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Ridge Augmentation Using a Self-Retaining Block Bone Material in Damaged Extraction Sockets: A Multi-Centre Randomized Controlled Clinical Trial

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Keywords: alveolar bone grafting | alveolar ridge augmentation | dental implantation | tooth extraction

ABSTRACT

Aim: To compare the dimensional stability of a self-retaining synthetic block bone (srBB) and synthetic bone particles (SBP) for alveolar ridge augmentation (ARA) in damaged extraction sockets.

Materials and Methods: ARA was randomly performed in two centres 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 ARP (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.

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, $p < 0.05$). Significantly less volume decrease was seen at the bucco-coronal level for srBB (srBB: $3.2 \pm 0.6\,mm^3$; SBP: $10.4 \pm 2.3\,mm^3$, $p < 0.05$).

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.

Trial Registration: Korean Clinical Research information service (CRIS) (KCT0005462)

1 | Introduction

After tooth extraction, the alveolar bone surrounding the extraction socket undergoes remodelling processes including physiological resorption (Araujo and Lindhe 2005; Tan et al. 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 et al. 2014),

thereby simplifying implant placement (Barone et al. 2012; Park et al. 2020).

However, the characteristics of the extraction socket should be considered for ARP. 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 have applied ARA in damaged extraction sockets using particulate bone substitute materials (Koo et al. 2020; Lee, Cha, and Kim 2018; Lee et al. 2015; Seo et al. 2023a, 2023b). However, its weak space-maintaining capability and susceptibility to pressure during wound closure may not be ideal to minimize the subtractive ridge changes after ARA (Mir-Mari et al. 2016). Particulate bone substitute materials can be displaced towards the missing alveolar bone wall(s). 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 et al. 1989). Otherwise, the integration of the block bone is likely to fail; however, fixation of the material can be complicated. Block bone materials even can fracture during fixation by screws, resulting in insufficient stability.

To overcome those limitations and ease the procedures, 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. Thereby, the fit between the block bone and the socket was optimized. 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 was to compare the dimensional changes in hard tissue between a self-retaining synthetic block bone (srBB) and synthetic bone particles (SBP) in ARA for damaged non-molar extraction sockets.

2 | Materials and Methods

The details of the present study can be found in Appendix 1.

3 | Study Design

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

3.1 | Study Population

Patients in need of extraction of at least one non-molar tooth and implant treatment were recruited. Extraction sockets showing > 50% bone loss of root length on either buccal or lingual/palatal wall were included. Patients were fully informed of the study aim and procedures. Informed consent was obtained by a designated investigator.

3.2 | Study Groups

- SBP group: extraction sockets were filled with SBP and covered with a collagen membrane (CM).
- srBB group: extraction sockets were filled with srBB and covered with a CM.

3.3 | Experimental Materials

- SBP: OSTEON 3 (Genoss, Suwon, Korea): particulate biphasic calcium phosphate composed of 60:40 ratio of hydroxyapatite and β-tricalcium phosphate (Figure 2a).
- srBB: OSTEON 3 Block (Genoss, Suwon, Korea): block bone made of OSTEON 3 formed in a cylindrical shape with a diameter of 4–6 mm (Figure 2b).
- CM: Collagen Membrane P (Genoss, Suwon, Korea), a cross-linked resorbable membrane using 1-ethyl-3-(3-dime

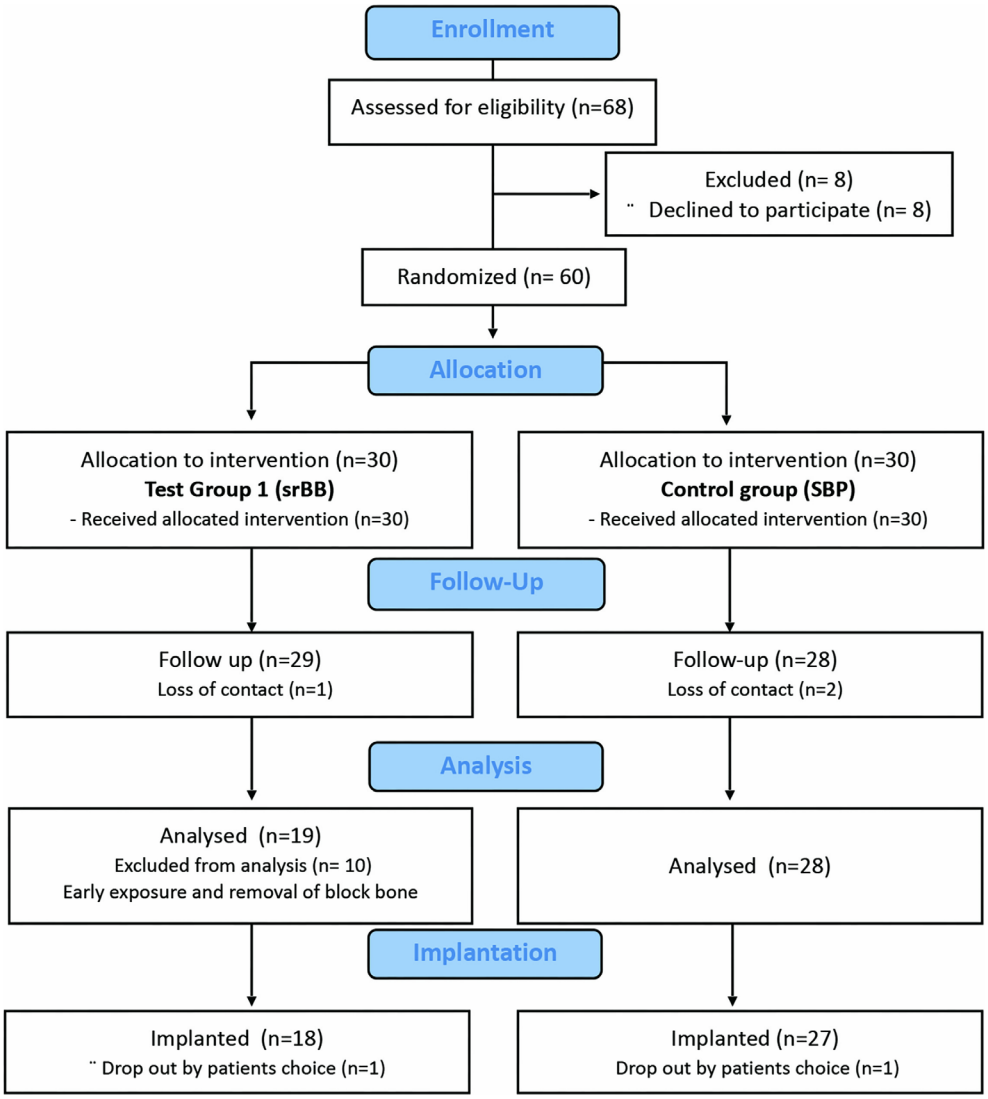

FIGURE 1 | CONSORT flow chart.

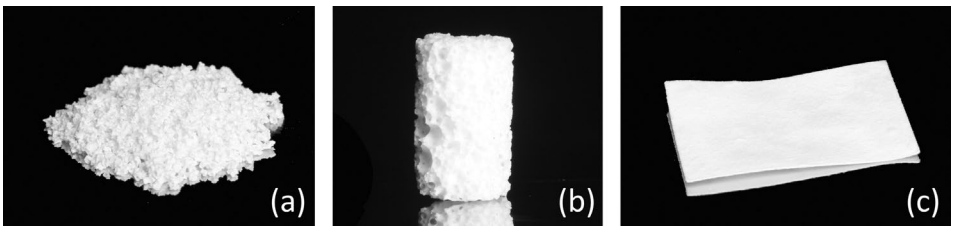

FIGURE 2 | Experimental materials. (a) Synthetic bone particles used in the SBP group. (b) Synthetic bone block used in the srBB group. (c) Porcine-derived resorbable collagen membrane used in both groups. SBP group: Alveolar ridge augmentation (ARA) using synthetic bone substitute particles and a collagen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

thylaminopropyl) carbodiimide (EDC) as the cross-linking agent (Figure 2c).

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

3.4 | Alveolar Ridge Augmentation

An infiltration anaesthesia using 2% lidocaine hydrochloride with 1:100,000 epinephrine was applied at the surgical site. Sulcular incisions were made around the tooth to be extracted and the neighbouring 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 3a,f). Upon group assignment, the following treatment was performed:

- **SBP group**: SBP was grafted into the extraction socket using a syringe (Figure 3b). Horizontally, SBP was grafted up to

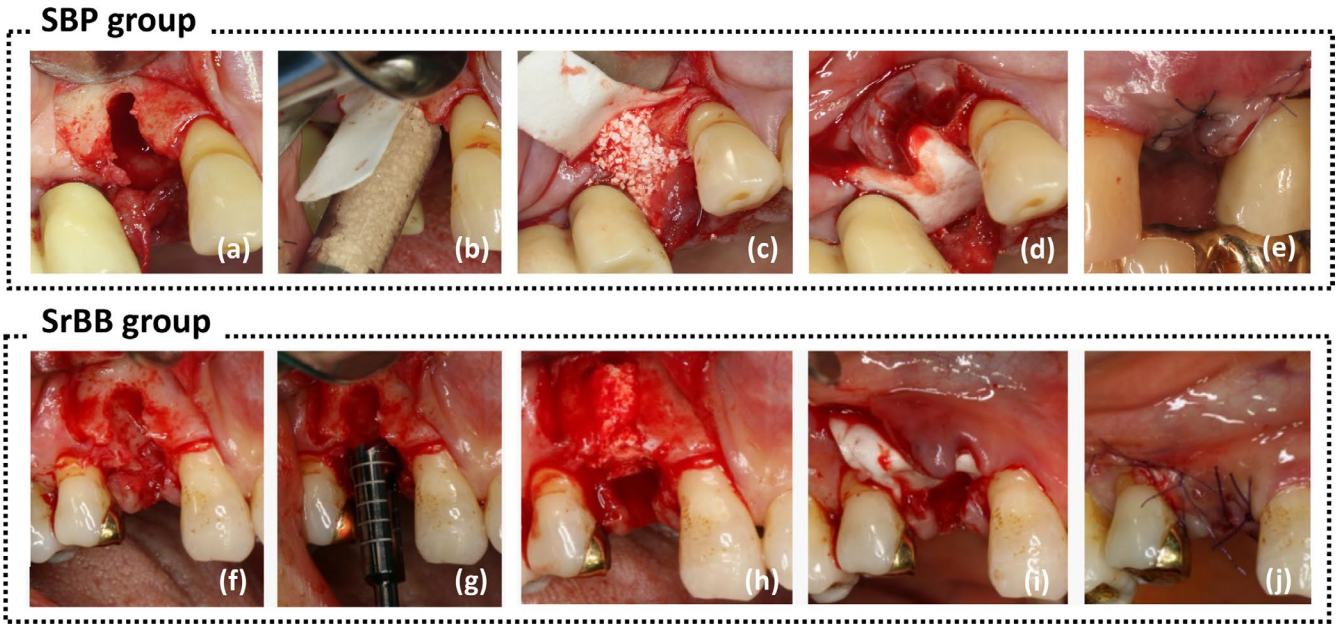

FIGURE 3 | Clinical photographs of ARA procedure of SBP (a–e) and srBB (f–j) groups. (a) After flap elevation. (b, c) Particulate bone grafting to the extraction socket. (d) Coverage with collagen membrane. (e) Primary suture of flap. (f) After flap elevation. (g) Extraction socket preparation with trephine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

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 3c).

- **srBB group**: the extraction site was drilled with a trephine bur to fit the cylindrical block bone (Figure 3g). The diameter of the trephine bur was slightly more than the mesiodistal length of the extraction socket. As the block bone was 8 mm in height, the depth of trephine preparation was matched to that height. The block bone with the same diameter as the trephine bur (Figure 3g) was gently inserted (Figure 3h). After fitting the block bone to the prepared bed, none of the blocks showed mobility. In some sites, small gaps were present between the block bone and adjacent bone walls (due to root length and extent of bone loss), but the stability of the block was not affected. No additional grafting was performed to the gaps. The detailed surgical protocol can be found elsewhere (Park et al. 2024). The outline of the augmented ridge depended on the shape of the cylindrical block bone. With respect to the neighbouring sites, this resulted in slight over-augmentation.

The grafted site was completely covered with the CM (Figure 3d,i). No additional pin fixation was used either group. The buccal flap was advanced using a periosteal releasing incision, and primary flap closure was performed (Figure 3e,j).

Sutures were removed 7–10 days after ARA. Patients were recalled at 1, 3 and 6 months post ARA. In case of adverse events, such as wound dehiscences, swelling or bleeding, additional visits were scheduled. Cone beam computed tomography (CBCT, Alphard 3030 device; Asahi Roentgen, Tokyo, Japan) was performed immediately after ARA (baseline; T0) and at 6 months post ARA (T1).

3.5 | Implant Placement

At 6 months post ARA, implant placement was performed. After local anaesthesia, a full-thickness flap was elevated, followed by osteotomy preparation and implant placement (Figure 4). When bony dehiscence, fenestration or a thin bone plate around the implant (< 1 mm) 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 month post implant placement.

3.6 | Postoperative Regimen

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

3.7 | Outcome Measures

The present study adopted the implant dentistry core outcome set and measurement (ID-COSM), proposed by Tonetti et al. (2023).

3.7.1 | Primary Outcome

- Horizontal ridge change between T0 and T1

3.7.2 | Secondary Outcomes

- Vertical ridge change between T0 and T1

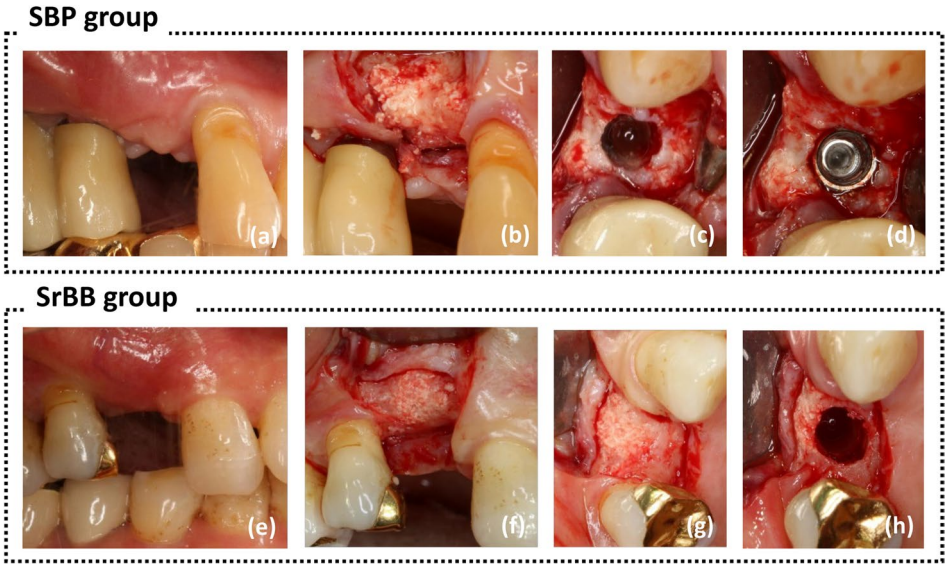

FIGURE 4 | Clinical photographs of SBP (a–d) and srBB (e–h) groups at 6 months post ARA. (a) Before flap elevation. (b) Lateral view after flap elevation. (c) Occlusal view after drilling. (d) Occlusal view after fixture implantation. (e) Before flap elevation. (f) Lateral view after flap elevation. (g) Occlusal view after flap elevation. (h) Occlusal view after final drilling. 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.

- 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
- 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

3.8 | Measurements

3.8.1 | Clinical Measurements

The defect size was measured using a periodontal probe up to nearest 1 mm, as follows (Figure 5a): (1) mesio-distal width, measured at the crestal level, (2) bucco-lingual width, that is, the distance between the imaginary intact socket wall (at the damaged wall) and the undamaged socket wall and (3) height between the imaginary intact crest and the most apical level of the damaged socket wall. The amount of bone substitute material used in ARA was recorded. Biological complications and wound dehiscences were evaluated at the recall visits.

3.8.2 | 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 neighbouring anatomical structures such as adjacent teeth and the cranial base of the maxilla/mandibular inferior cortex. The superimposed files were then manually checked.

On the superimposed images, the long axis of the extraction socket was identified. A vertical reference line (green line in Figure 5b) was drawn along the centre of the extraction socket. The horizontal reference line (blue line in Figure 5b) was drawn perpendicular to the vertical line at the apical point of the socket. For horizontal measurement, the crest of undamaged socket wall (H0; at T0) and five additional levels by incrementing 1 mm in an apical direction (H1, H2, H3, H4 and H5) were marked along the vertical reference line. At each level, the bucco-lingual horizontal width was measured (Figure 5b). For vertical measurement, outermost point (*op*), mid-crestal point (*mp*) and the 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 5c). The planes 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 the digital image-analysing software (SMOP, Swissmeda AG, Baar, Switzerland), followed by superimposition using fixed reference structures, such as neighbouring teeth. Subsequently, volume decrease at bucco-crestal area with ROI (5 mm × 5 mm) was measured. Volume decrease per standardized rectangular area (ROI) between T0 and T1 was calculated by the software and recorded.

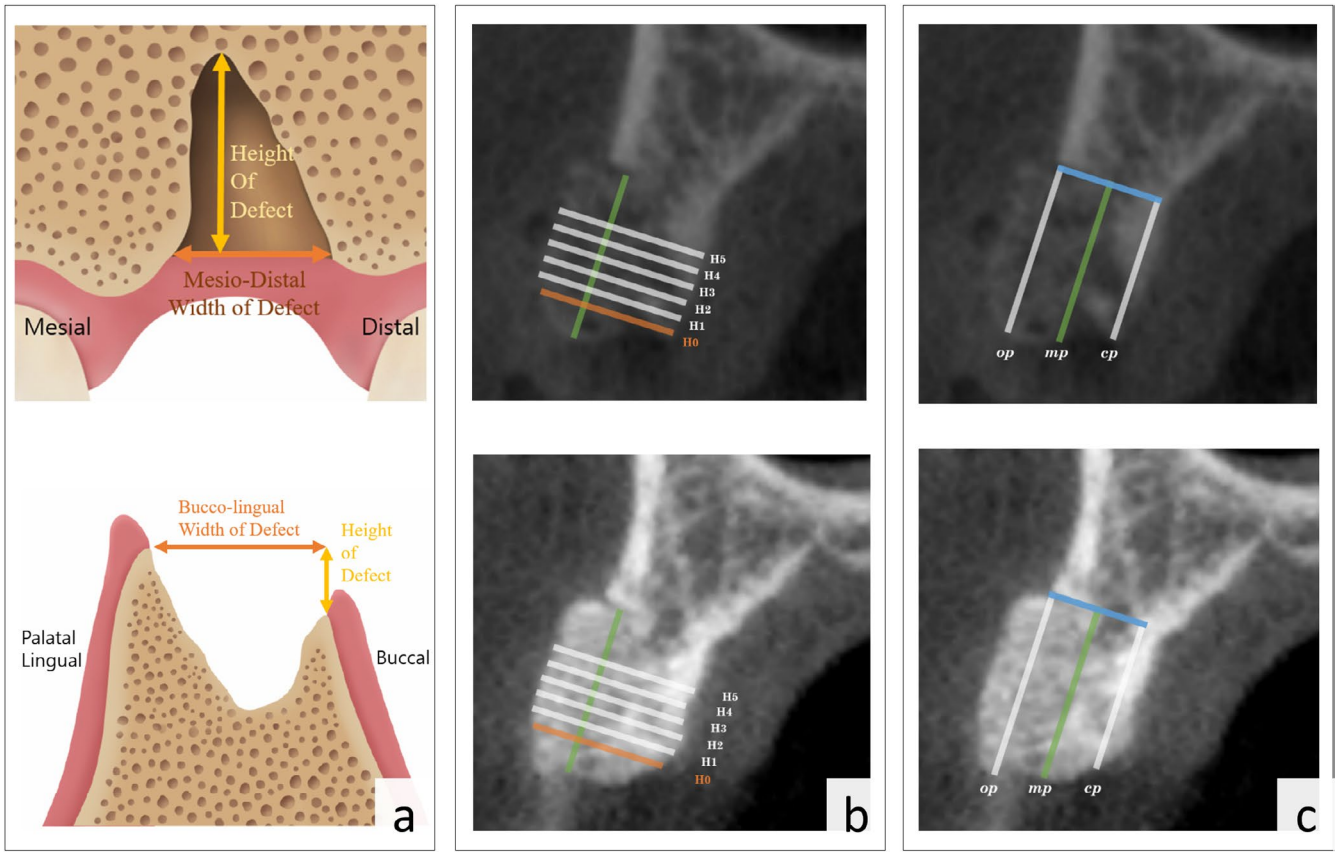

FIGURE 5 | Schematic images of the measurements. (a) Clinical measurements of bone defect. (b) Horizontal radiographic measurements. (c) Vertical radiographic measurements.

3.8.3 | 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 and (4) willingness to undergo the same surgery. Each item was evaluated using a Likert scale.

3.9 | Statistical Analysis

Data were statistically analysed using SPSS (version 26.0, IBM Corp., NY, USA). Mean ± standard deviation values for all parameters were calculated. Independent *t*-test and chi-squared test were applied to compare srBB and SBP value, and paired *t*-test was applied to compare T0 and T1 within srBB and SBP value. To evaluate the robustness of the primary outcome results, post hoc sensitivity analyses were carried out, incorporating multiple imputation as well as best case and worst case scenarios for missing data. Statistically significant difference was set at $p < 0.05$.

4 | Results

Sixty-eight patients were initially screened in this study, and finally 60 patients were included. The included patients were randomly assigned to the SBP ($n = 30$) and the srBB groups ($n = 30$). Three participants were lost during the follow-up period before implant surgery (two in the SBP group, one in the srBB group). Another two patients withdrew their consent for implant treatment, 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 10 patients in the srBB group. For those in the srBB group, additional recall visits were scheduled, and a 0.12% chlorhexidine gargle solution was further recommended to use. However, the exposed block bones were eventually removed. Further details for block bone removal are presented in Appendix 2. During implant placement, no detachment of the grafted block was observed.

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

4.1 | Demographic Information

Detailed information is presented in Table 1. Reasons for extraction were predominantly of periodontal nature. Tooth type and location were mostly premolar and maxilla, respectively. Differences between the two groups were statistically insignificant ($p > 0.05$).

4.2 | Clinical Measurements

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

TABLE 1 | Demographic information.

	srBB	SBP
Number of patients (*n*)	30	30
Sex		
Male	14 (47%)	17 (57%)
Female	16 (53%)	13 (43%)
Age, Mean ± SD	58.2 ± 10.5	62.0 ± 11.1
Reason for tooth extraction		
Perio. *n* (%)	23 (77%)	21 (70%)
Root fracture, *n* (%)	5 (17%)	4 (13%)
Others, *n* (%)	2 (7%)	5 (17%)
Tooth type		
Incisor, *n* (%)	12 (40%)	10 (33%)
Premolar, *n* (%)	18 (60%)	20 (67%)
Tooth position		
Maxilla, *n* (%)	19 (63%)	23 (77%)
Mandible, *n* (%)	11 (37%)	7 (23%)

Note: 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.

4.3 | Digital Measurements

4.3.1 | Linear Measurements

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 (0.8 ± 1.0 mm [10.7% ± 10.7%] vs. 1.9 ± 2.2 mm [31.3% ± 36.4%], $p = 0.03$). Sensitivity analysis of the impact of missing data in the srBB group revealed a similar trend when applying best case scenario and multiple imputations (Appendix 3). However, this stability in favour of the srBB group was no longer observed when applying the worst case scenario.

The final horizontal width at H0 was greater in the srBB group (6.4 ± 2.0 mm) than the SBP group (5.1 ± 3.3 mm) but without reaching a statistically significant difference ($p > 0.05$). At the remaining levels (H1–H5), the changes in horizontal width were smaller for the srBB group compared to the SBP group; however, the differences were not statistically significant ($p > 0.05$, Figure 6, Appendix 4).

All vertical height changes for *op, mp* and *cp* were smaller for the srBB group compared to the SBP group ($p > 0.05$, Figure 6, Appendix 4). Values between T0 and T1 were significantly different for both srBB and SBP for most horizontal and vertical measurements, except at H2 and H3 for the srBB group and at H2 for the SBP group.

4.3.2 | Volumetric Measurement

Within the ROI of STL files, the srBB group showed less volume decrease than the SBP group (3.2 ± 0.6 mm^3 vs. 10.4 ± 2.3 mm^3, $p < 0.05$). Moreover, the SBP group showed greater variability in between sites (Figure 6, Appendix 4).

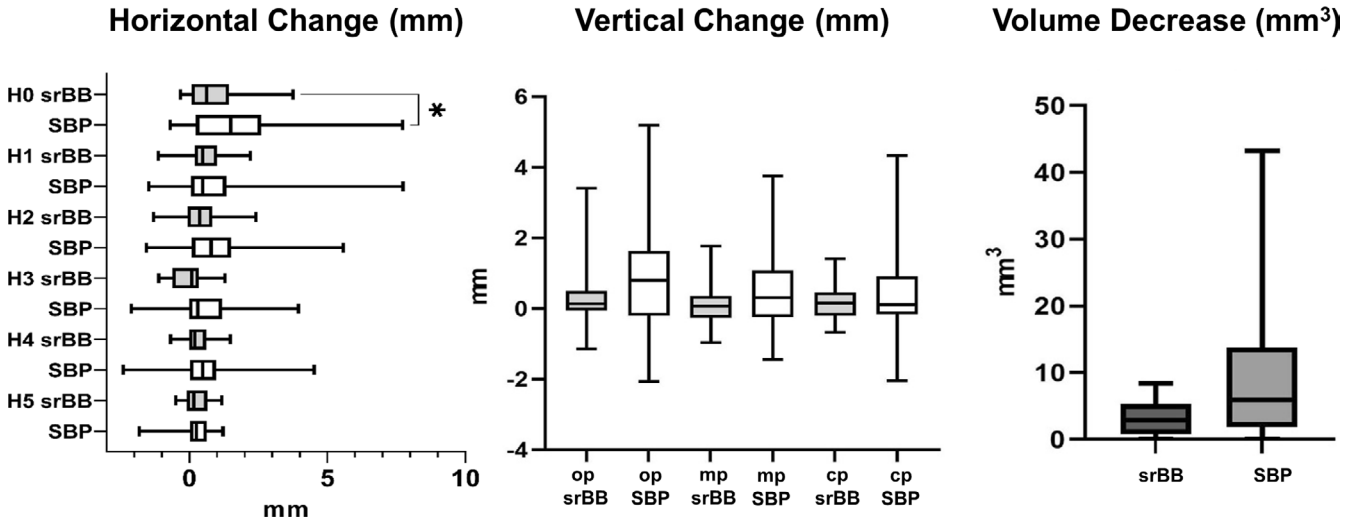

FIGURE 6 | Box plots of linear difference in horizontal width, vertical height reduction in alveolar ridge and volumetric decrease. The plots show first and third quartiles, and median indicated inside the box. The top and lowest points indicate the maximum and minimum of the data, respectively. Data are based on difference between CBCT measurement at baseline and at 6 months (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 ($p < 0.05$).

4.4 | PROMs

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 (Appendix 5).

4.5 | 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.

4.6 | Implant Survival

One implant each in both groups presented insufficient osseointegration during implant prosthetic treatment. Those two implants were removed and replaced with new ones after 2–3 months 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.

4.7 | Peri-Implant Clinical and Radiographic Parameters

No statistically significant differences were found between the groups in PPD, BOP or marginal bone level change (Appendix 6).

5 | 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 ARA or ARP 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 favourable 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 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 rigid fixation. So far, a 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 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.

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 preclinical 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 neighbouring dentition, which means that the facio-oral position was not necessarily at the centre 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 occlusiveness 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 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 favour of the srBB as shown in the sensitivity analysis. 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.

6 | Conclusion

srBB may offer greater space-maintaining capability in the coronal area of damaged extraction sockets than SBB. 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.

Author Contributions

Shinyoung Park contributed to data acquisition and data interpretation and drafted and revised the manuscript. Joo-Yeon Lee contributed to data collection. Jin-Young Park, Young Woo Song, Jae-Kook Cha and Seung-Yun Shin contributed to data acquisition and critically revised the manuscript. Franz J. Strauss contributed to data analysis and interpretation of the study. Daniel S. Thoma and Ronald E. Jung contributed to the conception of the study. Hyun Chang Lim and Ui-Won Jung contributed to conception, design, data acquisition and data interpretation of the study and critically revised the manuscript.

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Ethics Statement

This study was approved by the Institutional Review Board of Yonsei University Dental Hospital (2–2020-0043) and Kyung Hee University Dental Hospital (D20-016-003).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Appendix 1

Inclusion and Exclusion Criteria

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.

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;

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.

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.

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 buccooral width measured at the coronal level (primary outcome). Using the mean difference of 0.2 mm 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%, $\alpha = 0.05$ and drop-out rate =15%, 60 patients were recruited.

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 centre instructed the surgeons on the concept of using srBB and surgical protocol. Intercentre and intra-centre meetings were regularly held during the study period to check for any deviation from study protocols.

Justification of Multiple CBCTs

Even though CBCT scans (at a 6-month interval) were needed to answer the study question (the dimensional change post alveolar ridge

augmentation), radiation from radiographic examinations should be considered. Literature indicated that (1) the average radiation dose for a CBCT of the jaws taken for implant treatment is approximately 130 μSv, (2) the average dose for a CBCT is similar to having approximately nine panoramic radiographs (conservatively ~14 μSv), (3) the daily background radiation dose is approximately 8.2 μSv per day, indicating that the average dose from CBCT is similar to that received on the earth for approximately 16 days and (4) the radiation from a medical CT of the head (~860 μSv) is much higher than CBCT (Ludlow, Davies-Ludlow, and White 2008; Miles et al. 2004; Tyndall et al. 2012). Such points indicate that the frequency of CBCT in the present study was acceptable. Ethical committees approved CBCT examination at T0 and T1.

Appendix 2

Reason of Block Bone Removal

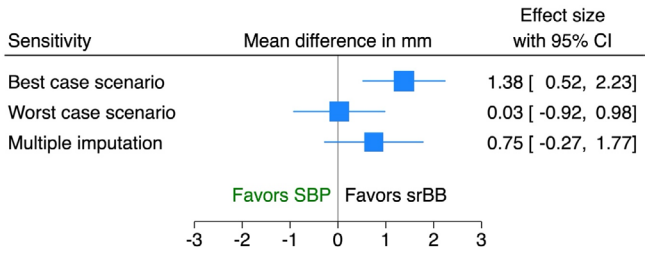
#	Reason for removal block bone in the srBB group
1	Early exposure of block bone.
2	Due to pinpoint pus discharge and infection of block bone, lower part of the block bone seemed integrated, yet upper part was infected. Infected area of block bone was removed.
3	Exposure of block bone.
4	Exposure of block bone.
5	Exposure of block bone.
6	Exposure of block bone.
7	Exposure of block bone.
8	Early exposure of block bone.
9	Exposure of block bone.
10	Exposure of block bone.

Note: srBB group: ARA using self-retaining synthetic block bone and a CM.

Appendix 3

Sensitivity Analyses for the Primary Outcome

Treatment effects for the primary outcomes using different imputation methods: best case scenario, worst case scenario and multiple imputation. Effect sizes are adjusted mean difference (95% CI). 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.



Appendix 4

Results From Linear Measurements and Volumetric Measurements

		srBB				SBP				
		T0	T1	Δ	%	T0	T1	Δ	%	*p*-value for Δ
Horizontal diameter (mm)	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
Vertical dimension (mm)	Grafted	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	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
	Pristine	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
Volume (mm^3)	Decrease	3.2 ± 2.7				10.3 ± 12.0				0.014
	Statistic on Signed Distances	0.6 ± 0.4				0.6 ± 0.4				0.617

Note: 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.

Appendix 5

Patient-Reported Outcome Measures

	srBB	SBP	*p*
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

Note: 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.

Appendix 6

Peri-Implant and Clinical Parameters

	srBB	SBP	*p*
Probing pocket depth (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 (between implant placement and 1 year thereafter)	−0.3 ± 0.7	−0.3 ± 0.7	0.983

Note: 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.