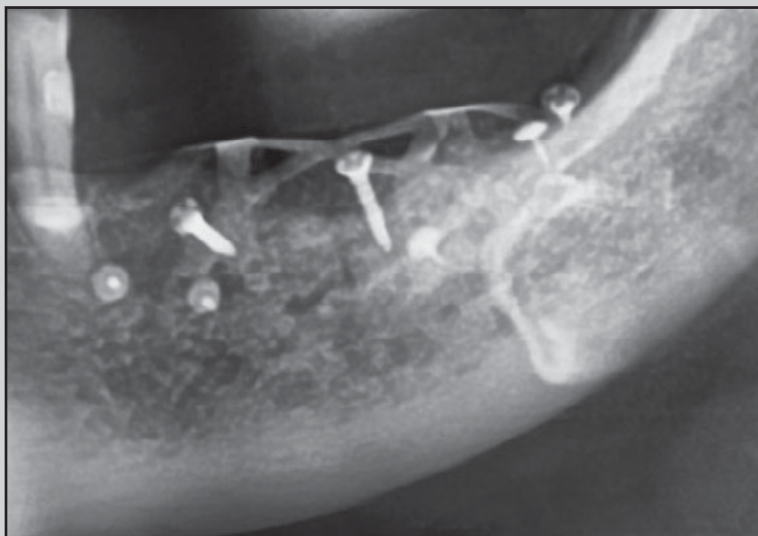
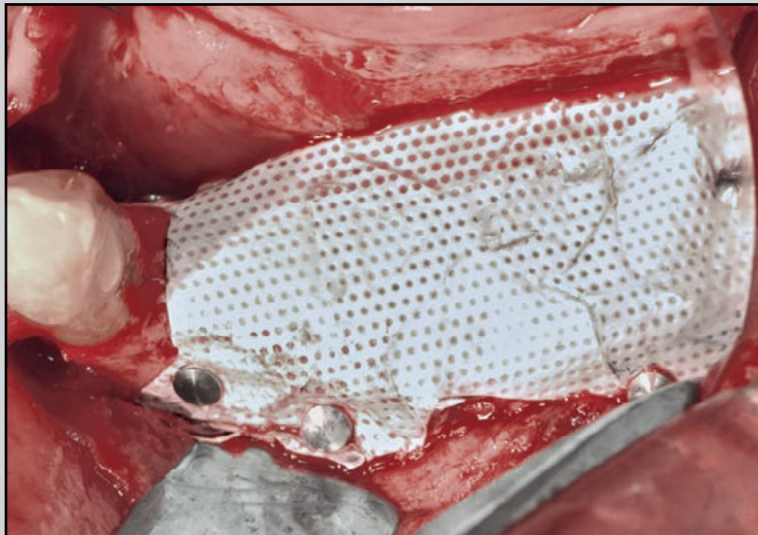
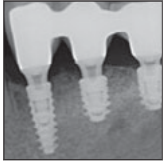




Guided Bone Regeneration with Nonresorbable Membranes in the Rehabilitation of Partially Edentulous Atrophic Arches: A Retrospective Study on 122 Implants with a 3- to 7-Year Follow-up



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The aim of this retrospective study was to evaluate clinical and radiographic outcomes of guided bone regeneration (GBR) procedures in the rehabilitation of partially edentulous atrophic arches. A total of 58 patients were included with a follow-up of 3 to 7 years after loading. Data seem to indicate that GBR with nonresorbable membranes can be a good clinical choice and suggest that it could be used to vertically reconstruct no more than 6 mm of bone in the posterior mandible. However, this technique remains difficult and requires expert surgeons. Int J Periodontics Restorative Dent 2020;40:685–692. doi: 10.11607/prd.4522

Tooth loss and edentulism often bring negative repercussions. The missing dentition can be replaced by removable dentures, which may not always be appreciated by patients. Implant-supported fixed prostheses have become a well-established treatment option in order to rehabilitate patients with partial or total edentulism. However, the limiting factors for implant placement are insufficient bone height and/or width that are often needed for bone augmentation procedures.^{1–5} Various techniques have been proposed and widely used to augment bone vertically and horizontally, but it is still unclear which methods are the most efficient.¹

Guided bone regeneration (GBR) was firstly proposed by Dahlin et al in 1988 in order to reconstruct bone by using grafts and barriers to allow mechanical exclusion of undesirable soft tissue, favoring osteogenic cells to grow into the osseous defect.⁶ Four fundamental elements necessary for successful GBRs were later proposed by Wang and Boyapati in 2006 and named PASS principles: Primary wound closure, Angiogenesis, Space maintenance, and Stability of the clot.⁷ Nowadays, GBR has become a treatment option to provide support for osseointegrated implants.^{8–10} Nevertheless, GBR remains a potential challenge due to the complexity of the tech-

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nique and because of the need for experienced operators, especially in managing complications. Results from the literature are encouraging, but little data exist about the long-term stability and resorption of the augmented bone. In addition, very limited available data indicate how much bone it is possible to regenerate with success and with an acceptable complication rate.^{1,11,12}

The aim of this study was to evaluate clinical and radiographic outcomes of GBR procedures in the rehabilitation of partially edentulous atrophic arches with a 3- to 7-year follow-up, with a special focus on trying to evaluate a possible threshold on maximum vertical bone gain, especially in the posterior mandible.

Materials and Methods

A retrospective chart review was conducted. Patients were treated by two expert surgeons (R.P. and P.F.) and had to fulfill the following inclusion criteria: pre-existing partial edentulism, bone atrophy treated with GBR (one- or two-stage implant positioning approach) performed with nonresorbable membranes and with at least 3 years of follow-up. Smokers were included and divided into three groups: nonsmokers, moderate smokers (up to 10 cigarettes per day), and heavy smokers (more than 10 cigarettes per day). Patients received thorough information about the surgery and signed a specific written consent form. This retrospective study was approved by the Ethical Committee Board (Prot. N. 347/18).

Surgical Procedures

Prior to GBR reconstructive surgery, all treated patients received antibiotic prophylaxis with a following postoperative long-course therapy. Surgeries were performed under local anesthesia.

Flap design was made to ensure a primary tension-free closure. A midcrestal incision was made in the posterior mandible, reaching the proximity of the retromolar pad. Subperiosteal detachment was then made on the lingual side with the help of the digitoclastic technique, used to coronally displace the lingual flap.¹³ On the vestibular side, the flap was carefully raised to disclose the neurovascular bundle in the mental foramen area, and a periosteum incision was made with the tip of a scalpel in order to elongate the flap. In the maxilla, a paracrestal buccal incision was made in order to obtain a longer palatal flap, and flap elongation approaches were made only buccally. In the posterior maxilla, sinus elevation surgeries were performed when necessary before GBR bone augmentation.

In the one-stage approach, implants were placed after releasing flaps. The recipient bone bed was prepared with multiple cortical bone perforations to obtain the activation of the regional acceleratory phenomenon favoring blood supply.¹⁴ Perforations were performed after the collection of the autologous bone using a safescraper. A 1:1 mixture of particulate autogenous bone and of bovine-derived xenograft (Bio-Oss, Geistlich) was used. Polytetrafluoroethylene titanium-reinforced non-

resorbable membranes (Cytoplast, De Ore) were used. The membrane was adapted and fixed first on the lingual/palatal side using osteosynthesis screws. At this point, the graft was placed on the defect and the membrane was then fixed on the buccal side with titanium pins. Membrane contact with neighboring teeth was carefully avoided. In the two-stage approach, tenting screws were used when needed. At the end, flaps were closed using nonresorbable sutures.

Nonsteroidal analgesics and cortisone were administered. Post-surgical instructions included a soft diet and appropriate oral hygiene, avoiding brushing and trauma at the level of the surgical sites. Patients were instructed to rinse with a 0.2% chlorhexidine mouthrinse twice a day for about 2 weeks. Sutures were removed about 14 days postoperatively. Antibiotic therapy with amoxicillin (1 g) and clavulanic acid three times a day for 8 days and metronidazole (250 mg) twice a day for 6 days were prescribed. All patients were recalled for additional postoperative checkups and registered in a maintenance hygiene program.

In the two-stage approach, nonresorbable membranes were removed by a second surgery at least 9 months after vertical augmentation. In the one-stage approach, nonresorbable membranes were removed ideally 7 months after vertical augmentation and replaced with collagen membranes (Medicipio C Collagen Fleece, De Ore). After another 2 months, the implants were exposed.

In the two-stage approach, implants were placed after the removal of the membrane, left submerged, and exposed 4 months later.

In both one- and two-stage approaches, temporary progressively loaded acrylic prostheses were delivered 3 to 4 weeks after implant exposure. Definitive prostheses were delivered 6 months later. If necessary, soft tissue grafts were utilized at the implant exposure surgery.

Outcome Measures

The outcomes measures were biologic complications; implant failures (implant mobility and/or removal of stable implants due to marginal bone loss or infection); prosthetic failures (planned prostheses that were not placed due to implant failure or GBR failure, loss of the prosthesis secondary to implant failure, and prosthesis replacement for any reason); vertical mean bone gain evaluated only in the posterior mandible (by measuring the distance between the upper border of the crestal bone before bone reconstruction and the upper edge of the crestal bone at the second surgical stage on computed tomography scans using the OsiriX software [Pixmeo]); horizontal mean bone gain evaluated only in the posterior mandible (by measuring the perpendicular linear distances between the more coronal-lingual/palatal points and the more coronal-vestibular points of the crestal bone on computed tomography scans); peri-implant marginal bone level changes (evaluated on radiographs using the

OsiriX software, calibrated with the known implant length, at implant placement and at 1, 3, 5, and 7 years after loading); and keratinized tissue (KT) height, measured (in mm) with a periodontal probe at baseline and categorized as < 2 mm or ≥ 2 mm.

Statistical Analysis

Data were summarized using frequencies, means, and standard deviations. The patient was the statistical unit of the analyses. With regard to dichotomous outcomes, Fisher exact probability test and chi-square test were used. To detect any changes in peri-implant marginal bone levels and to compare bone height and width at baseline and before membrane removal, dependent t tests were used. With regard to continuous outcomes, Mann-Whitney U and Kruskal-Wallis tests were used. All statistical analyses were conducted using SPSS (IBM). $P < .05$ was set as the level for statistical significance.

Results

A total of 58 GBR procedures with nonresorbable membranes were taken into consideration, and 122 tapered implants with an internal connection (In-Kone, Global D) were placed. Of the procedures, 31 (53.4%) were performed in the maxilla (17 in the posterior area) and 27 (46.6%) in the mandible (23 in the posterior area) (Figs 1 and 2). All 58 patients had a follow-up of 3 years, 38 patients had a follow-up of 5

years, and 28 patients had a follow-up of 7 years.

Mean patient age at the time of the first surgery was 57.16 years, and 69% were women. Seventeen patients (29.3%) were smokers. The mean timeframe between membrane positioning and membrane removal was 9.17 months. KT at baseline was < 2 mm in 30 cases (51.7%) and ≥ 2 mm in 28 cases (48.3%). Twenty-four cases were grafted with autogenous soft tissue grafts. The main baseline patient and intervention characteristics are presented in Table 1.

The healing was uneventful, and no complications occurred in the majority of patients (40 patients). Regarding adverse events, 18 patients experienced one (16 patients, 88.9%) or two complications (2 patients, 11.1%). Twelve cases of temporary paresthesia, lasting from 1 to 8 days, occurred after the augmentation procedure with full recovery. In addition, 4 (6.9%) premature exposures of the membrane to the oral environment were reported. Moreover, 2 implants and consequently the prosthesis failed in the same patient (survival rate: 98.4%) (Table 2). In 3 cases, membranes became exposed in the middle after their placement (between 5 weeks and 5 months), so they were removed; a resorbable collagen membrane (Medicipio C Collagen Fleece) was placed, promoting second-intention healing. Patients then underwent the standard rehabilitation protocols uneventfully. The remaining middle exposure was seen 3 weeks after bone augmentation and was very small, so it was checked and

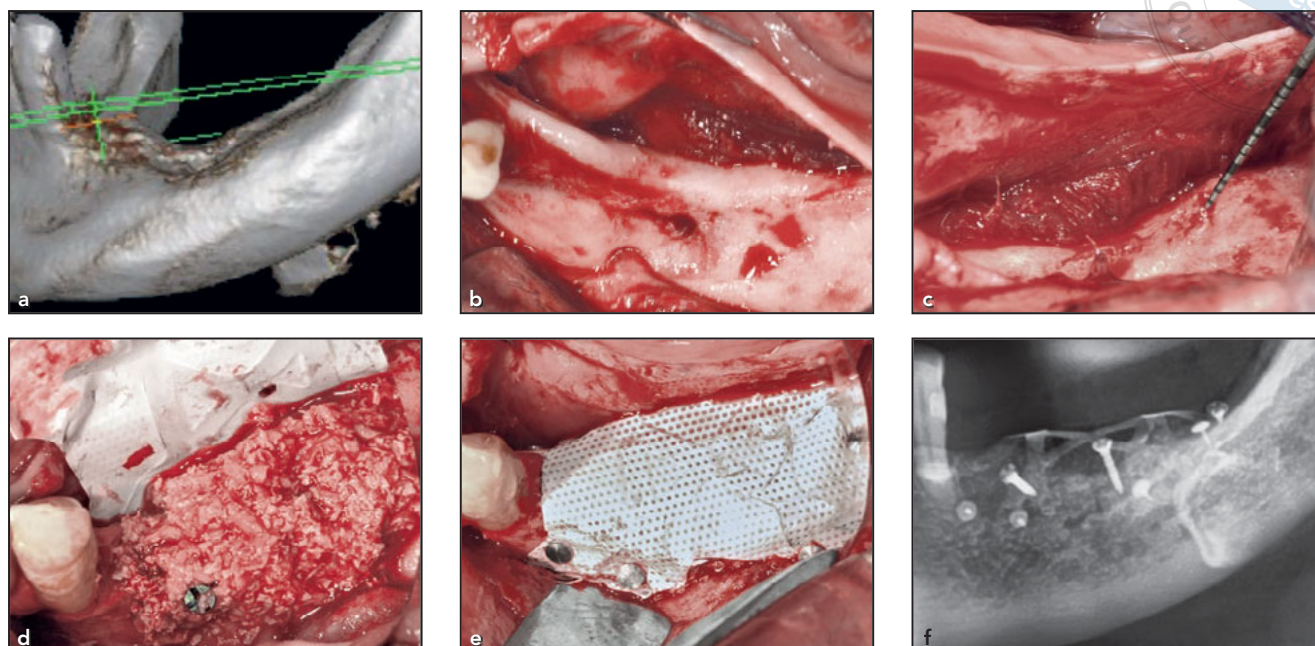


Fig 1 Two-stage GBR procedure in a posterior atrophic mandible. (a) Three-dimensional preoperative computed tomographic view before membrane-positioning surgery. (b) Flap elevation. (c) Lingual flap elongation. (d) Lingual membrane fixation and placement of a 1:1 ratio of autogenous and heterologous bone chips. (e) Nonresorbable membrane placed and fixed vestibularly. (f) Postoperative orthopantomogram after membrane positioning.

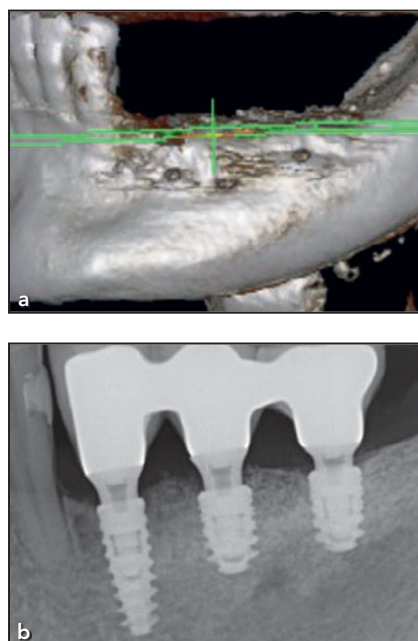


Fig 2 Two-stage GBR procedure in a posterior atrophic mandible. (a) Three-dimensional computed tomographic view after 9 months healing, before membrane-removal surgery and implant positioning. (b) Radiographic view 7 years after loading.

Table 1 Patient and Intervention Characteristics

Women, n (%)	40 (69.0%)
Age (y) at recruitment, mean $\pm$ SD	57.16 $\pm$ 11.08
Smokers, n (%)	17 (29.3%)
Smoking $\leq$ 10 cigarettes	13 (22.4%)
Smoking $>$ 10 cigarettes	4 (6.9%)
Maxillae, n (%)	31 (53.4%)
Mandibles, n (%)	27 (46.6%)
Implants, n	122
Months before membrane removal, mean $\pm$ SD	9.17 $\pm$ 2.11
Follow-up, n	
3-y patients	57
5-y patients	38
7-y patients	28

Table 2 Main Complications

Membrane exposures, n (%)	4 (6.90%)
Implant failures, n (%)	2 (1.64%)
Prosthetic failures, n (%)	1 (1.72%)

Fig 3 Failure of a one-stage GBR procedure in a posterior atrophic mandible. (a) The patient never came to the clinical checks after suture removal, and an orthopantomogram taken 11 months after membrane positioning shows bone resorption due to an infection. (b) Orthopantomogram taken 5 years after loading. The case was treated using a 4-mm supershort implant placed in the residual bone in the zone of the previous infection.

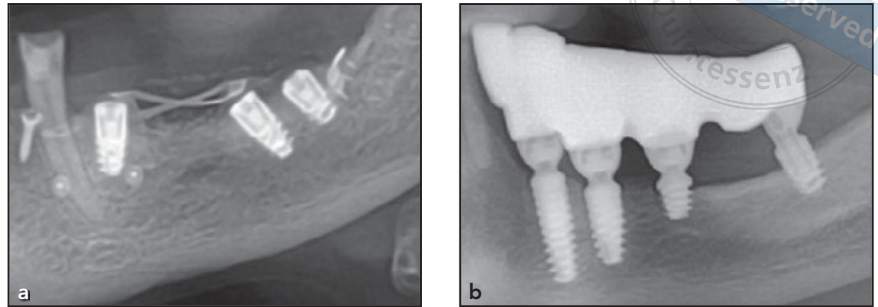


Table 3 Mean Bone Gain in the Posterior Mandible

	Bone height, mm	Bone width, mm
T0, mean $\pm$ SD	6.29 $\pm$ 1.99	6.62 $\pm$ 2.44
T1, mean $\pm$ SD	12.32 $\pm$ 1.40	8.03 $\pm$ 1.45
T1 – T0, mean $\pm$ SD (95% CI)	6.03 $\pm$ 1.90 (5.21, 6.85)	1.40 $\pm$ 1.37 (0.81, 2.00)

T0 = baseline before reconstructive surgery; T1 = before membrane removal; CI = confidence interval. Measurements were made on computed tomography scans.

decontaminated every week, and the patient was also instructed to use a 1% chlorhexidine gel twice a day. After 5 weeks, the nonresorbable membrane was removed and replaced by the resorbable one. The patient was then treated with the standard protocol. In 1 case, an infection occurred in the posterior mandible 11 months after surgery (the patient never came to the clinical visits after suture removal). The graft, the membrane, and two of the three one-stage implants were removed; 1 implant (located more distally) was stable and it was maintained. After 1 year, the patient was rehabilitated with an implant-supported prosthesis using a 4-mm supershort implant exploiting the little residual bone left (Fig 3). In 3 patients, at the removal of the membrane, vertical bone gain was not sufficient to place standard-length implants as planned, so shorter implants were used.

A statistically significant difference was found in the number of patients with complications (14 complications in patients with bone height increase > 6 mm, $P = .046$) and paresthesia when the bone height increase was > 6 mm in the posterior mandible ($n = 9$ patients; 3 had an increase ≤ 6 mm; 75% vs 25%; $P = .039$). Smoking habits were found to be unrelated to complications ($P = .693$).

Mean residual bone height and width before reconstructive surgery in posterior atrophic mandibles were 6.29 ± 1.99 mm and 6.62 ± 2.44 mm, respectively. Mean vertical bone height before membrane removal was 12.32 ± 1.40 mm with a mean increase of 6.03 ± 1.90 mm (95% confidence interval [CI]: 5.21 to 6.85 mm). Mean bone width after reconstructive surgery was 8.03 ± 1.45 mm with a mean increase of 1.40 ± 1.37 (95% CI: 0.81 to 2.00 mm) from baseline (Table 3).

At 1 year after loading, the marginal bone loss was 0.72 ± 0.36 mm. At 3, 5, and 7 years after loading, implants gradually lost statistically significant marginal peri-implant bone: 1.27 ± 0.62 mm, 1.55 ± 0.82 mm, and 1.72 ± 1.03 mm, respectively.

Discussion

Treatment of partially edentulous atrophic arches with GBR procedures in order to augment bone vertically and/or horizontally allowing for conventional-length implant placement is a well-documented procedure.^{8–10,15}

However, the authors found that the literature is still missing long-term follow-ups of a large number of patients with advice and data on the maximum bone increase that can be attempted with current non-resorbable membranes.^{1,11,12}

In the present study, four membrane exposures (6.90%) occurred. This rate seems to be lower than percentages reported in the literature, and all the exposures were small (< 3 mm), central, and did not interfere with the final result. This approach, as stated in the literature, can be associated with relatively high complication rates.^{1,16,17} A systematic review on the use of non-resorbable membranes for vertical ridge augmentation by Rocchietta et al encountered a range of complications with a frequency of up to 45.5%.¹² A membrane-exposure event can have a significant detrimental influence on the final outcome. In the present study, the good exposure-rate results could be explained by considering the mean vertical increase of 6.03 mm, which is lower than in other studies; this could have led to less tension on the flaps and a better blood supply to the coronal bone chips than seen in vertical increases up to 12 mm described in the literature. However, bone peaks should be always taken into consideration when planning a GBR, and the successful large vertical increases reported in the literature could be considered limited to those performed by talented and experienced surgeons and cannot be generalized. Moreover, in the posterior mandible, the present authors detected more complications in cases of vertical increases > 6 mm. This is probably because the limited access and poor blood supply in this area contribute to more complications.¹⁸ Further, paresthesia cases were linked with a vertical increase > 6 mm, possibly because of the

severity of the baseline bone atrophy with an inferior alveolar nerve more towards the surface.

If a membrane exposure occurs in the middle 5 weeks after bone augmentation, as in the majority of the cases reported in this study, the authors advise (based on their experience) to remove it in order to avoid any kind of bone contamination, followed by placing a resorbable membrane with second-intention healing. The following steps and healing timeframes are basically the same as in nonexposed patients. However, the authors do not presently know how these cases will react over long follow-up periods because the level of bone contamination in cases of partial membrane exposure remains unknown.¹⁹

Taking into consideration peri-implant marginal bone levels (1.72 mm after 7 years), the present results are in agreement with the literature, if not better. Chiapasco et al showed a mean marginal bone loss of 2.96 mm around 25 implants placed in 11 patients 3 years after prosthetic loading.²⁰ Avoiding massive vertical bone augmentations, the present study probably obtained more biologic active bone, which should be less prone to resorption over time. Supporting the present results, Troeltzsch et al in 2016²¹ reported a threshold of around 4 mm for obtaining vital biologic bone after GBR procedures with particulate bone. In the present authors' opinion, the real problem is the quality of the residual bone, especially in the posterior mandible. The present authors gave their own definition of "biologically active bone," which should not

be considered only a regenerated bone but a regenerated bone that lasts over time.

Regarding KT presence, no statistically significant differences were found in the current study. The available literature data that support the need for KT around implants to maintain health and tissue stability is limited. However, Souza et al reported that implant sites with a KT band < 2 mm were more prone to brushing discomfort, plaque accumulation, and peri-implant soft tissue inflammation when compared to implant sites with a KT band $\geq$ 2 mm.²² For this reason, when possible and in agreement with the patient, areas with an insufficient KT band were grafted with autogenous soft tissue in the present study.

Taking into consideration other possible approaches that could have been performed to treat these partially atrophic cases, the interpositional technique could be a good method, especially in the posterior mandible. However, a limitation of this approach is that it can be used with pure vertical defects or limited horizontal defects.^{23,24}

Short implants have been also proposed as an alternative to overcome vertical reconstructions thanks to reduced morbidity, rehabilitative times, and costs. However, their use is mainly limited to posterior nonesthetic areas.^{25–28}

Regarding the clinical choice between a one- or two-stage GBR approach, though simultaneous or staged implant placement can be chosen according to the preference of the clinician, the staged approach for implant placement should be

used in cases requiring > 4 mm of newly formed bone.²⁹

Conclusions

GBR with nonresorbable membranes can be a good clinical choice in the treatment of three-dimensionally atrophic and partially edentulous arches.

Within the limitations of this retrospective study, in order to reduce the number of complications, increase success rate, and increase bone stability during time, vertical augmentation in the posterior atrophic mandible should probably be limited to a maximum of 6 mm. A possible reason for the present findings is the biologic features of the augmented site: the greater the increase, the longer the distance away from the native bone that guarantees blood supply and cells. However, this is a technique that requires expert surgeons. In addition, these findings should be confirmed by randomized controlled clinical trials with long follow-up times. Moreover, the surgeons of the present study were experienced with the delivered interventions, and this might limit extrapolations of the present results.

Acknowledgments

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