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significant difference was shown in other horizontal levels (H1-H5) and other vertical level as well. Significantly less volume decrease was seen at the bucco-coronal level for srBB (srBB: 3.2 ± 0.6 mm^3; SBP: 10.4 ± 2.3 mm^3, $p < 0.05$). srBB group also showed significantly lower amount of applied bone volume during ARA as well as lower level of pain.

Conclusion: Compared to synthetic bone particles, synthetic bone blocks have the potential to more effectively augment and maintain the coronal horizontal dimension and width of damaged extraction sockets for up to 6 months. However, this advantage is offset by their relatively high rates of early wound dehiscence.

Key words : **alveolar bone grafting, alveolar ridge augmentation, dental implantation, tooth extraction, self-retaining block bone, block bone, damaged extraction socket, synthetic bone, dimensional stability, bone particles**

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1. Introduction

After tooth extraction, the alveolar bone surrounding extraction socket undergoes remodeling processes including physiological resorption (Araújo & Lindhe, 2005; Tan, Wong, Wong, & Lang, 2012). Minimal alveolar ridge change is needed to simplify implant therapy and avoid additional augmentation procedures. Numerous studies have shown that alveolar ridge preservation (ARP) can minimize horizontal and vertical bone resorption compared to spontaneous healing (Avila-Ortiz, Elangovan, Kramer, Blanchette, & Dawson, 2014; R. E. Jung et al., 2013), thereby simplifying implant placement (Antonio Barone et al., 2012; S. H. Park et al., 2020).

When performing ARP, the characteristics of extraction socket healing must be taken into account. In case of a partial or complete loss of the buccal bone plate following tooth extraction (i.e., damaged extraction socket), a larger dimensional decrease with a higher variability is anticipated compared to an intact extraction socket (Avila-Ortiz et al. 2014; Lee, Cha, and Kim 2018; Lee et al. 2015). Moreover, missing bone wall(s) should be re-built to properly manage damaged sockets, which puts the relevant interventions on a different level than conventional ARP. In a consensus report, ARP was defined as preserving the ridge volume within the envelope existing at the time of extraction, and alveolar ridge augmentation (ARA) as increasing the ridge volume beyond the skeletal envelope existing at the time of extraction (Hammerle et al. 2012). In the course of the bone re-building process for damaged sockets, over-augmentation is generally attempted (similar to guided bone regeneration) to compensate for post-surgical shrinkage of the re-established ridge (Lim et al. 2019) and to minimize the need for an additional augmentation procedure at implant placement (Barone et al. 2015).This indicates that ARA is a more suitable intervention for damaged sockets, even though most past research conceptually did not discriminate between ARP and ARA.

Several studies applied ARA in damaged extraction sockets using particulate bone substitute materials (Antonio Barone et al., 2015; J.-S. Lee et al., 2015; J. S. Lee et al., 2018). However, its weak mechanical stability and susceptibility to pressure during wound closure may not be ideal to minimize the subtractive ridge changes after ARA

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(Mir-Mari, Wui, Jung, Hämmerle, & Benic, 2016). Particulate bone substitute materials can be displaced or even migrate due to the partial/complete loss of the buccal bone plate. Indeed, a significant loss of dimension at the coronal area of the ridge was shown after ARA (Ben Amara et al. 2021; Cha et al. 2019; Seo et al. 2023a). Thus, alternative materials, such as block bone materials, may be required to enhance the dimensional stability of the augmented ridge (Lim et al. 2021, 2023; Zuercher et al. 2023). Given that block bone materials have been found to yield a greater final ridge dimension compared to particulate bone substitute materials (Gultekin et al. 2016; Mir-Mari et al. 2016; Rocchietta et al. 2016), it is worth investigating the use of the latter materials in ARA.

Aside from the conceptual need for a block bone in ARA, its usage is technically demanding and requires greater surgical experience. One of the prerequisites for the success of block bone grafting materials is to obtain a stable and intimate contact with the recipient bed (Burchardt, 1983; LaTrenta, McCarthy, Breitbart, May, & Sissons, 1989). Otherwise, the integration of the block bone is likely to fail. Furthermore, a fixation of the block bone material can be complicating. Block bone materials can fracture during the fixation by screws resulting in insufficient stability.

In order to overcome these limitations, a self-retaining block bone method has been evaluated pre-clinically (Kwon et al., 2024). To ensure self-retention, the following method was applied: First, the damaged extraction socket was prepared with a trephine bur to form a cylindrical bed. Second, the cylindrical block bone having the same diameter as the trephine bur was gently plugged into the prepared site. Consequently, the fit between the block bone and the socket was optimized. This ensured a press-fit configuration and eliminated the need of additional mechanical fixation. In that study, the self-retaining block bone method showed a greater volume stability especially at the coronal aspect of the socket compared to other types of bone substitute materials.

To date, there has been no clinical trials to validate the effect of the self-retaining block bone method in ARA over ARA using particulate bone substitute materials. The aim of this randomized controlled clinical study was to compare hard tissue-dimensional changes between a self-retaining synthetic block bone (srBB) and synthetic bone particles (SBP) in ARA for damaged non-molar extraction sockets.

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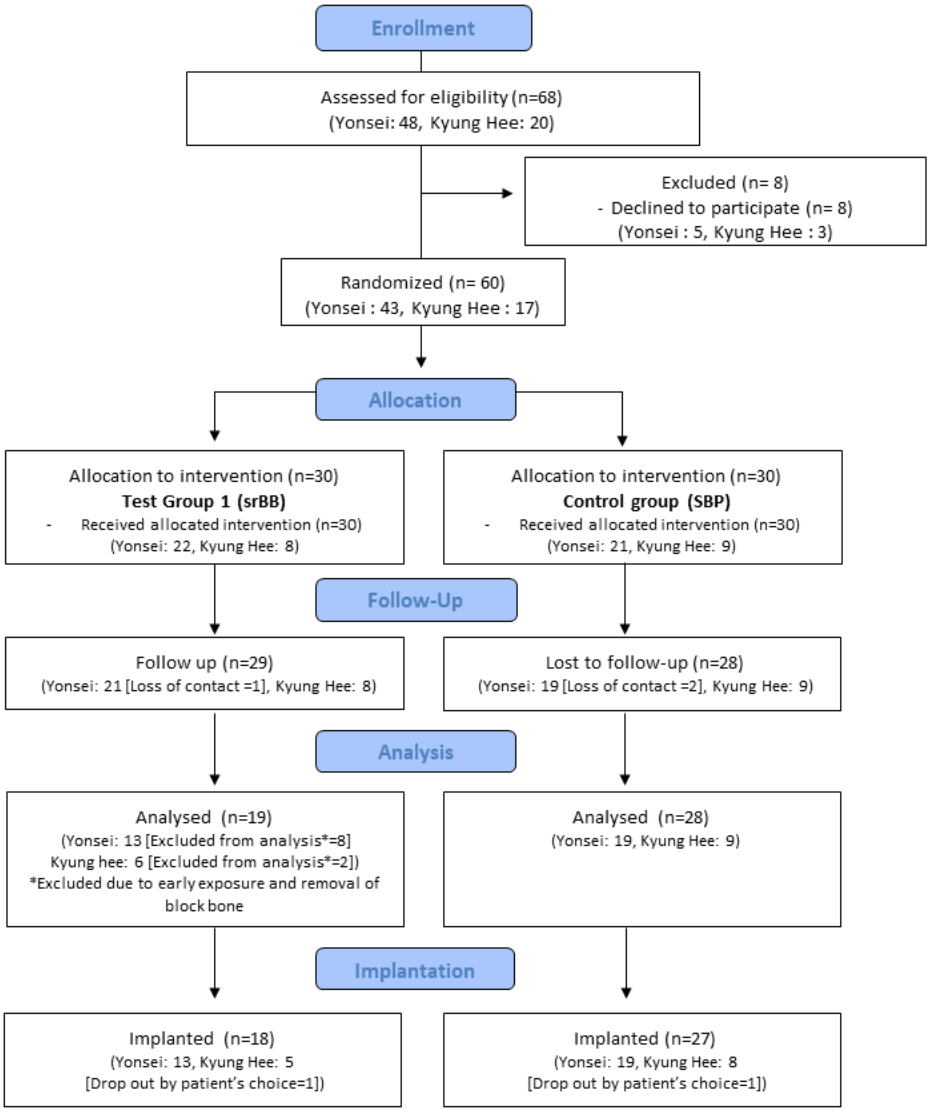
2. Materials and Methods

2.1. Study Design



<Fig 1> CONSORT flow chart.

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This study was designed as a randomized controlled clinical trial. The study protocol was designed according to the Helsinki Declaration and was approved by Institutional Review Board of Yonsei University Dental Hospital (2-2020-0043) and Kyung Hee University Dental Hospital (KH-DT20023). It is registered in Clinical Research Information Service (2-2020-0043). The present article was prepared according to the CONSORT guidelines (Moher et al., 2010) [Figure 1].

2.2. Study Population

Patients in need of extraction of at least one non-molar tooth were recruited. The extraction sockets showing >50% bone loss of root length on either buccal or lingual/palatal wall were included.

2.2.1 Inclusion Criteria

Patients Who

a. were systemically healthy and over 18 years of age;
b. required extraction of maxilla or mandibular incisor, canine, premolar tooth;
c. had resorption more than 50% of root length on the buccal or palatal wall shown on the extraction socket after extraction;
d. could abide to procedure of the study;
e. provided consent to study.

2.2.2 Exclusion Criteria

Patients With

a. resorption less than 50% of root length of the buccal or palatal wall after extraction;
b. uncontrolled generalized severe periodontitis;
c. severe vertical resorption on mesial or distal wall on extraction socket;

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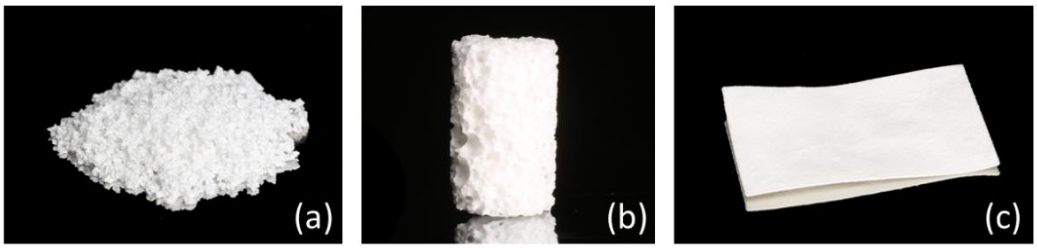
d. history of oromaxillofacial radiotherapy or chemotherapy;
e. history of bisphosphonate medication in the past 4 months;
f. uncontrolled diabetes;
g. pregnancy or breast feeding.

2.3. Study Group

- SBP group: extraction sockets were filled with synthetic bone substitute particles (SBP) and covered with a collagen membrane (CM).
- srBB group: extraction sockets were filled with self-retaining synthetic block bone (srBB) and covered with a CM.

2.4. Experimental Materials



<Fig 2> Experimental materials. *(a) Synthetic bone particles used in the SBP group. (b) Synthetic bone block used in the srBB group. (c) Porcine-derived resorbable collagen membrane used in both groups. SBP group: Alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM); srBB group: ARA using self-retaining synthetic block bone and a CM.*

- SBP: OSTEON 3 (Genoss, Suwon, Korea): particulate biphasic calcium phosphate composed of 60:40 ratio of hydroxyapatite and β-tricalcium phosphate [Figure 2-a].

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- srBB: OSTEON 3 Block (Genoss, Suwon, Korea): block bone made of OSTEON^{TM} 3 formed in a cylindrical shape with a diameter of 4 to 6 mm [Figure 2-b].
- CM: Collagen Membrane P (Genoss, Suwon, Korea), a crosslinked resorbable membrane using 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide (EDC) as the crosslinking agent [Figure 2-c].

Details on the applied materials can be found in a previously published study (J. Park et al., 2024).

2.5. Randomization

The enrolled patients were randomly assigned to the SBP or srBB group through a computer-generated random number created with a block size of 4. Group assignment was hidden in a sealed envelope and revealed immediately after extraction by an assistant.

2.6. Sample Size Calculation

The sample size calculation was performed using G*Power version 3.1.9.6 via the t-test for two independent means based on the change in bucco-coronal width measured at the coronal level (primary outcome). Using the mean difference of 0.2mm and an SD of 0.25 from a previous clinical trial (Barone et al. 2017) in which similar outcome measurements were performed using different bone grafting materials, an effect size d of 0.8 was calculated. As a result, a sample size of 25 patients per group was needed to detect a difference between groups. Considering a power of 80%, α=0.05 and drop-out rate =15%, 60 patients were recruited.

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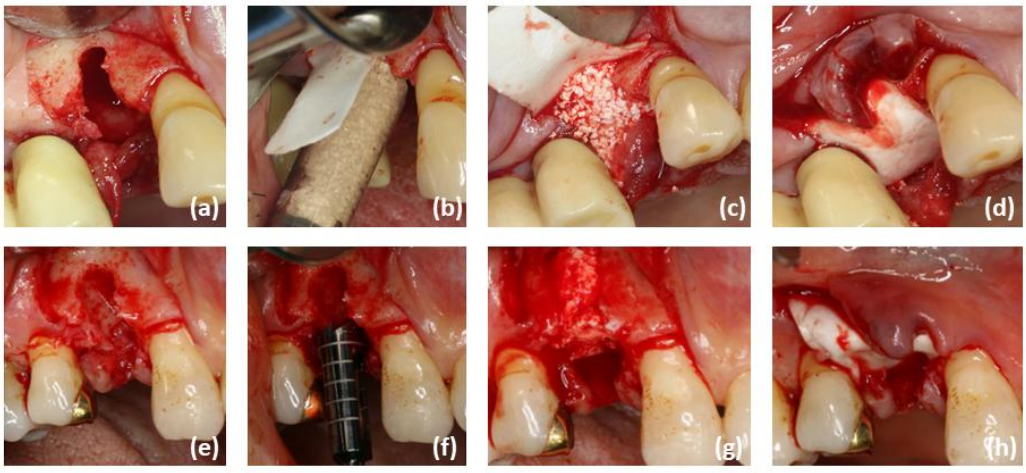
2.7. Standardization and Calibration

Twelve surgeons were involved in the trial (six surgeons in each institution, respectively). Each institution had one designated investigator responsible for data collection, recording and follow-up. Since many surgeons were involved in the trial, we paid extra attention to the standardization of procedures and calibration of examiners. Before commencing the trial, handouts and video clips were made for the surgery. Each step was clearly presented in those materials. Using the materials, principal investigators (U.-W.J. and H.-C.L.) in each center instructed the surgeons on the concept of using srBB and surgical protocol. Inter-center and intra-center meetings were regularly held during the study period to check for any deviation from study protocols.

2.8. Alveolar Ridge Augmentation



<Fig 3> Clinical photographs of ARA procedure of SBP (a–d) and srBB (e–h) groups.
(a) After flap elevation. (b, c) Particulate bone grafting to the extraction socket. (d) Coverage with collagen membrane. (e) After flap elevation. (f) Extraction socket preparation with trephine bur. (g) Insertion of srBB, fitted well into the prepared socket. (h) Grafted site coverage with collagen membrane.

SBP group: ARA using synthetic bone substitute particles and a collagen membrane (CM); srBB group: ARA using self-retaining synthetic block bone and a CM.

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An infiltration anesthesia using 2% lidocaine hydrochloride with 1:100,000 epinephrine was performed at the surgical site. Sulcular incisions were made around the tooth to be extracted and the neighboring tooth/teeth, followed by a vertical incision at the distal line angle of the designated tooth. Subsequently, a full-thickness flap was elevated, and the designated tooth was gently removed. Granulation tissue was thoroughly debrided [Figure 3-a, e]. Upon group assignment, the following treatment was performed:

- SBP group: SBP was grafted into the extraction socket using a syringe [Figure 3-b]. Horizontally, SBP was grafted up to being slightly over-augmented with respect to an imaginary intact ridge outline horizontally and up to the level of the mesial and distal ridge crest vertically [Figure 3-c].

- srBB group: the extraction site was drilled with a trephine bur to fit the cylindrical-shaped block bone [Figure 3-f]. The diameter of the trephine bur was slightly wider than the mesio-distal length of the extraction socket. A block bone with the same diameter as the trephine bur [Figure 2-b] was gently inserted [Figure 3-g]. The detailed surgical protocol can be found elsewhere (J. Park et al., 2024).

The grafted site was completely covered with the CM [Figure 3-d, h]. No additional pin fixation was used in both groups. The buccal flap was advanced using a periosteal releasing incision, and primary flap closure was performed

Sutures were removed 7 -10 days after ARA. Patients were recalled at one, three and six months post-ARA. In case of adverse events, such as wound dehiscence, swelling and bleeding, additional visits were scheduled. Cone-beam computed tomography (CBCT, Alphard 3030 device; Asahi Roentgen, Tokyo, Japan) was taken immediately after ARA (baseline; T0) and at 6 months post-ARA (T1).

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2.9. Implant placement

At 6 months post-ARA, implant placement was performed. After local anesthesia, a full thickness flap was elevated, followed by osteotomy preparation and implant placement. When a bony dehiscence or a fenestration was present, additional bone grafting was performed using SBP and CM. Sutures were removed after 7 – 10 days. Patients were recalled at 1, 3, 6 and 12 months' post-implant placement.

2.10. Post-Operative Regimen

Antibiotics and analgesic were prescribed for 5 - 7 days. A 0.12% chlorhexidine gargle solution was recommended to use twice a day.

2.11. Outcome

2.11.1. Primary outcome

- Horizontal ridge change between T0 and T1

2.11.2 Secondary outcomes

- Vertical ridge change between T0 and T1
- Volumetric change in region of interest (ROI) between T0 and T1
- The applied amount of bone substitute material in ARA
- Patient- reported outcome measures (PROMs)
- Frequency of additional augmentation at the time of implant placement

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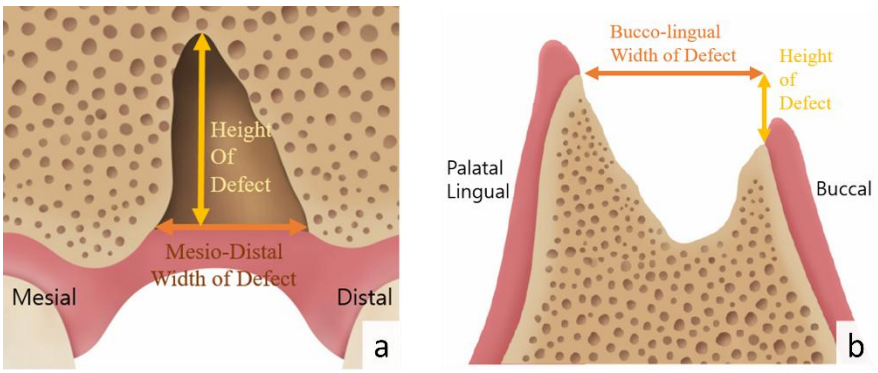
- Implant survival without complication
- Peri-implant clinical and radiographic parameters, such as probing pocket depth (PPD), bleeding on probing (BOP) and marginal bone level change

2.12. Measurements

2.12.1 Clinical Measurements



<Fig 4> Schematic images of the clinical measurements of bone defect. *(a) Sagittal plane view. (b) Coronal plane view.*

The defect size was measured using a periodontal probe up to nearest 1mm, as follows: 1) mesio-distal width, measured at the crestal level [Figure 4-a], 2) bucco-lingual width, distance between the imaginary intact socket wall (at the damaged wall) and the undamaged socket wall) [Figure 4-b], and 3) height distance between the imaginary intact crest and the most apical level of the damaged socket wall [Figure 4-a, b]. The amount of bone substitute material used in ARA was recorded. Biological complications and wound dehiscence were evaluated at the recall visits

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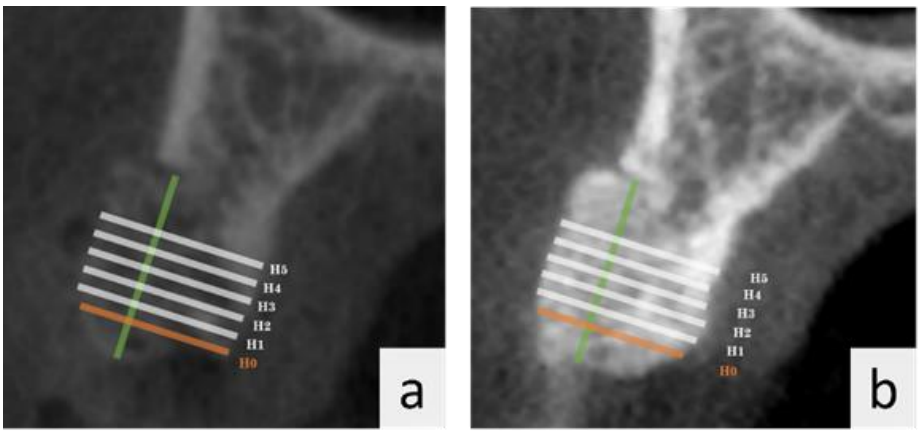
2.12.2 Digital measurements for linear and volumetric ridge changes

The obtained DICOM (Digital Imaging and Communication in Medicine) files at T0 and T1 were imported into a computer software program (OnDemand3D; Cybermed, Seoul, Korea). The files were superimposed through built-in automatic tools based on neighboring anatomical structures such as adjacent teeth and the cranial base of the maxilla /mandibular inferior cortex. The superimposed files were then manually checked.



<Fig 5> Horizontal radiographic measurements. Labelling of H0 to H5 on CBCT image *(a) at T0 (b) at T1*

On the superimposed images, the long axis of the extraction socket was identified. A vertical reference line [Figure 5 & 6 green line] was drawn along the center of the extraction socket. For horizontal measurement, the crest of undamaged socket wall (H0; at T0) and five additional levels by incrementing 1mm in an apical direction (H1, H2, H3, H4 and H5) were marked along the vertical reference line. At each level, bucco-lingual horizontal width was measured [Figure 5].

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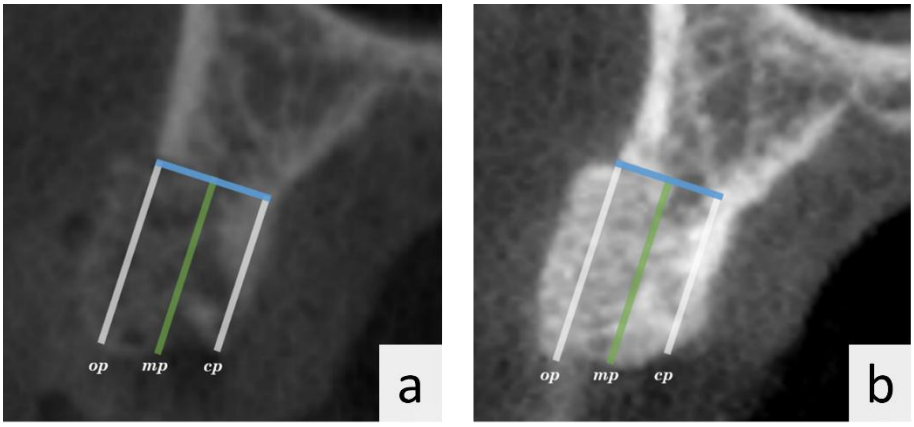

<Fig 6> Vertical radiographic measurements. *Labelling of op, mp, cp on CBCT image (a) at T0 (b) at T1*

For vertical measurement, horizontal reference line [Figure 6, blue line] was additionally drawn perpendicular to the vertical line at the apical point of the socket. outermost point (*op*), mid-crestal point (*mp*) and most-coronal point (*cp*) of the undamaged socket wall were identified based on T0. Subsequently, the distances between those three points and the horizontal reference line were measured [Figure 5]. The plane for horizontal and vertical measurements were perpendicular and parallel to the vertical reference line, respectively.

Additionally, volumetric change was measured. For this, the DICOM files were transformed to stereolithography (STL) files using an open-source software (3D slicer 5.3, www.slicer.org). The STL files were imported to digital image analyzing software (SMOP, Swissmeda AG, Baar, Switzerland), followed by superimposition using fixed reference structures, such as neighboring teeth. Subsequently, volume decrease at bucco-crestal area with region of interest (ROI, 5mm x 5mm) was measured. Volume decrease per standardized rectangular area (ROI) between T0, and T1 was calculated by the software and recorded.

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2.12.3 PROMs

Four questions were given to the patients at the time of suture removal:

(1) appropriateness of the surgery time

(2) level of pain

(3) general satisfaction to the surgery

(4) willingness to undergo the same surgery.

Each item was evaluated using a Likert scale

2.13. Statistical analysis

Data was statistically analyzed using SPSS (version 26, IBM corporation). Mean ± standard-deviation values for all parameters were calculated. Independent t-test was applied to compare srBB and SBP value; paired t-test was applied to compare T0 and T1 within srBB and SBP value. Statistically significant difference was set at $p<0.05$.

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3. Results

Sixty-eight patients were initially screened in this study and a total of 60 patients were included. The included patients were randomly assigned to the SBP (n=30) group and the srBB group (n=30). Total of three participants were lost during the follow-up period before implant surgery (two in the SBP group, one in the srBB group, both from Yonsei University group). Another two patients withdrew their consent for implant treatment (one in SBP group, one in srBB group, both from Kyung Hee University group), yet CBCT for these two patients were still taken, and their data were included.

While wound healing was uneventful in all patients in the SBP group, there was partial exposure of the block bone material in ten patients in the srBB group (eight patients from Yonsei University, and two patients from Kyung Hee University). For those in the srBB group, additional re-call visits were scheduled, and a 0.12% chlorhexidine gargle solution was further recommended to use. However, the exposed block bones were eventually removed. The reason for block bone removal was: (i) early exposure of block bone (2 patients), (ii) exposure of block bone (7 patients), and (iii) pin point discharge and infection of upper part of the block bone thereafter only infected area of block bone was removed (1 patient).

Due to the block bone removal in the SBP group, 28 patients in the SBP group and 19 patients in the srBB group remained in the analyses using CBCT

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3.1. Demographic information

Table 1. Demographic Data of Participants of this Study

Patient Parameter	srBB (test)	SBP (control)
Number of patients *(n)*	19	28
Sex		
Male *(n[%])*	8 (42%)	16 (57%)
Female *(n[%])*	11 (58%)	12 (43%)
Average age (years) Mean ± SD	60.3 ± 10.2	61.8 ± 10.2
Reason for tooth extraction		
Perio *(n[%])*	13 (68%)	20 (71%)
Root fracture *(n[%])*	6 (32%)	8 (29%)
Tooth type (incisor / premolar)		
Incisor *(n[%])*	6 (32%)	10 (36%)
Premolar *(n[%])*	13 (68%)	18 (64%)
Tooth position		
Maxilla *(n[%])*	11 (58%)	21 (75%)
Mandible *(n[%])*	8 (42%)	7 (25%)

SBP group: alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM), srBB group: ARA using self-retaining synthetic block bone and a CM.

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Detailed information of the demographic information of patients is presented in Table 1. Reasons for extraction were predominantly of periodontal natures. Tooth type and location were mostly premolar and maxilla, respectively. Difference between two group were statistically insignificant (p>0.05).

3.2. Clinical measurements

Defect sizes in the SBP group and the srBB group were as follows: 6.3±2.3mm and 5.3±2.1mm for the mesio-distal width, respectively. The bucco-lingual width measured 8.3±1.5mm and 7.45±1.5mm, and the defect height was 7.0±3.4mm and 6.5±2.7mm (p>0.05). The mean applied volume of bone in ARA was significantly smaller for the group srBB compared to the SBP group (srBB: 193.8mm^3 vs. SBP: 498.2mm^3, p<0.05).

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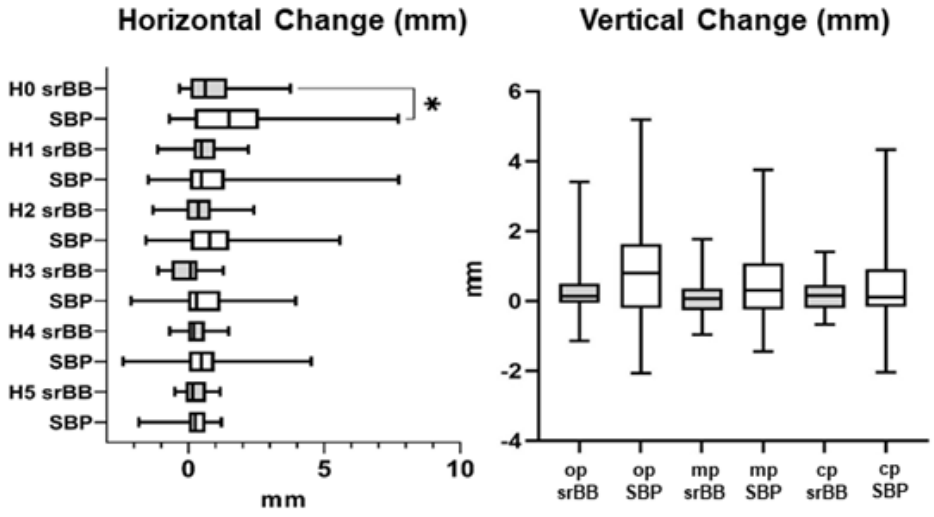
3.3. Digital measurements

3.3.1. Linear measurements



<Fig 7> Box plots of linear difference in horizontal width, vertical height of alveolar ridge. *The plots show first and third quartiles, and median indicated inside the box. The top and lowest points indicate the maximum and minimum of the data, respectively. Data are based on difference between CBCT measurement at baseline and at 6months (T0–T1). SBP group: Alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM); srBB group: ARA using self-retaining synthetic block bone and a CM. *Statistical significance ($p<0.05$).*

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Table 2. Results from Linear Horizontal Measurements

	srBB				SBP				
	T0 (mm)	**T1 (mm)**	**Δ (mm)**	**Δ% (%)**	**T0 (mm)**	**T1 (mm)**	**Δ (mm)**	**Δ% (%)**	**Δ *p*-value**
H0	7.2 ±2.3	6.4 ±2.0	0.8 ±1.0	10.7 ±10.7	7.0 ±2.3	5.1 ±3.3	1.9 ±2.2	31.4 ±36.4	0.048
H1	8.0 ±1.9	7.4 ±1.6	0.5 ±0.8	5.4 ±10.9	8.3 ±1.9	7.2 ±3.1	1.1 ±2.1	15.3 ±30.2	0.297
H2	8.7 ±1.9	8.2 ±1.7	0.4 ±1.0	12.0 ±21.9	9.2 ±2.0	8.2 ±2.7	1.0 ±1.5	12.0 ±21.9	0.154
H3	9.3 ±2.2	9.3 ±2.0	0.0 ±0.6	5.4 ±15.6	9.4 ±1.7	8.9 ±2.1	0.5 ±1.3	5.4 ±15.6	0.128
H4	9.5 ±2.5	9.2 ±2.4	0.3 ±0.5	2.7 ±5.1	9.8 ±1.6	9.2 ±1.8	0.6 ±1.1	5.9 ±12.5	0.259
H5	10.1 ±2.9	9.9 ±2.7	0.2 ±0.5	2.0 ±4.3	10.2 ±1.8	9.9 ±1.9	0.3 ±0.6	2.6 ±6.3	0.883

SBP group: alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM), srBB group: ARA using self-retaining synthetic block bone and a CM.

The change in horizontal width (primary outcome) at H0 was statistically significantly smaller in the srBB group than the SBP group between T0 and T1 (srBB: 0.8±1.0mm [10.7±10.7%] vs. SBP: 1.9±2.2mm [31.3±36.4%], $p<0.05$). The final horizontal width at H0 was greater in the group srBB (6.4±2.0mm) than the SBP group (5.1±3.3mm) without reaching a statistically significant difference ($p>0.05$). At the remaining levels (H1-H5), the changes in horizontal width were smaller for srBB

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compared to SBP, yet the differences were not statistically significantly different [p>0.05, Figure 7, Table 2].

Table 3. Results from Linear Vertical Measurements

	srBB				**SBP**				
	T0 (mm)	**T1 (mm)**	**Δ (mm)**	**Δ% (%)**	**T0 (mm)**	**T1 (mm)**	**Δ (mm)**	**Δ% (%)**	**Δ *p*-value**
Outer most point (*op*)	8.4 ±2.1	8.0 ±2.2	0.4 ±1.0	4.5 ±12.1	8.6 ±2.5	7.6 ±3.4	1.1 ±1.8	14.9 ±24.6	0.146
Mid-crestal point (*mp*)	9.1 ±1.7	8.9 ±1.6	0.3 ±0.7	2.3 ±7.3	9.4 ±2.2	8.9 ±2.6	0.6 ±1.2	6.3 ±13.8	0.319
Most coronal point (*cp*)	8.4 ±1.6	8.3 ±1.7	0.1 ±0.5	1.7 ±6.3	8.7 ±2.1	8.3 ±2.3	0.4 ±1.1	4.5 ±11.4	0.337

outermost point (op), mid-crestal point (mp) and most-coronal point (cp)

All vertical height changes for *op, mp* and *cp* were smaller for the srBB group compared to the SBP group [p>0.05, Figure 7, Table 3]. Values between T0 and T1 were significantly different for both srBB and SBP for most horizontal and vertical measurements, except at H2, H3 for srBB and at H2 for SBP.

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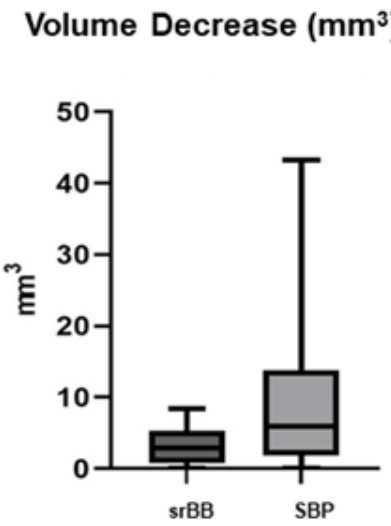
3.3.2. Volumetric Measurements

Table 4. Results from Volumetric measurements

	srBB (mm^3)	SBP(mm^3)	Δ *p*-value
Volume decrease	3.2±2.7	10.3±12.0	0.014
Statistic on Signed Distance	0.6±0.4	0.6±0.4	0.617



<Fig 8> Box plots of volumetric decrease of alveolar ridge. *The plots show first and third quartiles, and median indicated inside the box. The top and lowest points indicate the maximum and minimum of the data, respectively. Data are based on difference between CBCT measurement at baseline and at 6months (T0–T1). SBP group: Alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM); srBB group: ARA using self-retaining synthetic block bone and a CM. *Statistical significance ($p<0.05$).*

Within the ROI of STL files, the srBB group demonstrated less volume decrease than the SBP group (3.2±0.6mm^3 vs. 10.4±2.3mm^3, $p<0.05$). Moreover, the SBP group exhibited greater variability in between sites [Figure 8, Table 4].

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3.4. PROMs

Table 5. Patient Reported Outcome Measures

	srBB	SBP	*p*-value
Q1: appropriateness of the surgery time	8.4±2.5	8.6±2.5	0.903
Q2: level of pain	6.1±2.8	7.8±2.4	0.019
Q3: general satisfaction to the surgery	8.5±1.5	8.9±1.4	0.287
Q4: willingness to undergo the same surgery	7.9±2.0	8.0±3.1	0.507

SBP group: alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM), srBB group: ARA using self-retaining synthetic block bone and a CM.

The level of pain was significantly lower in the srBB group than the SBP group ($p<0.05$). Other items were not significantly different between the two groups.

3.5. Frequency of Additional Augmentation

At the time of implant placement, 4 out of 19 sites in the srBB group and 6 out of 28 sites in the SBP group required additional bone augmentation ($p>0.05$). The reasons for the augmentation were dehiscence (n=3)/thin buccal bone on the buccal side of the implant (n=1) in the srBB group and dehiscence (n=5)/fenestration defect (n=1) in the SBP group.

3.6. Implant Survival

One implant each in both groups presented insufficient osseo-integration during implant prosthetic treatment. Those two implants were removed and replaced with new

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ones after 2–3months of healing. The rest of the implants did not show any specific complications throughout the follow-up period (up to 1 year after implant placement). The survival rate was 94.1%(16/17) in the srBB group and 96.2% (25/26) in the SBP group.

3.7. Peri-implant Clinical and Radiographic parameters

No statistically significant differences were found between the groups in PPD, BOP or marginal bone level change.

Table 6. Peri-Implant Clinical Parameters

	srBB	**SBP**	***p*-value**
Probing pocket depth (mm, at 1 year post implant placement)	2.6±0.7	3.0±0.7	0.100
Bleeding on probing (at 1 year post implant placement)	0.4±0.3	0.3±0.3	0.157
Marginal bone level changes (mm, between implant placement and 1 year thereafter)	−0.3±0.7	−0.3±0.7	0.983

SBP group: alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen membrane (CM); srBB group: ARA using self-retaining synthetic block bone and a CM.

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4. Discussion

Dental implants should be supported by a solid hard tissue structure for long- term stability including aesthetics and peri-implant health (Cosyn, Hooghe, and De Bruyn 2012; Merheb, Quirynen, and Teughels 2014; Monje et al. 2016). Therefore, ideal hard tissue profile following ARP or ARA should provide a sufficiently large dimension compared to future implant. However, in sites with a partial or complete loss of the buccal bone, it appears to be challenging to achieve proper ridge contour (Ben Amara et al. 2021; Lee, Cha, and Kim 2018; Lee et al. 2015; Seo et al. 2023a). This has been shown previously with greater dimensional ridge alterations after ARP for damaged sockets compared to intact sockets (Lee, Cha, and Kim 2018). To assess the influence of the choice of material in damaged extraction sockets, two types of bone substitute materials (srBB or SBP) were evaluated for ARA in the present study. We found that the srBB led to greater dimensional stability compared to SBP, especially at the coronal level, over a 6-month healing period. Moreover, the level of pain was significantly lower in the srBB group compared to the SBP group.

srBB was more favorable in maintaining the grafted bone volume at the coronal level with less volume resorption between T0 and T1. The linear measurements using CBCTs provided further details on this. Based on these measurements, the srBB group showed significantly less horizontal resorption at H0 compared to the SBP group. The SBP group showed a mean horizontal resorption of 1.9 mm at the H0 level. This is in line with a recent clinical study in which the grafted particulate bone showed approximately 2 mm of horizontal resorption 4 months after ARA in damaged extraction sockets (Lee, Cha, and Kim 2018). Even greater horizontal resorption was noted in another study using particulate bone (−4.86 and −4.19 mm) (Seo et al. 2023a). Moreover, when using a bone substitute material containing collagen, the horizontal bone resorption was also significant (> 5 mm) (Ben Amara et al. 2021; Cha et al. 2019). However, the srBB group maintained ridge stability up to 6 months effectively with a resorption of < 1 mm. In a previous clinical study on horizontal onlay block bone grafting, the resorption rate was similar to that in the present study (von Arx and Buser 2006). Other studies also showed that block bone maintains the

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coronal dimension despite the applied pressure due to flap closure (Kwon et al. 2024; Mir-Mari et al. 2016). Furthermore, it is worth mentioning that the srBB group required less bone grafting material but yielded greater total horizontal width after 6 months at H0.

As horizontal reference point approaches apically (H0 > H5), the amount of bone resorption decreases, a pattern seen in another previous study regarding ARA (Lee et al. 2015). Such a pattern can be explained by the low physical stability of particulate bone substitute materials. In previous studies, particulate bone showed higher reduction of the horizontal width due to wound closure and an apical displacement of bone substitute particles followed by collapse of the grafted site (Mir- Mari et al. 2016; Schwarz et al. 2007).

Overall, the srBB group showed less dimensional changes compared to the SBP group, yet most values, including all vertical values, were statistically insignificant due to the high variability in between sites in the SBP group. In all horizontal, vertical and volumetric measurements, the srBB group showed a lower standard deviation compared to the SBP group. Clinically, obtaining a consistent desired outcome is crucial.

In 19 block bone sites, the integration of the material into the native bone was successful without further additional rigid fixation devices. So far, rigid fixation has been used to immobilize the block bone at the recipient site using materials such as screws and pins, among other options. In a previous experimental study, block bone grafting without rigid fixation showed no difference in grafted volume retention and graft survival compared to block bone with rigid fixation (Bae et al. 2014). Especially, in the present study, stabilization of the block bone without rigid fixation was maintained in an oral environment with continuous movement and pressure due to mastication. Therefore, the present study demonstrates that block bone grafting can be successfully performed without additional rigid fixation even in a clinical environment and can create an alveolar bed with sufficient width for implantation despite the absence of a buccal wall. Until recently, there was limited evidence on successful application of synthetic block bones in clinical cases, especially because some synthetic block bones are brittle and break when a fixation device is used. In future studies, the self- retaining method using an alloplastic material can be extended to more challenging sites including alveolar augmentation.

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One common concern of the self- retaining block bone method is the partial but necessary removal of the native bone by a trephine bur to fit the block bone. However, only minimal bone in the apical area is prepared for block bone fixation. Moreover, the obtained autogenous bone chips can be grafted in the coronal and buccal area, providing osteogenic properties (Wang, Misch, and Neiva 2004). The use of a trephine drill allows the grafted alloplastic bone material to be in direct contact with cancellous areas while at the same time increasing the surface contact area. This increases angiogenesis, leading to a potentially higher success of bone grafting (Wang and Boyapati 2006). In fact, in a pre-clinical study, the srBB group showed more new bone formation than the SBP group (4.9 mm^2 vs. 1.3 mm^2) (Kwon et al. 2024). In a clinical pilot study, a synchrotron analysis showed new bone formation inside srBB grafts to be 16.5% (Park et al. 2024).

The level of pain was significantly lower in the srBB group than in the SBP group. This might be due to less amount of graft material for ARA in the srBB group, which led to the less extent of flap advancement, thus resulting in less pain post operation.

While the frequency of additional augmentation did not show a significant difference between the two groups, it is important to consider the following. Despite the smaller dimensional change in the srBB group compared to the SBP group, the srBB group still experienced a loss of approximately 10% of the initially augmented thickness (at the crestal level). Furthermore, the implant position was determined based on the opposing and neighboring dentition, which means that the facio-oral position was not necessarily at the center of the newly formed ridge.

In the present study, a cross-linked CM was used to protect the bone substitute materials. Cross-linked CMs are less degradable than non-cross-linked ones, indicating that the former can provide cell occlusiveness for a longer time. Clinical situations for ARA present a greater extent of alveolus loss than for ARP. Such difference in bone destruction may be one of the criteria for choosing biomaterials, and we thought that cell occlusive ness was needed more for damaged sockets than intact sockets. Until now, those two membranes were compared in a few studies without restriction regarding the extent of socket wall destruction, resulting in no significant difference in maintaining ridge

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dimension (Chang et al. 2017; Lim et al. 2017). However, no comparison was performed for damaged sockets.

The present study has some limitations. First, the srBB group showed a relatively high exposure rate of 34% (10 sites). The failure rate is similar to the graft exposure rate of a previous study reporting on onlay block bone grafting (Chaushu et al. 2010). The graft exposure might be explained by inadequate soft-tissue quality of the extraction site and tension following suturing. The surgical site immediately after extraction requires an extensive advancement of the flap for primary closure, leading to a high wound dehiscence rate similar to that in a previous study reporting on primary closure of extraction sites (Seo et al. 2023a). Most of these exposures were observed at an early time point in the present clinical trial, implying a learning curve for this procedure. To reduce such exposure, extra care should be taken in flap management, and careful case selection (especially regarding soft- tissue conditions) is needed. Second, due to these exposures, the number of patients in the srBB group decreased and was lower than the calculated sample size, which may explain the significant differences in favor of the srBB. Therefore, further studies are needed to verify the present findings. Third, a long-term follow-up of the sites is needed, considering the short observation period and implant failure (one each in both groups) during the prosthetic phase. It should also be noted, however, that implant-related data regarding ARA for damaged sockets are scarce.

5. Conclusion

srBB may offer greater space-maintaining capability in the coronal area of damaged extraction sockets than SBP. However, the relatively high rate of wound dehiscence in the srBB group indicates the need for careful flap management and consideration of the inherent learning curve. Long-term follow-up is warranted to confirm the safety and efficacy of this treatment.

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Abstract in Korean

손상된 발치와에서 자가 고정성 블록 골을 사용한 치조골 증대술: 무작위 대조 임상실험

본 논문은 손상된 발치와에서 자가 고정형 합성 블록 골(self-retaining synthetic block bone, srBB)과 합성 골입자(synthetic bone particles, SBP)의 치조골 증대 부피 유지력을 비교하기 위한 목적으로 진행되었다. 발치와를 둘러싼 치조골은 발치 직후 생리적인 흡수를 비롯한 골의 재형성 과정을 겪는다. 특히 손상된 발치와의 경우, 더 큰 골 흡수가 일어나게 된다. 이러한 발치 후 치조골 퇴축을 최소화하기 위해 치조골 증대술 (Alveolar Ridge Augmentation, ARA)를 진행하였다. 특히 입자형 이식재를 ARA 에 사용할 경우, 치관부에서 낮은 부피 안정성을 보이기 때문에, 기계적인 특성과 부피 유지 면에서 더욱 우수한 블록형 골 이식재를 사용하였다.

연세대학교과 경희대학교를 방문한 환자 중 전치 또는 소구치에 손상된 발치와를 가진 57 명의 참가자를 대상으로 ARA 를 진행하였다. 환자는 다음 두 가지 군으로 무작위 배정되었다: (i) srBB 와 콜라겐 막으로 치조골 증대술을 시행한 경우 (srBB, n=29) (ii) SBP 와 콜라겐 막으로 치조골 증대술을 시행한 경우 (SBP, n=28).

증대술 직후(T0)와 6 개월 후 (T1)에 CBCT(콘빔전산화단층 촬영)가 촬영되었다. T0 와 T1 의 CBCT 이미지를 중첩하여 수평 너비 (H0-H5), 수직 높이 및 부피 변화를 t 검정을 통해 평가하였다. 추가로 환자 보고 결과(PROMs), 임플란트 식립 시 추가 증대 필요성 여부, 임플란트 생존율, 임플란트 주변 임상 및 방사선 지표도 비교하였다.

창상 열개(wound dehiscence)로 인해 10 명의 srBB 환자에서 골 이식재가 제거되었다. srBB 에서 치조정 수평 너비(H0)의 변화는 SBP 에 비해 유의하게 더 작았다

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(srBB: 0.8 ± 1.0 mm; SBP: 1.9 ± 2.2 mm, $p < 0.05$). 그러나 나머지 수평 넓이(H1−H5)와 수직 높이, 그리고 부피에서는 두 군간의 유의할 만한 차이를 보이지 않았다. 추가로 srBB 그룹은 이식에 사용된 골 이식재 양이 SBP 에 비교하여 유의하게 적었으며 술 후 환자가 느낀 통증 또한 적은 것으로 나타났다.

합성 블록 골은 합성 입자형 골에 비교하여 손상된 발치와에서 치관 부위의 수평적 너비를 최대 6 개월까지 더욱 효과적으로 증대하고 유지할 수 있다. 그러나 이러한 장점은 상대적으로 높은 조기 열개 발생률로 인하여 한계가 존재한다.

핵심되는 말 : 치조골 이식, 치조골 증대술, 임플란트 식립, 발치, 자가 고정성 블록 골, 블록 골, 손상된 발치와, 합성골, 부피 안정성, 입자형 골