Long-term stable vertical bone regeneration after sinus floor elevation and simultaneous implant placement with and without grafting

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Abstract

Background: Less invasive surgical approaches to regenerate bone intra-sinus and allow long-term functional implant stability are needed.

Purpose: To evaluate long-term vertical bone regeneration after sinus floor elevation and simultaneous implant placement with and without bone grafting.

Methods: Vertical bone gains (VBG) post-sinus elevation, with and without grafting, were evaluated in thirty individuals presenting an average residual bone height (RBH) of 4.2 mm using a standardized digital technique. Measurements were taken preoperatively, and at an average of 64.6 months follow-up. Clinically, peri-implant tissues were assessed for pocket formation and presence of inflammation to evaluate established success criteria.

Results: Overall, RBH averaged 4.2 ± 1.1 mm (range: 1.8-5.8) and VBG 7.7 ± 1.6 mm (range: 6.0-12.9). Mean difference of 7.6 mm between vertical bone heights (VBH) at augmented implants sites and initial RBH, 11.8 versus 4.2 mm, (P < .0001, CI95%: 6.9-8.2) was statistically significant. RBH averaged 4.5 ± 0.8 mm and 3.8 ± 1.2 (P = .07) and VBG 6.8 ± 0.5 and 8.5 ± 1.9 mm (P = .003, CI95%: 0.6-2.7), for nongrafted and grafted individuals, respectively. The grafting group received an average graft volume of 0.35 ± 0.1 cc (range: 0.25-0.5) per implant site. Long-term follow-ups average 64.6 months (range: 36-144) and all implants met the success criteria. VBG ≥ 7 mm were 7.3 times more likely to develop on grafted sites (OR 5 7.3, P = 0.02, CI95%: 1.2-46.2).

Conclusion: None to negligible amounts of grafting material are required to regenerate substantial amounts of autogenous bone into atrophic sinus cavities after simultaneous implant placement. The regenerated VBH seems stable for functional implant stability long-term. Implant success rates were 100% at an average of 64.6 months.

KEYWORDS
bone grafting, bone transplantation, dental implant, maxillary sinus floor augmentation

1 | INTRODUCTION

Patients seeking implant rehabilitation of edentulous areas frequently present with deficient ridges and pneumatized sinuses. Hard and soft tissue reconstruction and sinus augmentation are often necessary for functional and esthetic implant rehabilitation. A variety of materials are available for bone grafting, including: intra- and extra-oral autologous bone, and bone substitutes such as allografts, xenografts, and alloplast. Intramembranous autologous bone transplants are considered the gold standard because they contain the appropriate concentration of specific growth factors and high concentrations of bone morphogenetic proteins for that particular individual.
Maxillary sinus cavities possess significant potential for bone regeneration without the use of additional bone grafts or bone substitutes due to the principle of periosteal guided bone regeneration and surrounding bony walls. Bone formation after membrane elevation without the use of grafting materials was described well over a decade ago; however, since then, mean reported vertical bone gains have been relatively low (3.8 mm) and wide ranging, 1.8-7.9 mm, indicating inconsistent outcomes. A less invasive crestal approach seems to deliver stable long-term augmentation outcomes in highly atrophic sinuses. Minimally invasive surgical approaches in sinus augmentation, such as eliminating the need of lateral window access or using minimal amounts of grafting material in large sinuses, would increase patient acceptance, and reduce morbidity, if stable long-term outcomes are successfully achieved.

Quasi-experiments are studies that aim to evaluate the associations between an intervention (eg, sinus floor elevation) and an outcome (vertical bone gain: VBG) without randomization. Similar to randomized trials, quasi-experiments aim to demonstrate causality between an intervention and an outcome. The present quasi-experimental study aimed to evaluate the stable 3–12 year long-term outcomes in vertical bone regeneration of a minimally invasive sinus augmentation technique, with or without grafting, and simultaneous implant placement, in patients presenting an average residual bone height (RBH) of 4.2 mm.

2 MATERIALS AND METHODS

2.1 Study population

This study was conducted in accordance to the requirements of the Helsinki Declaration of 1975 as revised in 2008. Patients were verbally informed about the surgical procedures and follow-up and gave their written consent. Ethical approval was obtained from the University of Basque Country as part of a doctoral thesis research project.

Patients requiring sinus augmentation for implant placement to restore masticatory function were recruited and followed from 2000 through 2016. They received either no grafting material (n = 14) or a negligible amount (0.35 cc average) per implant site (n = 16). A total of 30 consecutive patients with an average age of 64.5 ± 9.5 years entered the study after meeting the following inclusion criteria: healthy individuals with good oral hygiene and motivation, without systemic uncontrolled diseases or sinus pathology, or currently taking drugs known to modify bone metabolism, with a minimum of 1.5 mm of cortical RBH to achieve implant stability. The exclusion criteria eliminated: untreated periodontitis, poor oral hygiene, diabetes (HbA1C > 6.5%) as cutoff value according to the American Diabetes Association, uncontrolled cardiovascular disease, sinus pathology, or having received previous sinus augmentation. All patients received a full-mouth periodontal examination, oral hygiene instructions, and scaling prior to the augmentation procedure.

2.2 Sinus augmentation surgery

One experienced surgeon (FV) performed all surgical procedures. Patients received 500 mg of amoxicillin TID for one week starting the day prior to the surgery. Surgical procedures were conducted under local anesthesia. After a single crestal incision, a full thickness mucoperiosteal flap was raised to expose the crestal aspect of the alveolar process. A round tungsten carbide burr was used to mark the osteotomy site, and osteotomes were used thereafter to infracture the sinus floor. No drills were used to prepare the osteotomy site. Sinus floor elevation osteotomes Ø2.8-3.5-4.2 (Institut Straumann AG, Basel, Switzerland) were used to widen the osteotomy and lift the sinus floor to the desired height. The Schneiderian membrane was lifted by gently mallet tapping to elevate the sinus floor upwards. The Valsalva maneuver was used to evaluate the integrity of the membrane. Sinus cavities were grafted with either autogenous cortical bone particles, harvested with a bone scraper from adjacent sites, or lifted with the osteotomes without additional bone graft. The amount of cortical particulate bone harvested was on average 0.35 cc per implant site and was measured using a sterile graduated cylinder with 0.5 cc markings, as previously described. Dental implants were simultaneously inserted achieving primary stability in all cases, independent of the height of residual alveolar bone, by undersizing the crestal osteotomy. The main system used was the Straumann SLA SP/1.8 mm collar tissue level implant. The 4.1 x 11.5 mm were 3i Osseotite implants. All implants were one-stage. The implant length chosen (8–10-11.5 mm) was based on the clinician preference at the time and not on RBH or any other CBCT parameter. Impressions were taken at an average of 3–4 months after augmentation.

2.3 Radiographic evaluation

The radiographic assessment has been recently explained elsewhere. Briefly, standardized digital panoramic radiographs were obtained using a 3-point fixing system for the patient. The operator was instructed to position the patient biting a special device to ensure ideal chin and forehead position with the designated support system, as well as using light localizers for determining Frankfort and mid-sagittal planes. A 5° head sagittal tilting and a 5 mm forward/backward shifting does not significantly affect vertical measurements of the posterior maxilla provided that the reference lines are in the same vertical plane as the teeth or implants.

A CBCT was used to confirm RBH preoperatively, from the crestal cortical bone line to the sinus floor cortical bone line. Standardized digital panoramic radiographs were analyzed preoperatively and at final follow-up. Conventional panoramic radiographs were digitized by scanning them with a flatbed scanner for transparencies at 600 ppp resolution grayscale and measurements made in pixels using Adobe Photoshop CS4 software program. Linear measurements were taken by the same calibrated examiner. At follow-up postoperatively, three linear measures were taken for each augmented implant site (from the implant neck area in contact with crestal bone to the most apical extent of bone augmentation) at the mesial, distal, and mid-center areas and averaged to determine total vertical bone heights (VBH).
VG were calculated by subtracting RBH to VBH at follow-up. Marginal bone loss (MBL) was evaluated from periapical radiographs taken with the long-cone technique immediately after surgery and final follow-up (Figures 2 and 3). Karoussis and colleagues success criteria were evaluated, therefore, assessing absence of clinically detectable implant mobility, pain, or persistent subjective complaints, absence of recurrent peri-implant infection, no continuous radiolucency around the implant, no bleeding on probing with pockets over ≥5 mm, no suppuration, and after the first year of function the annual vertical bone loss was not greater than 0.2 mm.17

2.4 | Statistical analysis

Descriptive analysis of data was expressed as mean ± standard deviation and a commercially available software program (SPSS, version 14.0, SPSS Inc., Chicago, Illinois) was used to evaluate mean differences.
in VBG between grafted vs. nongrafted sites. The Student’s t test was used for paired observations to assess RBH and VBG. Significance of group comparisons for binary variables, within-subjects design, was determined by the McNemar’s and Fisher’s Exact test. The likelihood of grafted implants sites vs. nongrafted sites presenting VBG/C21 and 7.5 mm at follow-up was expressed as the odds ratio (OR). Box plot graphics were drawn to compare mean values between the two groups. Statistical significance (SS) was set at $P < .05$.

### RESULTS

#### 3.1 Descriptive and inferential analysis

From the total 30 patients entering the study, three dropped out within the first year due to unavailability, moving out of the area, or unwillingness to be part of a periodontal maintenance program. Inferential statistical analysis was conducted on 27 individuals. Table 1 displays the

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RBH, residual bone height before sinus augmentation; VBH, vertical bone height at follow-up; VBG, vertical bone gain (VBH-RBH); mm, millimeters; cc, cubic centimeters.
Table 2: Residual crestal bone height, vertical bone gain, and marginal bone loss at follow-up

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<th>RBH* (mm)</th>
<th>VBG* (mm)</th>
<th>MBL (mm)</th>
<th>Graft volume (cc)</th>
<th>Follow-up (months)</th>
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<td>8.5 ± 1.9 (6.3–12.9)</td>
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<td><strong>No grafting</strong> n = 14</td>
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<td>6.8 ± 0.5 (6.0–7.5)</td>
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<td>62.5 ± 32.5 (36–144)</td>
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Mean difference

- RBH: 0.7 CI 95%: 0.07–1.5
- VBG: 1.7 CI 95%: 0.6–2.7
- MBL: 0.1 CI 95%: 0.0–0.2
- Graft volume: 0.35 CI 95%: 0.25–0.5

P value (SS):

- OR*: P = .07
- VBG ≥ 7 mm: 7.3; P = .02 CI 95%: 1.2–46.2
- VBG ≥ 7.5 mm: 43.3; P < .001 CI 95%: 3.8–481.8

*Mean ± SD (range). RBH, residual bone height before sinus augmentation; VBG, vertical bone gain in millimeters (mm) at last follow-up; MBL, marginal bone loss in mm; cc, cubic centimeters; P value, statistically significant (SS) for Fisher’s Exact Test and independent T-test. **OR, odds ratio = likelihood of obtaining ≥7 and 7.5 mm of VBG for grafted sites versus nongrafted sites.

3.2 | Residual bone height versus vertical bone gains in grafted and nongrafted groups

Overall, RBH averaged 4.2 ± 1.1 mm (range: 1.8–5.8) and VBG 7.7 ± 1.6 mm (range: 6.0–12.9). RBH mean difference of 0.7 mm between grafted and nongrafted groups was not SS (P > .05). The 7.6 mm mean difference between vertical bone heights (VBH) at augmented implants sites and initial RBH, 11.8 versus 4.2 mm, (P < .0001, CI95%: 6.9–8.2) was statistically significant. RBH averaged 4.5 ± 0.8 mm and 3.8 ± 1.2 (P = .07) and VBG 6.8 ± 0.5 mm and 8.5 ± 1.9 mm (P = .003, CI95%: 0.6–2.7), for nongrafted and grafted individuals, respectively.

3.3 | Graft volume and vertical bone gains

The grafting group received an average graft volume of 0.35 ± 0.1 cc (range: 0.25–0.5) per implant site. VBG ≥7 mm were 7.3 times more likely to develop on sites receiving an average of 0.35 cc of autogenous grafting (OR = 7.3, P = .02, CI95%: 1.2–46.2) and VBG ≥7.5 mm 43 times more likely (OR = 43.3, P < .0001, CI95%: 3.8–481.8). The VBG at final follow-up, apical to the implant apex, was on average 2.04 ± 1.0 mm.

3.4 | Marginal bone loss and success criteria

Routine radiographs showed that after the first year of implant function vertical bone loss did not exceed 0.2 mm interproximally. No radiolucencies were present around the implants. Two out of the 30 study patients had no history of periodontitis. Two noncompliant past history of periodontitis patients (two implants) developed localized 6 mm facial and palatal pockets at months 84 and 72 and were successfully treated with osseous surgery. Only osteoplasty around the affected implants, to remove thick facial ledges and lingual exostosis, was performed eliminating the existing circumferential defects without grafting. The exposed implant threads were decontaminated using titanium micro-brushes and curetts, and a combination of sterile saline, 3% hydrogen peroxide, 5% povidone iodine, and finishing again with sterile saline. At final follow-up, the implants were stable, with absence of inflammation or further bone loss, and probing depths ≤3 mm. Karoussis success criteria confirmed 100% implant success. MBL, at final follow-up, average 0.8 ± 0.7 and 0.9 ± 0.6 mm for grafted and non-grafted groups, respectively (P > .05). At an average of 64.6 months all implants met the success criteria. A CBCT was taken on three individuals requiring more implants over 3 years after initial sinus augmentation. VBG measurements confirmed stable vertical augmentation (Figure 1).

4 | DISCUSSION

The outcome analysis of the present clinical quasi-experimental study shows the predictability of a minimally invasive sinus augmentation crestal approach and simultaneous implant placement with and without grafting on atrophic sinuses using mainly 8–10 mm long implants. The regenerated VBG seems stable for functional implant stability. This raises the question of how much bone regeneration and grafting is necessary for long-term functional implant stability? Do we need to graft at all? The authors’ biological rationale for using small amounts of autogenous bone comes from its potential to induce new bone formation. In addition to the release of growth factors, research has shown that, in as little as 9–10 days, human cortical bone particles will start shedding osteoblast, creating a layer of osteoblastic confluence in approximately 4–6 weeks, plausibly enhancing, and shortening osseous healing. This also explains the significantly greater VBG achieved in the grafting group (Table 2) and, thus, makes biological sense. VBG ≥7 mm
were 7.3 times more likely to develop on grafted sites (OR = 7.3, \( P = 0.02 \)). Implant length may be a factor in achieving greater VBG due to the tenting effect and space maintenance for bone regeneration under the sinus membrane, however, the present study does not allow for such an analysis due to the limited sample.

Although there is no histological evidence of osseointegration within regenerated bone, the present study shows radiographic evidence of bone formation. It would be unlikely, after 65 months in function, to still present functional implant stability with only 4 mm of RBH, some as little as 1.8 mm, mainly due to the high likelihood of mechanical failure. More implant failures would be expected if the implants had been supported by only the RBH and not by the regenerated bone as well. Primary stability was achieved by undersizing the crestal osteotomy, thus making the cortical RBH the source of implant stability, not the implant thread design.

None to negligible amounts of grafting material were used to regenerate substantial amounts of autogenous bone intra-sinus after simultaneous implant placement. The new VBH seems stable for functional implant stability long-term, and implant success rates were 100% at an average of 64.6 months. If a clinical decision of sinus grafting is reached, the amount of autogenous bone needed to augment any given site is, on average, 2–4 times less than the pre-surgical CBCT sinus volume calculation, considering that the volume of a 4.1 x 11.5 mm implant is 1.25 cc. The authors used only an average of 0.35 cc per implant site, 3.6 times less than the volume occupied by the implant itself. If we add an extra 1.5 mm of surrounding bone to the perimeter of a 4.1 x 11.5 mm implant, the volume would increase to 3.8 cc. Well over 2 mm of surrounding regenered bone was achieved in all cases (Figures 1–3). The principle of periosteal guided bone regeneration, with the elevated Schneiderian membrane acting as the new ceiling and surrounding bony walls, plausibly boosts new bone formation.9 Elevating the membrane alone creates a space that allows de novo bone formation.8

Recent meta-analysis on graft-free sinus elevation shows that mean vertical bone gains are low (3.8 mm) and the wide range of vertical gains, 1.8–7.9 mm, implies inconsistent outcomes.10 Intra-sinus bone gain occurs primarily during the first 3 years after sinus elevation and seems to stabilize over time.11 The present study overall mean VBG of 7.7 ± 1.6 mm, 8.5 ± 1.9 for the grafted group, at approximately 65 months indicates predictable and stable long-term outcomes. Similar 10-year stable outcomes on a group of 15 patients with mean RBH of 5.4 ± 2.3 and intra-sinus bone gain of 3.0 ± 1.4 have been recently reported.11 None of the 17 implants placed in RBH ≤4.8 mm failed in the present study. All implants were clinically stable at final follow-up. No patient complained of pain, and there were no signs of suppuration. Multicenter retrospective research has shown that RBH under 4 mm seem to negatively affect implant survival rates decreasing to 85.7% when a grafting biomaterial was used.19 Meta-analysis research has shown implant survival rates of 94.2% and 97.2% with RBH of <5 mm and ≥5 mm, respectively, when no grafting was performed.20 However, minimal RBH ≤4 mm has not been shown to decrease implant success rates or increase MBL.21 Success rates, using β-tricalcium phosphate or autogenous grafting, were 100% for RBH ≤4 mm and 98.51% for >4 mm at 6–100 months postloading.21 The present study also concurs with the aforementioned study in that outcomes were independent of age and gender. A group of 45 patients, 180 implants, receiving osteotome sinus floor elevation with and without grafting, using β-tricalcium phosphate and deproteinized bovine bone, with mean RBH of 6.59 ± 0.45 mm, has shown 100% implant success after 2 years.22 The authors concluded that the bone gained inevitably and significantly shrinks regardless of the biomaterial used.22 The present VBG, with and without grafting, emphasizes the long-term stability of VBH with minimal shrinkage, particularly, when autogenous cortical bone was used. The CBCT cross-sections further confirmed such VBG in the most severe clinical scenario of sinus atrophy (Figure 1).

Patients with history of periodontitis are 8.4 times more likely to present >2 mm of MBL.16 Therefore, regular periodontal maintenance is key to sustain a healthy ecological balance and detect early signs of inflammation.23 A personalized 3-month supportive therapy may help prevent risks by sustaining ecological symbiosis, decreasing specific pathogen proportions and maintaining ideal plaque control.23

Out of the 30 individuals treated in the present study, only two had no history of periodontitis. Two patients with past history of periodontitis (two implants) developed localized 6 mm facial and palatal pockets at months 84 and 72 and were successfully treated with pocket reduction/osseous surgery. These two patients had missed several maintenance appointments over a 2-year period and were deemed noncompliant. At final follow-up, the implants and adjacent teeth were stable, with absence of inflammation or further bone loss and probing depths ≤3 mm.

The present study supports the concept of a minimally invasive sinus augmentation crestal approach with and without grafting and simultaneous implant placement in patients with atrophic sinuses and reduced RBH <5 mm. Further research is needed to understand the craniofacial regeneration paradigm through our own skeletal progenitor and stem cells. The potential for osseous regeneration through periosteal-guided bone regeneration can boost such a model and should not be underestimated or overlooked.7

5 | CONCLUSIONS

None to negligible amounts of grafting material are required to regenerate bone into atrophic sinus cavities after simultaneous implant placement. The regenerated VBH seems stable for functional implant stability long-term, at an average of 64.6 months.

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REFERENCES


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