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VOLUMETRIC CHANGES IN EDENTULOUS ALVEOLAR RIDGE SITES USING REINFORCED PTFE MESH

by

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A thesis submitted to the Faculty of the
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ABSTRACT

Volumetric Changes in Edentulous Alveolar Ridge Sites Using Reinforced PTFE Mesh

Meredith C. Swisher, DDS, 2023

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Introduction: Guided bone regeneration (GBR) is a subset of surgical procedures commonly performed at edentulous sites lacking proper hard tissue dimensions for implant placement. Success of hard tissue regeneration requires primary wound closure, maintenance of space at the site, angiogenesis, and clot stability. Occlusive non-resorbable polytetrafluoroethylene (PTFE) membranes with and without integrated titanium reinforcements are biocompatible options to assist in space maintenance. However, these membranes suffer from limited nutrient diffusion and angiogenic potential. A titanium-reinforced PTFE membrane with macropores has recently been introduced, combining high levels of biocompatibility and space maintenance with the added benefit of nutrient transmission, exhibiting promising clinical results. **Objective:** The purpose of this study is to quantitatively assess volumetric hard and soft tissue changes of edentulous sites following GBR with a titanium-reinforced PTFE mesh featuring macropores. **Methods:** Twelve subjects requiring ridge augmentation will be enrolled and will receive GBR with the titanium-reinforced PTFE mesh in a standardized

fashion. Volumetric hard tissue changes will be analyzed from cone beam computed tomography (CBCT) imaging obtained prior to augmentation and at 6 months of healing. Soft tissue changes will be analyzed from intraoral scans obtained at baseline, 2-4 weeks, and 4 months following implant placement. **Results:** A model of anticipated outcomes for this ongoing study was developed based on clinical experience and previously published work. Trends indicate an inverse relationship between initial ridge dimensions and expected augmentation outcomes. An average baseline ridge width of 3.01±0.58 mm with an average increase of 94.5±55.1% in ridge dimension is projected. Preliminary observations of enrolled subjects highlight the importance of sound surgical principles in ridge augmentation. **Conclusions:** The use of titanium-reinforced PTFE mesh in GBR is a highly technique sensitive surgical procedure with the potential for excellent clinical outcomes. Future results will supplement the promising evidence of the regenerative potential of this mesh.

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LIST OF ABBREVIATONS

AAP	American Academy of Periodontology
CBCT	Cone beam computed tomography
DFDBA	Demineralized freeze-dried bone allograft
FDBA	Freeze-dried bone allograft
GBR	Guided bone regeneration
PTFE	Polytetrafluoroethylene
STL	Standard tessellation language

CHAPTER 1: Introduction

DENTAL IMPLANTS AND RIDGE DEFICIENCIES

Dental implant therapy is a well-accepted option for restoring missing teeth. Optimizing the esthetic and functional outcomes of implant therapy requires positioning an implant fixture into the alveolar bone at the edentulous site to allow for restorability with a dental crown capable of withstanding the forces of mastication. Therefore, the dimension and location of available bone at the proposed surgical site are critical parameters to consider when planning dental implant treatment. The alveolus must have an appropriate height, width, and spatial angulation to support implant fixture placement without impingement on neighboring anatomical structures or placing the fixture at risk of bacterial exposure. When the existing bone at the edentulous site is sufficient, implant therapy may proceed without additional procedures. However, treatment becomes more complex when the edentulous area is deficient in bone.

Alveolar ridge deficiencies are often multifactorial. Before tooth loss, a patient may have deficient bone due to developmental defects, trauma to the alveolus, or advanced periodontal disease. Once a tooth is removed, natural healing of the socket leads to further deformation of the bone. Schropp et al. (2003) reported atrophy of up to 50% of the ridge width during remodeling in the first year following extraction, with over two-thirds of that loss occurring in the first three months. Vertical bone loss was not as pronounced, but the height of healed bone in the extraction socket was never observed to reach the levels of the natural bone found mesial and distal to the site. The use of ridge preservation procedures can mitigate bone remodeling after extraction. Iasella et al.

(2003) demonstrated that placing freeze-dried bone graft into an extraction socket at the time of tooth extraction predictably improved the dimensions of a healed edentulous ridge. However, even with graft utilization, a small yet critical amount of horizontal ridge resorption was still observed. These findings suggest that additional hard tissue augmentation may still be required prior to implant placement in many cases.

Several successful techniques have been reported for augmenting the deficient alveolar ridge. These techniques include guided bone regeneration (GBR) using various particulate bone grafts, block grafts, ridge splitting, and the use of titanium meshes as protective barriers for augmentation (Yu & Wang, 2022). The choice of augmentation method should rely upon the extent of the defect. A therapeutic classification scheme proposed by Wang and Al-Shammari (2002) suggested that guided bone regeneration utilizing a membrane and particulate graft material is among the most adaptable of these methods, showing successful augmentation in horizontal defects ranging from less than 3 mm in size to those that were greater than 9 mm. Due to this versatility, clinicians often consider GBR to be the treatment of choice when it comes to preparing the deficient ridge for implant placement.

GUIDED BONE REGENERATION

The American Academy of Periodontology (AAP) defines GBR as "a surgical procedure with the goal of augmenting bone volume in edentulous or peri-implant areas using a barrier membrane, often in conjunction with bone grafting materials and/or biologics" (American Academy of Periodontolgy, 2022). The success of GBR centers upon the use of a membrane to exclude rapidly proliferating epithelial and connective

tissue cells from the healing ridge and allows osteogenic cells to proliferate and form new bone.

Augmentation may be carried out simultaneously with implant placement or staged, with grafting completed in a separate procedure preceding implant placement. The staged approach is typically preferred in cases of extensive ridge deficiencies or where the ridge geometry limits primary implant stability or prosthetic restorability (Buser et al., 1993). Buser et al. (1993) described two cases of a successfully staged augmentation applied to atrophied anterior maxillary ridges, utilizing a rigid, non-resorbable, fixed expanded polytetrafluoroethylene (e-PTFE) membrane with tenting screws. A bone graft was used under the membrane in one case and a collagen fleece in the other case. After nine months of undisturbed healing, the membranes and tenting screws were removed, revealing ridges in both cases now suitable for implant placement as result of the treatment received. Based on the success of these outcomes, Buser suggested four primary tenants which are required for successful bone regeneration: primary surgical closure, use of an appropriate cell occlusive membrane, adequate adaptation and stabilization of that membrane to the underlying bone, and protection of the osteogenic process in a secluded space underneath the membrane (Buser et al., 1993). Wang and Boyapati (2006) further expounded upon the biological basis behind those principles presented by Buser. This review established the “PASS” principles for the predictability of bone regeneration, which included: primary wound closure to allow for healing undisturbed by bacterial insult, early angiogenesis to provide the necessary nutrients to the graft site to enable the formation of new bone, creation, and maintenance

of space for regeneration to occur, and stability of the clot within the healing wound (Wang & Boyapati, 2006).

Guided bone regeneration does not necessarily require the use of a bone graft material. Buser et al. (1990) demonstrated that bone regeneration ranging from 1.5 to 5.5 mm was achievable using an occlusive membrane and a collagen material. However, a human histologic study by Simion et al. (1994) later showed that bone fill under an occlusive membrane was incomplete. A connective tissue layer with an average thickness of 2.1 mm was consistently found between the newly generated bone and the membrane, which was attributed, in part, to the amount of space left under the membrane. In a subsequent human histologic study, bone graft was placed under the same type of membrane (Simion et al., 1998). After healing, it was found that new bone filled nearly all the space under the grafted membranes, and the layer of soft tissue was limited to less than 1 mm. The authors suggested that GBR combined with a bone graft provided both increased structural support and stability of the membrane and an increased scaffold for new bone formation to be supported under the membrane (Simion et al., 1998). Therefore, it has become standard practice for clinicians to utilize bone grafts in conjunction with a membrane to maximize regenerative outcomes.

BONE GRAFT MATERIALS

Several types of bone grafts may be used in conjunction with membranes for GBR. Depending upon their source, bone grafts are categorized as autografts, allografts, xenografts or alloplasts. Autografts originate from the same host receiving the graft. Allografts originate from a different organism within the same species as the host receiving the graft. Xenografts are sourced from other species and alloplasts are grafts of

synthetic origin. A systematic review of nine studies evaluated different graft materials in ridge augmentation for placement of dental implants, and found that while autogenous bone is typically considered the "gold standard" for grafting due to increased vital bone production and host-graft compatibility, the use of such grafts comes at the cost of increased pain and morbidity from a secondary donor surgery site (Chavda & Levin, 2018). This review further suggested no clinically significant difference between autogenous bone and other graft types regarding implant outcomes (Chavda & Levin, 2018).

Both allografts and xenografts have demonstrated success in ridge augmentation in preparation for implant placement. Human allografts are sourced from cadaver donors and are available in a mineralized form, known as freeze-dried bone allograft (FDBA), and a demineralized form, known as demineralized freeze-dried bone allograft (DFDBA). Although DFDBA was shown to induce increased formation of new bone histologically when compared with FDBA (Wood & Mealey, 2012), both forms of allograft have demonstrated a statistically similar ability to regenerate bone for ridge augmentation. Cammack et al. (2005) augmented 49 ridges utilizing a membrane and either DFDBA or FDBA. After 6 to 36 months of healing, histological analysis indicated no significant difference in the amount or type of new bone formed by either type of graft material. However, due to its longer turnover time and increased duration of function as a scaffold for new bone, FDBA is typically favored as the allograft of choice for ridge augmentation (Feuille et al., 2003).

Xenografts are sourced from animal sources, including bovine, porcine, and equine species, and are considered to have a longer turnover time. These are commonly

used in Europe, where regulations do not permit using human-sourced bone grafts. Zitzmann et al. (2001) performed guided bone regeneration on six patients utilizing a xenograft of bovine origin and allowed the surgical sites to heal for 6-7 months before re-entry. Her results indicated that the xenograft underwent similar remodeling to host tissues and that new bone fill could be generated due to this remodeling. However, at six months, a significant amount of the xenograft particulate was still evident histologically, indicating a slower turnover of this graft than natural bone (Zitzmann et al., 2001). Nevertheless, allografts and xenografts are valuable alternatives to autografts for graft materials to supplement guided bone regeneration.

BARRIER MEMBRANES

At the crux of GBR is the use of a barrier membrane placed between the bone and the soft tissue. The ideal properties of a membrane for GBR were outlined in a review by Hammerle and Jung (2003). The membrane should be biocompatible so as not to elicit an undue inflammatory response or infection, capable of excluding rapidly proliferating epithelial and connective tissue cells, be easily handled by the clinician, and be rigid enough to maintain space for osteogenesis to occur (Hammerle & Jung, 2003). Membranes are broadly categorized as either bio-resorbable or non-resorbable. Commercially available resorbable membranes are either fabricated from animal collagen sources or synthetically derived, including materials like polyesters, polylactic acid, or calcium sulfate. Regardless of origin, bio-resorbable membranes are unique in that they turnover during the healing process into the patient’s own tissues and do not require a second surgery for removal (McAllister & Haghighat, 2007). However, as indicated by the AAP's commissioned review on guided bone regeneration, disadvantages to

resorbable membranes include a decreased ability to maintain defect space as well as high variability in the rate of resorption, especially in the event of early membrane exposure to the oral cavity (McAllister & Haghighat, 2007).

Non-resorbable membranes are well-documented in association with successful guided bone regeneration procedures. These membranes are made from biocompatible materials, with polytetrafluoroethylene (PTFE) and titanium being the most prominent. Non-resorbable membranes are typically indicated for use in areas requiring increased membrane rigidity including large span and vertical augmentation. PTFE membranes were shown to be effective in bone regeneration as early as 1990 (Buser et al., 1990). PTFE membranes may also be reinforced with a titanium framework offering increased rigidity for improved space maintenance. Titanium-reinforced PTFE membranes had reported success in ridge augmentation in combination with FDBA, providing an average of 3.2 mm ridge width increase, ranging from 1.5 mm to 5.0 mm (Feuille et al., 2003). Despite proven results, PTFE membranes do present some disadvantages. Commonly reported complications include a high propensity for soft tissue and flap perforation (Sanz-Sanchez et al., 2022). Non-resorbable membranes must be carefully trimmed to avoid sharp edges to prevent soft tissue dehiscence, which could lead to bacterial exposure at the grafted site (Sanz-Sanchez et al., 2022). Additionally, while these membranes are excellent at excluding epithelial cells from the grafted site, they also limit revascularization and nutrient transmission from the overlying periosteum (Wang & Boyapati, 2006). For this reason, pores have been proposed as a critical feature in the design of non-resorbable membranes.

A significant amount of research has been done to determine the ideal pore size in barrier membranes. Vascular and bony ingrowth have both been demonstrated in membranes with micropores of 100 micrometers while larger 150-micrometer pores have been shown to be compatible with osteon formation (Dimitriou et al., 2012). The "optimal" pore size for barrier membranes was investigated in a canine model by (Gutta et al., 2009). The study compared augmented bone volume achieved utilizing either non-porous membranes or barriers containing either 0.6 mm or 1.2 mm pores. The porous barriers were found to produce a significantly greater amount of new bone compared with non-porous membranes, and larger pore sizes tended to correlate to decreased amounts of soft tissue ingrowth (Gutta et al., 2009). Furthermore, successful ridge augmentation with porous barrier materials has been demonstrated clinically with the use of titanium meshes. These commercially available products typically feature holes between 0.6-1.2 mm and require trimming to custom fit each anatomic ridge. Sumi et al. (2000) demonstrated an average ridge width gain of 3.5 mm after 6-9 months of healing when a titanium mesh was used with an autologous bone graft. Despite their demonstrated success, titanium meshes carry a high risk for soft tissue dehiscence and membrane exposure, affecting an average of 38% or greater of all sites (Lizio et al., 2022). Their utilization is, therefore, highly technique sensitive, and healing should be closely monitored.

RPM MEMBRANE

A titanium-reinforced high density PTFE membrane has been introduced, designed with macropores to work like traditional titanium mesh for guided bone regeneration but with improved handling capabilities making it easier for the clinician to

trim and adapt to the edentulous ridge at the time of surgery. The presence of the macropores allows contact between the bone graft and the periosteum, increasing the opportunity for graft revascularization and cellular infiltration (Osteogenics Biomedical, 2016). The membranes are available in multiple shapes and sizes, specifically designed for different areas in the mouth. Urban et al. (2021) have described outcomes of vertical ridge augmentation utilizing this membrane, reporting a mean bone gain of 5.2 mm, with 89% of all sites achieving complete regeneration. However, there is little evidence documenting the overall volumetric bone gain that can be expected when conducting GBR with this membrane. Therefore, the aim of this study is to evaluate the overall volume of bone regeneration anticipated at deficient edentulous sites utilizing a titanium-reinforced PTFE mesh with macropores.

CHAPTER 2: Materials and Methods

The materials and methods for this study have been previously described (Palazzolo, 2021).

HUMAN SUBJECTS ENROLLMENT

Subjects were recruited from the Periodontics Department at the Naval Postgraduate Dental School (IRB Approval #: WRNMMC-2021-0343). Patients were qualified for this study if they were missing at least one tooth and were treatment planned for GBR prior to implant placement. Treatment plans were based on clinical evaluation, including information obtained from a cone beam computed tomography (CBCT) image. Included patients were systemically and periodontally healthy and met all inclusion criteria. Inclusion and exclusion criteria are summarized in Table 1. Qualifying patients were given a one-page summary of the study and those who expressed interest were consented to participate in the study. Patients who declined to participate were treated with GBR procedures as planned. Once consented, an intraoral camera was used to obtain an intraoral scan which was converted to a standard tessellation language (.stl) file. This .stl file was used by study investigators to determine the pre-augmentation total ridge volume of tissues at the edentulous site. Data from a previously obtained CBCT image for each consented participant was used to determine the pre-augmentation volume of hard tissue at the study site.

SURGICAL PROCEDURES & FOLLOW- UP

Surgical procedures were performed by NPDS periodontics residents under the supervision of board-certified periodontists. Prior to surgery, all subjects signed a

standardized written consent form for GBR. The basic surgical steps are depicted in Figure 1. Subjects were anesthetized with local anesthesia and paracrestal incisions were made across the edentulous sites. Full-thickness flaps were elevated from the alveolus and extended appropriately to allow complete access to the hard tissue defect. Corticotomies were made into the bone at the edentulous site to induce bleeding utilizing rotary instrumentation. The appropriately sized RPM membrane was chosen for the anatomic location and membranes were tacked on the buccal aspect using tacking screws. Sites were grafted using FDBA and the reinforced PTFE mesh was adapted. Surgical judgment determined whether an additional resorbable membrane was used over the reinforced PTFE mesh. Periosteal release incisions ensured appropriate flap mobility to allow for tension-free primary closure. Post-surgical care included pain medications, antibiotics, and daily use of 0.12% chlorhexidine mouth rinse. Participants were seen at 1, 2, 4, 6, 8, and 12 weeks post-operatively for reinforcement of post-operative instructions, oral hygiene instructions, and to monitor healing.

In the event of normal healing, subjects were sent for a follow-up CBCT 6-7 months following the grafting procedure to evaluate the hard tissue at the grafted site and plan for implant placement. Implants were placed via a one- or two-stage implant procedure. Subjects who had implants placed via a two-staged approach then had a second intraoral scan at two to four weeks following implant placement, and a third scan at four months following placement prior to implant uncovery to capture the dimensions of the entire ridge. The second CBCT and intraoral scans were then used to determine post-graft ridge volumes and volumetric bone gains were calculated.

Statistical analysis

The intended sample size for this pilot study is 12 subjects. Due to the nature of the study, descriptive statistics in the form of means, 95% confidence intervals, and standard deviations will be provided to describe the volumetric bone changes observed. Either a paired t-test or the Wilcoxon signed rank test will be completed on the data obtained from measuring the CBCT volumes, and an analysis of variance will be performed on the data obtained from the intraoral scans of the ridges.

CHAPTER 3: Results

ANTICIPATED OUTCOMES

Data collection for this long-term, patient-based study is ongoing. A total of two human subjects, one male and one female, have been enrolled. No participants have reached the data analysis stage as of this manuscript's writing.

A model of anticipated outcomes was developed based on clinical experience and previously published work on outcomes of GBR (Naenni et al., 2019). The data presented in the results section is not based on actual study participants, it is a best educated proximation based on a mathematical simulation which projects what may be seen in a population of 1000 participants. The anticipated participant demographics are shown in Table 2. The model projects that participants will be 57.1% female and 48.3% male, with an average age of 48 years.

The model estimates that the average initial width of hard tissue at the time of enrollment at the edentulous site will be 3.01±0.58 mm (Figure 2). It is generally anticipated that GBR with reinforced PTFE mesh will be at least comparable to or better than other particulate grafting methods. The model suggests that a baseline 3 mm ridge will experience a horizontal ridge gain of at least 2.62±0.93 mm, equating to an overall average increase of ridge dimension of 94.5±55.1% from the baseline. An inverse relationship (i.e., greater gain from narrower ridge prior to grafting) between initial ridge width and anticipated gain is also apparent. It should be noted that all models are a simplification of reality and inherently incomplete. Therefore, this estimation should be interpreted with caution and further validated by enrolling an adequate number of subjects in the future.

Clinical Observations

GBR with reinforced PTFE mesh is a highly technique sensitive procedure. Previous anecdotal clinical experience at NPDS utilizing this membrane has shown robust bone augmentation comparable to membranes without macropores. However, as of the writing of this manuscript, the two subjects enrolled in the study have experienced premature loss of the reinforced PTFE mesh due to non-study related post-surgical complications in healing. In both cases, primary wound closure over the surgical site was compromised within the first two months following the augmentation. These premature mesh exposures resulted in subsequent bacterial contamination and localized infection at the regeneration site (Figure 3). Prompt removal of the membrane was carried out in both cases, subjects were placed on antibiotics, and healing occurred without incident. These subjects have been exited from the study and will receive appropriate retreatment when healing is complete.

CHAPTER 4: Discussion

Clinical data collection is ongoing for this study, and the timeline requirements for the analysis of volumetric hard and soft tissue changes have not yet been reached. However, early clinical observations of subjects in this study support the importance of adhering to the principles of GBR. The four major tenants to successful regeneration include primary closure, angiogenesis, space maintenance, and wound stability (Wang & Boyapati, 2006). Reapproximating wound edges without tension allows for less tissue contraction, faster initial re-epithelialization of surface tissues, and establishment of a graft environment that is not subject to bacterial invasion from the oral cavity (Wang & Boyapati, 2006). However, early loss of primary closure and subsequent membrane exposure are not uncommon in GBR procedures, even when sound surgical principles are followed. A recent review by Sanz-Sanchez et al. (2022), reported that the incidence of soft tissue dehiscence and barrier material exposure was approximately 20%. With a total anticipated population size of 12 subjects, the two subjects in the current study experiencing early loss of primary closure resulting in contamination of the mesh and development of localized purulence and infection is consistent with this previously reported data.

The deleterious effects on bone augmentation outcomes due to membrane exposure are well documented. A systematic review and meta-analysis reported a six-fold increase in new bone formation in sites that maintained primary closure during healing versus those which were exposed to the oral environment (Machtei, 2001). Much of the effect of membrane exposure on augmentation outcomes is dependent upon the size, timing, and subsequent management. In the absence of purulent exudate, small membrane

exposures (<3 mm) may be monitored and swabbed twice daily with chlorhexidine or may be subject to localized removal of the contaminated material. Larger exposures (>3 mm), as well as any exposure with purulence, should immediately undergo membrane removal upon discovery to limit the effect on the underlying regenerating bone (Fontana et al., 2011). Typically, early exposures are more detrimental to overall regeneration due to the limited amount of time for the hard tissues to regenerate. The two subjects in this study experienced exposure within the first month of healing. Later exposures, however, do not necessarily compromise the desired augmentation. A recent case report from Belleggia (2021) outlined the management of a 4 mm exposure of the same reinforced PTFE mesh used in this study at 4 months post-placement. At the time of discovery, the patient was placed on a three-times daily regimen of 0.2% chlorhexidine mouth rinses, paired with daily swabbing of the area with 3% hydrogen peroxide on gauze for one month. No signs of purulence or infection developed, and after one month, the site was entered, and the membrane removed. The underlying regenerated bone was found to be adequate for implant placement without the need for further augmentation and remained stable for one year (Belleggia, 2021).

In the absence of healing complications, GBR utilizing reinforced PTFE mesh has shown promising results (Urban et al., 2021). It is theorized that the presence of the 0.66 mm macropores in these PTFE mesh membranes allow for increased and early vascularization of graft materials and therefore enhances regenerative outcomes (Urban et al., 2021). In a 2021 retrospective case series, Urban et al. demonstrated success in gaining 5.2 mm of vertical bone height and 89.2% complete regeneration with baseline vertical deficiencies of 5 mm or less (Urban et al., 2021). Vertical augmentation is often

considered the most challenging of all GBR procedures due to heightened technique sensitivity and demand placed on the healing process as compared to horizontal augmentation (Urban et al., 2021). Given the reported augmentation success in even the most challenging clinical situations, it is anticipated that the outcomes of the present study will show this mesh to be comparable, if not improved, to outcomes from conventional membranes in GBR (i.e., without micropores or mesh design) (Naenni et al., 2019). This study will provide future clinicians with scientific evidence to better inform their clinical decision-making processes when choosing materials for challenging regenerative cases.

CHAPTER 5: Conclusions

The overall volumetric hard and soft tissue ridge augmentation outcomes utilizing titanium reinforced PTFE mesh for GBR have yet to be reported. However, the potential for successful augmentation outcomes have been observed both clinically at NPDS and in previously published works. The early observations from this ongoing quantitative study highlight the technique sensitive nature of GBR procedures especially involving mesh design. It is anticipated that the results of this study will add to the existing literature, enhancing the clinical decision-making capabilities and materials choice for routine and complex regenerative cases.

Table 1. Detailed list of inclusion and exclusion criteria for subject qualification to enroll in the study.

Inclusion Criteria	Exclusion Criteria
• Male and female military health care beneficiaries 18 years or older. • Patient treatment planned for dental implants (to include CBCT) and requiring ridge augmentation. • Patient to remain in the geographic area for 14 months for appropriate monitoring and completion of treatment. • Patient has edentulous ridge site with at least 3 natural teeth adjacent to the area; patients with two sites in different dental arches, both sites may be included.	• Patient under the age of 18. • Patient moving from the geographic area prior to 14 months. • Pregnant or nursing patients. • Current smokers. • Patient with clinically uncontrolled or significant systemic disease (ASA III or greater). • Patient with allergy to medication or materials used. • Patient with poor oral hygiene unsuitable to undergo elective periodontal surgery. • Patient with active infection with lymphadenopathy. • Patient who does not consent.

Table 2. Anticipated demographics of subjects based on simulation model data.

Anticipated Participant Demographics	
Female	51.7%
Male	48.3%
Mean Age	48
Mean Baseline Hard Tissue Width (mm)	3.01±0.58
Anticipated Average Hard Tissue Width Gain (mm)	2.62±0.93
Anticipated Average Percentage Ridge Width Gain	94.5±55.1%

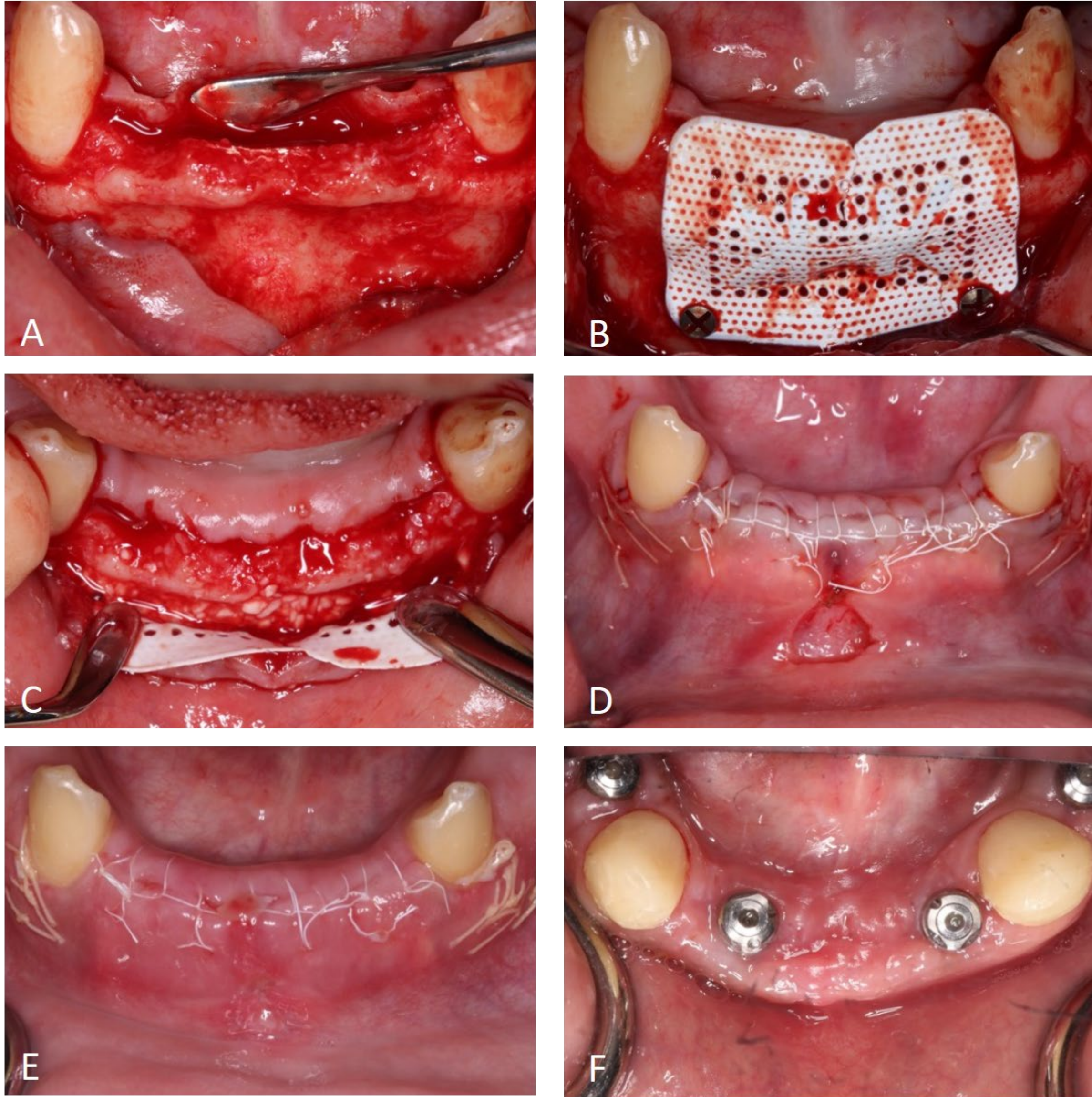

Figure 1. Guided bone regeneration procedure using reinforced PTFE mesh. (A) Paracrestal incision allowing for full thickness flap reflection on buccal and lingual aspects of ridge. **(B)** Fixation of reinforced PTFE mesh at apical extent of deficient alveolar ridge **(C)** Freeze-dried bone allograft (FDBA) placed under the reinforced PTFE mesh. (**D**) Primary closure at the graft site utilizing continuous interlocking PTFE suture. (**E**) Retained primary closure at 2 weeks post graft. (**F**) Final augmented ridge after implant placement.

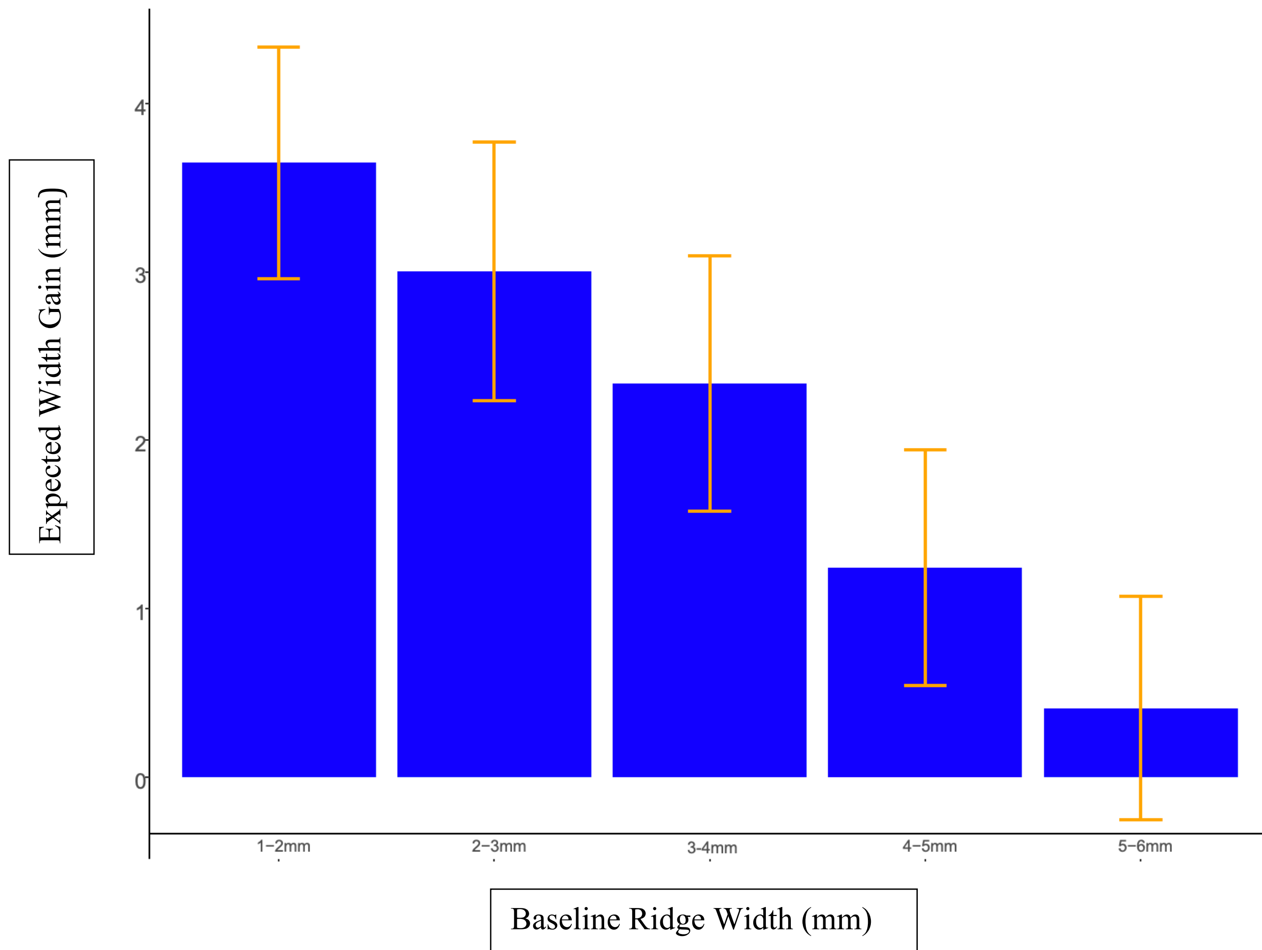

Figure 2. Simulated model of anticipated augmentation outcomes. Model created based on 1000 hypothetical patients based on published horizontal ridge augmentation data (Naenni et al., 2019) and clinical experience. It is anticipated that augmentation with reinforced PTFE mesh will be at least as good as other methods. Expected augmentation outcomes should have an inverse relationship with the overall dimension of the ridge at baseline.

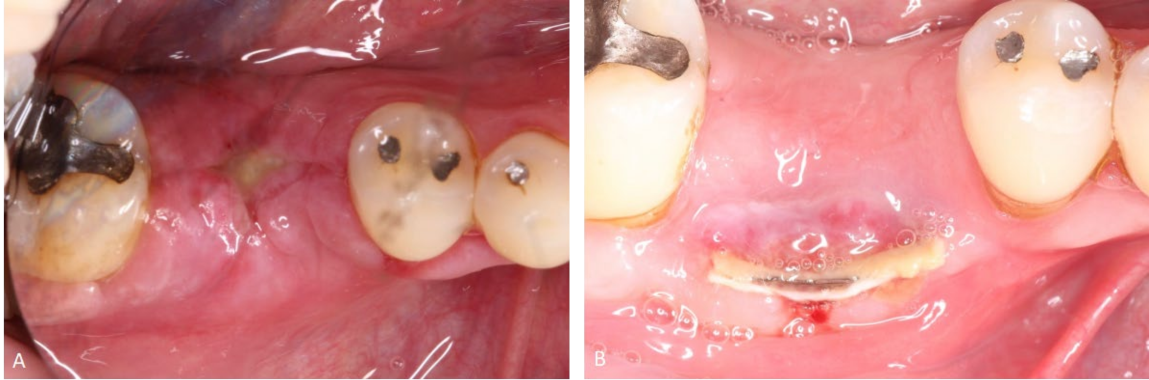

Figure 3. Localized infection due to premature reinforced PTFE mesh exposure. (**A**) Exposure of reinforced PTFE mesh at time of suture removal. Attempt was made to keep area clean with chlorhexidine swabs. The exposed membrane was later trimmed to retain a portion of the graft. (**B**) Soft tissue did not heal around the contaminated membrane prompting removal and debridement of the area.

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