A Case Series of Vertical Ridge Augmentation Using a Nonresorbable Membrane: A Multicenter Study

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Vertical ridge augmentation (VRA) using titanium-reinforced dense polytetrafluoroethylene (d-PTFE) membranes has been associated with promising clinical outcomes. This retrospective multicenter case series was prepared for the purpose of identifying the elements that contribute to the predictability of this surgical technique. VRA procedures were carried out in 35 patients (13 male and 22 female) with an age range of 43 to 76 years. The average bone gain was 5.44 mm. In the Kaplan-Meier estimates of cumulative survival calculated at 15 months, membrane exposure (P = .045) was a predictor for VRA. Int J Periodontics Restorative Dent 2018;38:811–816. doi: 10.11607/prd.3538

Implant site development therapy aims to reconstruct an edentulous ridge to allow for optimal implant placement.1,2 The effectiveness of guided bone regeneration (GBR) procedures for horizontal ridge augmentation (HRA) has been well documented as an implant-site development modality.3,4 Moreover, the stability of regenerated bone under functional loading has been demonstrated.

Vertical ridge augmentation (VRA) is a technically demanding approach, generally associated with less predictability than HRA. Different VRA techniques have been reported in the literature, involving the use of devices such as intraoral distractors,5 titanium meshes,6,7 expanded polytetrafluoroethylene (e-PTFE) membranes,8,9 and, more recently, dense PTFE (d-PTFE) membranes.10 Although promising results have been reported after using titanium-reinforced d-PTFE membranes with bone grafts for VRA, little is known about the role that local anatomic and technique-related factors may play in the occurrence of postoperative complications. This retrospective multicenter clinical investigation considered successful bone gain–based clinical criteria that allowed optimal implant placement and, with these considerations in mind, designed this study with the purpose of evaluating the possible factors of VRA predictability.
Materials and Methods

This study was designed as a retrospective multicenter case series trial and was conducted according to Good Clinical Practice (GCP) Guidelines. All patients received thorough explanations of the protocol and signed a written informed consent form prior to enrollment. The study participants were 13 males and 22 females with an age range of 43 to 76 years. The inclusion criterion was bone atrophy in local edentulous areas of the posterior maxilla or mandible, with a crestal bone height < 5 mm coronal to the mandibular canal. All patients had to be systemically healthy nonsmokers with acceptable or good oral hygiene and the absence of periodontal disease.

Thirty-five consecutive partially edentulous patients were treated with VRA in the posterior maxilla or mandible using GBR with autologous bone and anorganic bovine bone material (ABBM) (Bio-Oss, Geistlich Pharma) from July 2014 through March 2015. The patients were treated at Científica del Sur University, Lima, Peru, and the Institute for Training and Development in Oral Implantology, Bogota, Colombia.

The patients required vertical bone regeneration to achieve the necessary bone level to place dental implants and to improve the crown/implant ratio. Patients in good physical health who possessed the ability to maintain good oral hygiene were treated with the new titanium-reinforced d-PTFE membranes (Cytoplast Ti-250 Titanium-Reinforced Membrane, Osteogenics Biomedical) and bone grafting.

Surgical Protocol

All patients were premedicated with 2 g amoxicillin 1 hour before surgery and took 500 mg of amoxicillin three times a day for 1 week following surgery. In the event of a penicillin allergy, 600 mg clindamycin was used for premedication (600 mg) and following surgery (300 mg four times a day for 1 week). Oral sedation was accomplished with midazolam (0.50 mg) approximately 1 hour prior to surgery. Patients were instructed to rinse with 0.12% chlorhexidine solution for 1 minute to disinfect the surgical site, and a sterile surgical drape was applied to minimize the potential contamination from extraoral sources. A local anesthetic (Septanest with adrenaline, 1/100,000, Septodont) was applied.

Multiple perforations of the cortical bone were made to stimulate migration of osteoprogenitor cells and vascularization. Tenting screws (Osteogenics Biomedical) were inserted into the residual bone. In some cases, the membrane was adapted and stabilized lingually with fixation screws (Pro-Fix Tenting Screw, Osteogenics Biomedical) (Fig 2). Then, a graft composed of 50:50 proportions of autologous bone and ABBM was placed, filling the defect. Finally, the membrane was also stabilized on the buccal side using two or more fixation screws to ensure a complete and stable titanium-reinforced d-PTFE membrane.

The flap design was chosen to ensure primary tension-free closure after the bone grafting procedure despite the increased dimension of the bone construction. A flap was elevated using crestal and divergent vertical releasing incisions. A full-thickness midcrestal incision into the keratinized gingiva was made with a surgical scalpel. The two divergent vertical incisions were placed at least one tooth away from the surgical site. In edentulous areas, the vertical incisions were placed at least 5 mm away from the augmentation site.

After the primary incisions had been made, perioisteal elevators (Gerardo Periosteal, Glad) were used to reflect the full-thickness flap beyond the mucogingival junction and at least 5 mm beyond the bone defect in the posterior mandible. A lingual full-thickness mucoperiosteal flap was elevated to the mylohyoid line, and the mylohyoid muscle was detached from the inner part of the flap (Fig 1). In sensitive anatomical locations, such as the mental and infraorbital nerves in the upper maxilla, the nerves were protected. Multiple perforations of the cortical bone were made to stimulate migration of osteoprogenitor cells and vascularization. Tenting screws (Osteogenics Biomedical) were inserted into the residual bone. In some cases, the membrane was adapted and stabilized lingually with fixation screws (Pro-Fix Tenting Screw, Osteogenics Biomedical) (Fig 2). Then, a graft composed of 50:50 proportions of autologous bone and ABBM was placed, filling the defect. Finally, the membrane was also stabilized on the buccal side using two or more fixation screws to ensure a complete and stable titanium-reinforced d-PTFE membrane.

The flap was then sutured in two layers. First, horizontal mattress sutures (Cytoplast PTFE, Osteogenics Biomedical) were performed 4 mm from the incision line, then single interrupted sutures
were placed to close the edge of the flap, ensuring close contact between the inner connective portions of the flaps. The single interrupted sutures were removed 10 to 14 days postsurgery, and the mattress sutures were removed after 3 to 4 weeks. Intraoperative measurements of the alveolar ridge width were recorded at the time of surgery. In accordance with Fontana et al, the authors considered a minimal bone gain of 4 mm a success. A smaller bone gain would not allow optimal implant placement.

Statistical Analysis

For this statistical analysis, the authors evaluated the data via Stata 12.0 (Stata Corp) statistical software. Descriptive statistics were calculated for all variables, including median values, standard deviation, frequency, and percentages. Statistical regression was applied to examine bone gain and its relation with all the other variables. Kaplan-Meier graphs were used to analyze survival and failure, considering a minimal bone gain of 4 mm. All patterns were initially adjusted for covariate variables that had any influence over the dependent variable; the final pattern included variables such as age, arch, healing, hematoma, and membrane exposure.

Results

VRA procedures were carried out in 35 patients (13 men, 22 women; mean age 57.4 years). No dropouts occurred during the entire period of observation. Bone regeneration was recorded at the time of membrane removal. The same reference points were used to ensure vertical bone gain. The reference points were the line connecting the interproximal bone height between neighboring teeth, or the line connecting the interproximal bone height to the original bone crest of the edentulous area. The average bone gain was 5.44 mm.

There were two cases of minor temporary neurological complications: paresthesia caused by stretching of the mental nerve fibers during flap management, and edema compression on the mandibular nerve. The timing for complete healing of the injured nerves varied from 3 to 6 weeks. The logistical regression analysis showed that the following evaluated predictors for the bone gain procedure were not statistically significant: healing \( (P = .989) \), membrane exposure \( (P = .210) \), and hematoma \( (P = .053) \). Nevertheless, the odds ratio (OR), estimated with a 95% confidence interval, showed that the healing and hematoma predictors were not considered risk factors. The survival rate of the 26 patients without membrane exposure was 100% over a 5-month period. The percentage of success decreased considerably for those with membrane exposure, which was found to be greater in the maxilla than the mandible, before the 5-month follow-up; 9 of the 35 cases had this complication.

Membrane exposure decreased the amount of bone gained, and thus it should be considered a
predictor during the analysis of the long-term results. This is evidenced with the Kaplan-Meier test results.

The survival rate decreased considerably in the group that presented hematoma; this predictor could be associated with future clinical complications in postsurgical controls.

**Discussion**

It is crucial for clinicians to recognize factors that favor the predictability of VRA. In this retrospective case series, the authors analyzed outcomes of VRA procedures that encountered variables such as membrane exposure, hematoma, and whether the surgery was performed in the maxilla or mandible. The goal was to determine whether any of these factors could influence the final result of the VRA.

Based on the finding that the maxilla showed more membrane exposure than the mandible, it can be interpreted that the location of the flap plays an important role in the predictability of bone regeneration using titanium-reinforced d-PTFE membranes.\(^{13,14}\) Due to the maxilla’s anatomy, the palatal flap has limited coronal displacement, and achieving primary closure requires a tension-free method of closing the release flap. The flap of the maxilla suffers postsurgically from acute inflammation caused by stretching of the edges of the contoured and sutured tissues. For this reason, the vestibular tissue is the only one affected in its mobility.

An additional factor for VRA predictability was the use of membranes during the procedure. The desirable characteristics of barrier membranes used for GBR therapy include biocompatibility, cell occlusion properties, integration by the host tissues, clinical manageability, and space-making ability. Previous authors reported good results associated with the use of e-PTFE membranes,\(^ {15,16}\) but if these membranes are prematurely exposed, the likelihood of having complications is significantly increased.\(^ {12-17}\) Several biodegradable materials have been tested with varying success in periodontal/bone regeneration, including collagen type I, polyglactin 910, polyactic acid, polyglycolic acid, and different copolymers of polyactic and polygalactic acid.\(^ {18-20}\) However, these membranes also have the problem of contamination when exposed during surgery, compromising the treatment success.

In this case series, the authors were able to regenerate 4 mm of VRA, creating the height and opportunity to place implants in better positions, even in risky or impossible areas. This increased the predictability for implant rehabilitation (Figs 3 to 5). The average vertical gain was 5.44 mm, but in exposed cases the gain was 3 mm, because the cellular occlusal criteria were not altered. These results agree with Urban et al, who had an average vertical crest increase\(^{10}\) of 5.45 mm.\(^{10}\)

The location of the operation and types of membranes used affected the outcome of VRA in this study. Narrowing the potential VRA predictors, combined with an adequate postoperative protocol, controlled oral hygiene, and patient compliance, are fundamental factors of treatment success.

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**Fig 3** (a) Bone defect located in the posterior maxilla. (b) Ridge augmentation results after healing process. (c) Radiograph of implants placed in the regenerated bone.
Conclusions

The authors found that the treatment of vertically deficient alveolar ridges using the VRA procedure—a GBR technique utilizing autogenous bone in combination with ABBM and titanium-reinforced d-PTFE membranes—can be regarded as a predictable treatment. Membrane exposure was found to be a predictor that may influence the long-term outcome.

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References


