

Guided Bone Regeneration for Dehiscence and Fenestration Defects on Implants Using an Absorbable Polymer Barrier

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Background: Guided bone regeneration (GBR) using a non-absorbable barrier has provided clinicians the ability to place implants in sites compromised by insufficient bone, including immediate extraction sites. Recent evidence suggests that successful GBR outcomes may be possible using bioabsorbable polymer barriers.

Methods: This report presents a case series of 9 patients with 8 fenestration and 3 dehiscence defects on implants consecutively treated with GBR. A bioabsorbable polymer barrier of poly(DL-lactide) was used in conjunction with a composite graft of freeze-dried bone allograft (FDBA)/demineralized freeze-dried bone allograft (DFDBA) mixed in a ratio of 1:1. Second-stage surgeries were performed at 4 to 8.5 months (5.7 months average) post-placement. Biopsy material from 2 sites was obtained while exposing the implant for healing abutment connection.

Results: Ten of the 11 defects (90.9%) achieved complete coverage of the osseous defects. Histologic evaluations revealed the formation of viable bone, frequently in close amalgamation with residual graft particles.

Conclusion: These case reports suggest that a poly(DL-lactide) polymer can be used as a physical barrier with a composite bone replacement graft to achieve successful GBR results of dehiscence/fenestration defects when placing implants. *J Periodontol* 2001;72:250-256.

KEY WORDS

Guided bone regeneration; grafts, bone; membranes, barrier; membranes, bioabsorbable; polylactic acid/therapeutic use; follow-up studies.

Guided bone regeneration (GBR) has made the placement of implants possible in sites that were not a part of the original implant protocol.¹ GBR has expanded the predictable treatment options for clinicians to meet patients' esthetic and masticatory needs.

The principles of GBR date back over 30 years.²⁻⁴ Early experimental studies,⁵⁻⁸ clinical studies,⁹⁻¹⁴ and case reports¹⁵⁻⁴¹ demonstrated successful outcomes for GBR in a wide variety of osseous defects, thereby facilitating the placement of implants. The vast majority of GBR reports have discussed the successful use of expanded polytetrafluoroethylene (ePTFE),[‡] a non-absorbable barrier, either alone^{9-14,17-19,22,25,28,33,36-39} or in combination with a bone replacement graft.^{20,21,23,24,26,29-32,36,40} Because of the requirement for removal of non-absorbable barriers, considerable interest has emerged in developing alternative absorbable materials.

An absorbable barrier has been developed where a polymer of poly(DL-lactide) is dissolved in a carrier of N-methyl-2-pyrrolidone[§] which, upon contact with water or other aqueous solution, forms a barrier of firm consistency. Originally, a partially set barrier was formed at chairside that could be trimmed to the dimensions of a periodontal defect.^{42,43} Once placed, the polymer completely solidified *in situ*, forming an absorbable barrier for GTR.⁴⁴

A regenerative technique for periodontal defects has recently been described where this poly(DL-lactide) polymer was flowed *in situ* to form a custom fitting barrier directly over composite bone replacement graft, resulting in successful clinical outcomes.^{45,46} Since the polymer does not significantly degrade for 5 to 6 months,⁴⁴ the same benefits of clot stability, space maintenance, and tissue exclusion might also be gained in GBR procedures with implants. Consistent with this possibility, a barrier of polylactic acid/polyglycolic acid (PLA/PGA) used in combination with an autogenous bone replacement graft was recently shown to be effective

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‡ Gore-Tex, W.L. Gore & Associates, Inc., Flagstaff, AZ.
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in the treatment of dehiscence/fenestrations around implants.⁴⁷

The purpose of this report is to present consecutive clinical experiences with a poly(DL-lactide) polymer barrier in combination with a composite bone replacement graft for GBR of dehiscence/fenestration defects during implant placement. Implant sites requiring ostectomy for exposure of the fixture permitted histologic evaluation of the new bone formation.

CASE SERIES DESCRIPTION

Nine consecutively treated patients (7 male and 2 female) with an average age of 52.7 (range 32 to 81) years had a total of 11 implant fixtures^{||} placed in combination with a GBR procedure. All of the patients were non-smokers. The implant surgeries were conducted utilizing standard protocols of the respective implant systems, notwithstanding the GBR procedure. All implant placements were done in the absence of pre-tapping the site. Photographs were taken of the implant and GBR procedure, and clinical measurements were made of the dehiscence/fenestration defects treated. All measurements were done from the most coronal aspect of the implant collar to the base of the defect. All defects received a composite graft of demineralized freeze-dried bone allograft (DFDBA) (particle size 250 to 710 μm) mixed with freeze-dried bone allograft (FDBA) (particle size 250 to 710 μm) in a 1:1 ratio. Both graft materials were obtained from a tissue bank that has demonstrated inductivity for its DFDBA material.^{#48} The graft was rehydrated with sterile saline prior to its placement around the implants and the defect was filled incrementally using light pressure. A method of barrier placement was used where the poly(DL-lactide) polymer[§] was formed rapidly at chairside (M. Abou-Rass; unpublished data). Six to 10 drops of polymer were placed from the dose pack into a sterile glass dappen dish. Sterile saline was added in a ratio of one drop for every two drops of polymer. A 7A wax spatula** introduced the saline throughout the polymer and rapid mixing was performed for 8 to 10 seconds in order to drive off the N-methyl-2-pyrrolidone carrier. Care was taken to press the forming barrier against the sides of the dappen dish to begin barrier formation. Corn suture pliers** were used to remove the polymer barrier from the dappen dish to trim it to an appropriate size with suture scissors. If necessary, the barrier was handled with gloves to facilitate trimming. The barrier, which was approximately 0.5 to 1.0 mm thick, was placed at the graft site with 2 to 3 mm overlapping the adjacent osseous

structure. If additional barrier was needed, the same process was repeated with the new piece overlapping the prior barrier, thereby coalescing the pieces together by physical bond.

The endpoint of flap management was passive primary closure, which was achieved by using releasing incisions that extended well beyond the mucogingival junction and into the buccal turn of the vestibule. Partial thickness dissection in the apical portion of the facial flaps allowed the flaps to be passively drawn together. A monofilament suture was used of an absorbable^{††} or a non-absorbable[‡] material for flap adaptation.

The antibiotic regimen was 2 g of amoxicillin at the time of implant surgery followed by 500 mg t.i.d. for 8 to 10 days. This regimen was followed by doxycycline 100 mg, 2 capsules on the first day and then 1 capsule per day for 10 days. Two patients were allergic to amoxicillin and were placed on the doxycycline regimen for a total of 14 days. Doxycycline was administered primarily for its antimicrobial property but also, in part, for its anticollagenase activity.⁴⁹ Patients were instructed to use a 0.12% chlorhexidine rinse b.i.d. for the first 30 days or during the entire healing period if the barrier became exposed.

The success or failure of the GBR procedure was assessed at the second-stage surgery when flaps were reflected to place healing abutments. Clinical photographs were used to determine results of treatment. Complete success, partial success, and failure were based on previously published clinical criteria.²⁹ Complete success was defined as coverage of all threads or exposed implant surfaces. Partial success was deemed as incomplete coverage of most threads or exposed implant surfaces with a maximum of 2 threads or 2 mm of implant surface left uncovered. Failure was defined as no coverage beyond 2 threads or 2 mm of implant surface.

The osseous defects treated included 8 dehiscence and 3 fenestration defects. Representative clinical cases and outcomes are illustrated in Figures 1 and 2. Second-stage surgeries and evaluations were performed between 4.0 and 8.5 months (5.7 months average).

RESULTS

Table 1 summarizes the outcomes of the GBR procedures for all sites. The length of the defects ranged

|| Osseotite, Implant Innovations, Inc., Palm Beach Gardens, FL.

¶ Replace, Nobel Biocare, Yorba Linda, CA.

LifeNet, Virginia Beach, VA.

** Hu-Friedy, Chicago, IL.

†† Monocryl, Ethicon, Sommerville, NJ.

Case Series

from 2 to 13 exposed threads with an average of 8.5 exposed threads. With the exception of one dehiscence lesion that had partial coverage, all other defects had complete coverage of the implants, representing a 90.9% success rate.

Premature loss of the barrier occurred at one implant site approximately 4 weeks following clinical exposure; however, this site had complete coverage of the implant with hard tissue at stage 2 surgery. Premature loss of the barrier, based on patient report,

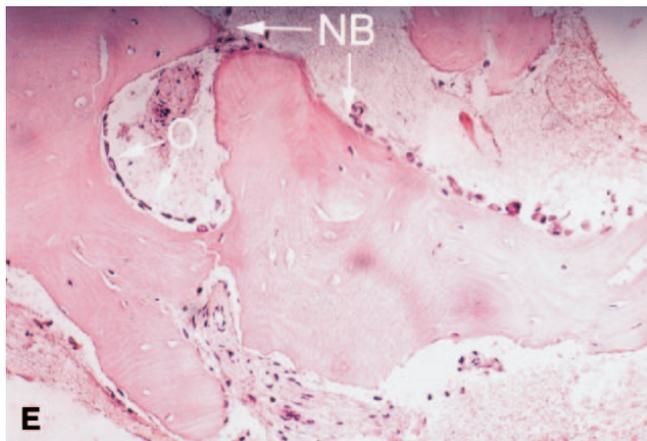
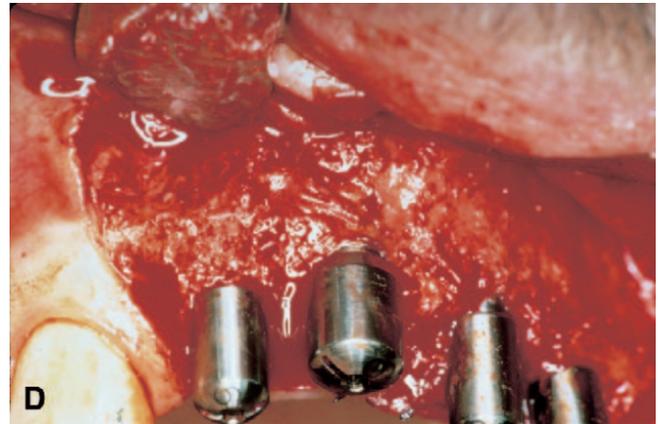
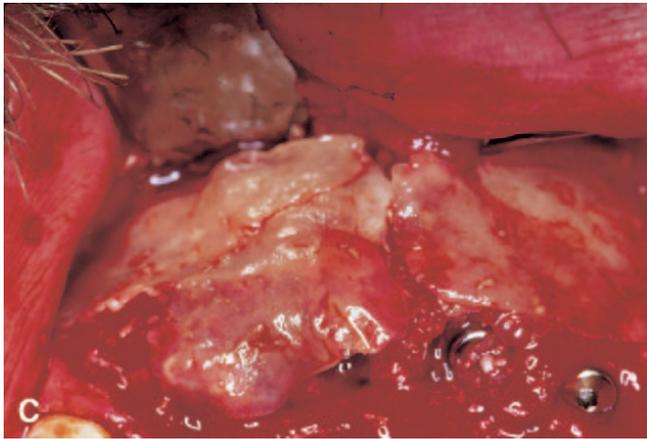
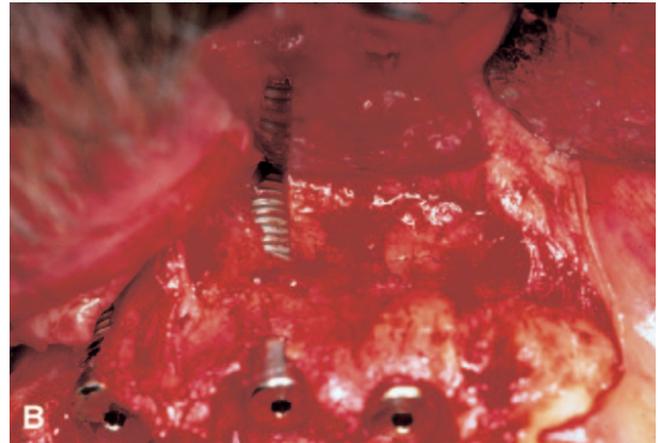
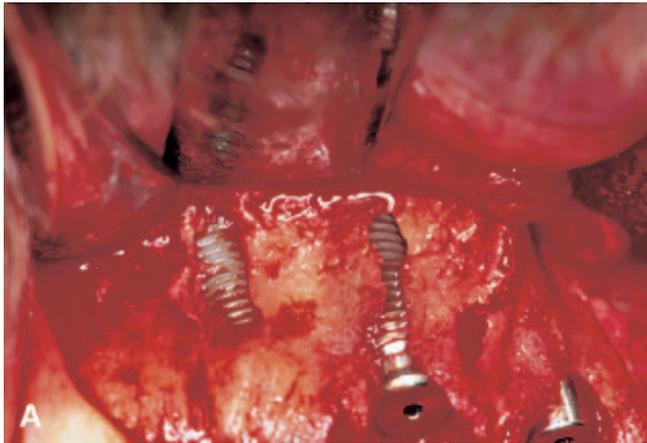


Figure 1.

A. Placement of 3.25 mm × 18 mm implant at maxillary right lateral incisor site, which shows a fenestration defect exposing 13 threads in this 32-year-old male. A dehiscence of 16 exposed threads is present on a 4.0 mm × 13 mm implant placed at the #8 site. Teeth had been lost due to a prior accident. **B.** A 3.25 mm × 15 mm implant placed at the #9 site, in the same patient, has a thin alveolar plate with a fenestration defect exposing 13 threads. The implant at the #10 site has a thin labial plate of bone. **C.** Two barriers have been rapidly formed at chairside and placed over a composite osseous graft of DFDBA/FDBA (ratio of 1 : 1) which covers the surfaces of the implants. **D.** Reentry at 6 months, with healing abutments in place, is consistent with amalgamated fibrous connective tissue and bone formed over the implant surfaces and the defects. **E.** Photomicrograph of tissue removed over cover screws at stage 2 procedure (original magnification ×10). Evidence of amalgamation of new bone (NB) with osteoblasts (O) rimming residual graft particles is seen.

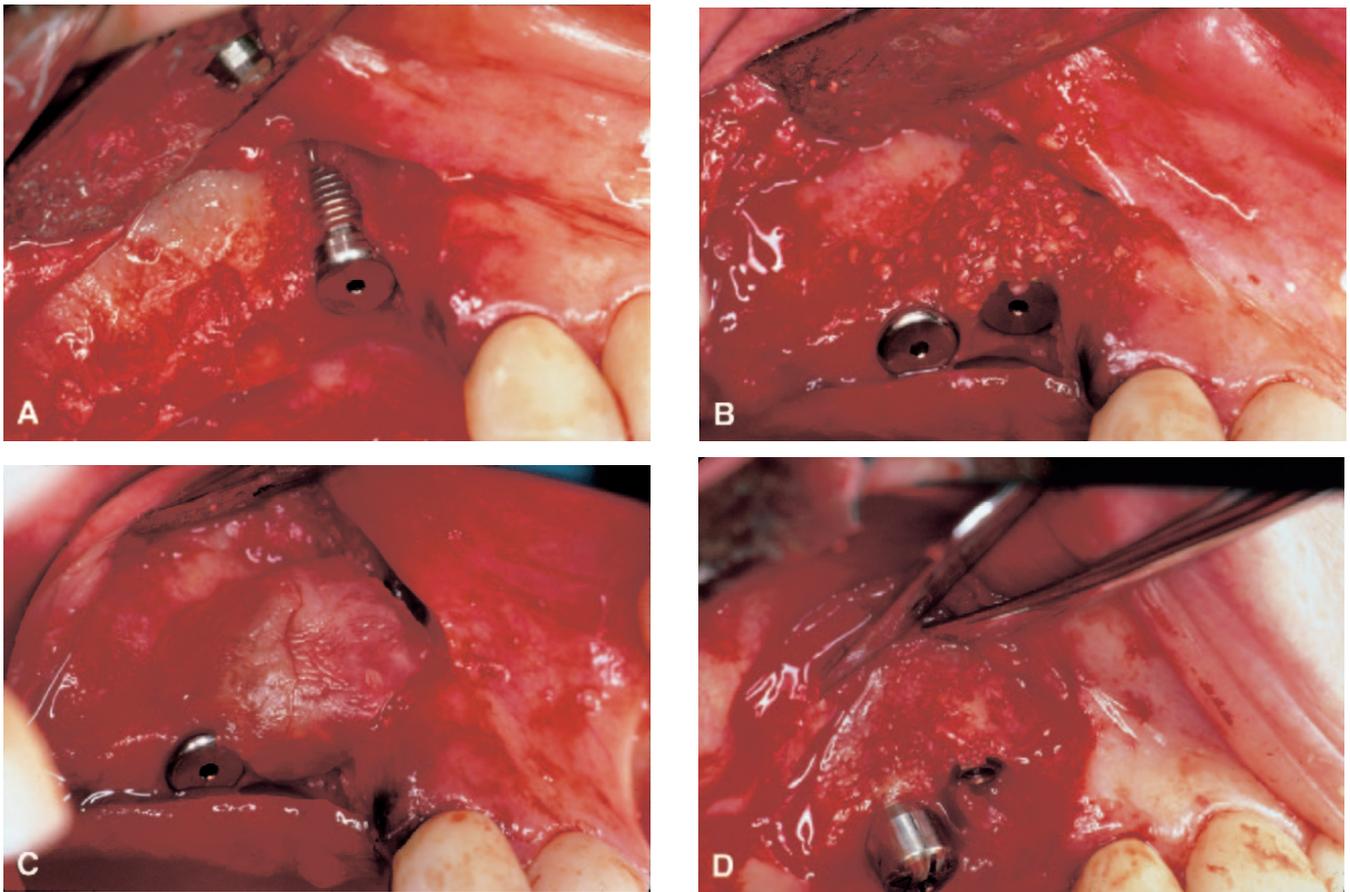


Figure 2.

A. Placement of 4 mm × 11.5 mm implant into maxillary right canine site, which shows a dehiscence defect of 8 exposed threads in this 55-year-old female. **B.** Composite osseous graft of DFDBA/FDBA in a ratio of 1 : 1 is placed over the implant and the defect. **C.** A barrier has been rapidly formed at chairside and placed over the site extending at least 2 mm beyond the graft and defect. **D.** Reentry at 6 months demonstrates that the defect and implant have been covered by hard tissue.

was presumably related to physical forces during mastication causing fragmentation. The barriers were otherwise well tolerated by the tissue with no sites demonstrating untoward granulation reactions or infection.

The histologic evaluation of biopsy specimens revealed the presence of viable bone and residual graft particles. Islands of viable bone were frequently observed in close amalgamation with graft particles. Notably absent in all specimens was evidence of an inflammatory cell infiltrate.

DISCUSSION

The clinical outcomes of this case series are consistent with the results of studies^{9,13} and case reports^{20,21,25,32} describing the application of non-absorbable and bioabsorbable barriers in GBR therapy. Nevertheless, comparisons across studies remain dif-

ficult because of differences in the variety of bone defects treated, temporal sequencing of implant and GBR surgeries, and surgical outcome measures. Given the concern for the preservation of esthetics, outcome criteria were chosen based on implant coverage by either bone and/or connective tissue.²⁹ Removal of any dense connective tissue present might have compromised regenerated bone, which could have impacted on the soft tissue height. Preservation of tissue height was of great concern since over half of the implants were placed in the maxillary anterior region.

A bone replacement graft was used in combination with the polymer barrier, in part, to avoid barrier deformation prior to its final formation. Consistent with this possibility, an absorbable barrier of PLA/PGA was previously associated with reduced regenerative outcomes, compared to ePTFE due to collapse of the

Table 1.

Dehiscence/Fenestration Sites Treated With a Bioabsorbable Polymer Barrier for GBR

Patient	Age	Gender	Site	Implant	Implant Size	Defect	Exposed Threads	Stage 2 (Months)	Success Outcome	Problem
1	49	M	13	Osseo	4 x 13	Fen	11	5	Complete	
2	48	M	21	Osseo	4 x 13	Deh	6	7	Complete	Exposure
3	32	M	7	Osseo	3.25 x 18	Fen	13	6	Complete	
			8	Osseo	4 x 13	Deh	12	6	Complete	
			9	Osseo	3.25 x 15	Deh	12	6	Complete	
4	50	M	12	Repl	4.3 x 16	Fen	13	8.5	Complete	
5	54	F	5	Osseo	3.25 x 13	Deh	2	4	Complete	
6	55	F	7	Osseo	4 x 11.5	Deh	7	6	Complete	
7	61	M	11	Osseo	3.25 x 13	Deh	5	5	Partial	
8	81	M	11	Osseo	4 x 15	Deh	7	4	Complete	
9	44	M	9	Repl	4.3 x 10	Deh	5	5	Complete	
Average	52.7						8.5	5.7		

Osseo = Osseotite; Repl = Replace; Deh = dehiscence; Fen = fenestration.

barrier.⁴⁹ In these case reports, the GBR procedure incorporated a composite graft of DFDBA/FDBA in a 1:1 ratio, which previously has been shown to support successful regenerative outcomes.²⁰ The concept of mixing these 2 graft materials capitalizes on combining the potential osteoinductive/osteoconductive capabilities of DFDBA^{48,51} with the osteoconductive and spacemaking advantages of FDBA.²⁰ Allograft materials used in this case series were obtained from the same tissue bank, which routinely verifies the osteoinductive potential of its processed DFDBA in the athymic mouse model.⁴⁸

Histologic evaluation of the new bone formation was possible at 2 sites, where ostectomy had been required to expose the implant for placement of the healing abutment. In all histologic specimens, viable bone was observed in the absence of an inflammatory cell infiltrate. These histologic findings are consistent with previous reports following the use of DFDBA in regenerative therapy.^{52,53}

There are a number of advantages to a liquid polymer barrier. Previous reports demonstrated the clinical benefits of the poly(DL-lactide) barrier, which can be formed chairside^{42,43} or *in situ*^{45,46} for GTR procedures. This case series documents the successful application of the poly(DL-lactide) barrier with bone

replacement grafts in GBR procedures involving implants. This dual capacity for GBR and GTR use simplifies the clinician's inventory of barriers since the material can be flowed or trimmed to a variety of clinical situations. This barrier material has also demonstrated an intrinsic antimicrobial property.⁵⁴ The polymer system permits repair or modification of the barrier if it is inaccurately cut or trimmed since additional material can be added to the existing barrier with the 2 coalescing. The barrier's final consistency is hard and rigid, adding to its space maintenance capabilities. It takes approximately 5 to 6 months for significant degradation of the barrier to begin, and since it is completely absorbed by 12 months, there is less concern that remaining barrier could affect the site.

There are also some limitations to this barrier. The final consistency of the material is hard and firm, making it susceptible to fracture and premature loss in the presence of untoward occlusal forces. Although this occurred in a patient at one implant site, the clinical outcome was still favorable. In the presence of large defects, premature loss of the barrier might substantially compromise the regenerative outcome. A second concern is that exposure of the poly(DL-lactide) barrier may also lead to premature loss versus a non-absorbable barrier. Exposure of non-absorbable

barriers, which remain intact, permits bacterial colonization and potentially affects the final regenerative outcome.⁵⁵ The regenerative consequences of barrier exposure and loss are related to the maturational stage of the wound healing process.

The results of this consecutive case series suggest that a poly(DL-lactide) polymer can be used as a physical barrier with a composite bone replacement graft to achieve successful GBR results at dehiscence and fenestration defects when placing implants. The compilation of case information is ongoing to determine whether similar results will be found in a larger series of patients.

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