CYTOFLEX®

RESORB

Resorbable PLA / PGA Membrane

Advantages

Easily Adaptable

Over 2-month barrier function

Non-pyrogenic, non-immunogenic

Composition

Cytoflex® Resorb® is a microporous membrane made of synthetic, bioresorbable polyglycolide (PGA), polylactide (PLA) and D, L-lactide /glycolide (PLGA) copolymers. PGA, PLA and PLGA are all biocompatible; these materials have been well-documented and widely used in implantable devices for medical and dental applications.

Physical Properties

Cytoflex® Resorb® membranes have a thickness of 370um and pore size of 10-100um (Figure 1). These micropores allow for nutrient permeation across the membrane (Figure 2). The membrane has a mechanical flexibility comparable to that of uncoated, standard copy paper. The material retains most of its rigidity when wet and during early days of implantation. In general, rigid membranes (including crosslinked collagen and non-resorbable membranes) have a tendency to revert back to their original shape instead of adapting to the graft site. These properties must be considered during treatment planning to decrease the likelihood of wound dehiscence.

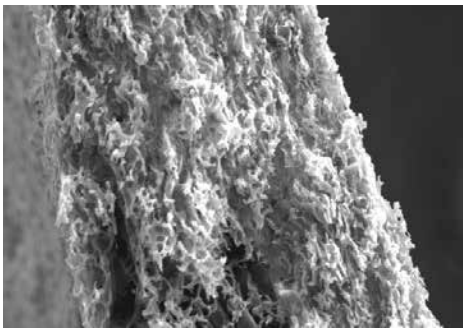


Figure 1 - Porous Matrix Barrier

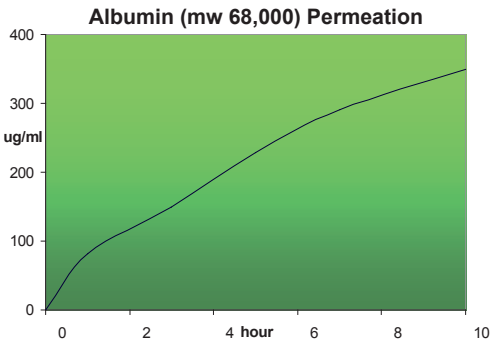


Figure 2 - Nutrient Permeable

Resorption Duration

Cytoflex® Resorb® membranes have a long resorption duration. Preclinical beagle dog studies have demonstrated that the membrane maintains barrier function for about 8 weeks and resorbs within 6 months (see Figures 3 & 4 below). The materials degrade through hydrolysis and are metabolized to CO_2 and H_2O by the Krebs cycle.

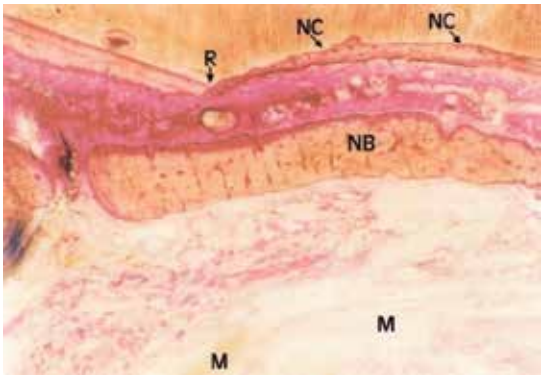


Figure 3 – 8 weeks Post-op.The barrier (M) maintained its structural integrity. New bone (NB) and new cementum (NC) grew toward the coronal end of the defect.

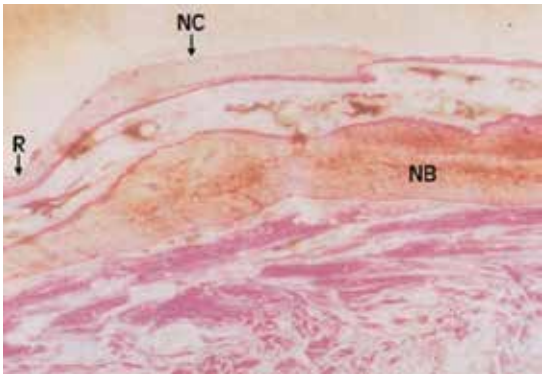


Figure 4 – 24 weeks Post-op. The barrier completely resorbed. New cementum and regenerated bone matured and reorganized into a Harversian structure.

Preparation of Membrane for Insertion

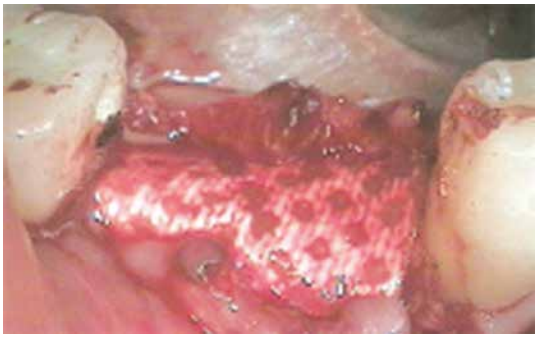
The membrane should be handled using only powder-free gloves and/or with sterile atraumatic forceps. Hold the membrane gently and cut the membrane to the desired configuration with sharp scissors. After trimming, there should be no sharp corners or rough edges which may cause tissue irritation and/or protrusion. To enhance space-making capabilities, the membrane may be curved over the fingertip or a sterile instrument handle to create a dome shape. This curving action may be used to soften the membrane matrix if needed.

The side with the distinct diamond pattern embossing (large grating) should face the gingival tissue. The smoother side should face the bony defect or bone graft site. Note: In the inner package, the layer facing the dentist should face the gingival tissue.

To enhance stability and provide adequate protection of the space over the bony defect, the membrane should be trimmed to extend 2-3mm beyond the defect margins and remain at least 1 mm from adjacent, uninvolved teeth; avoid using unnecessarily large membranes.

The use of a non-resorbable monofilament suture is recommended. Loss of tensile strength during the initial 2-week healing period can lead to premature membrane exposure. If additional stability is desired, the membrane may be stabilized with sutures. The use of bone tacks or bone screws to stabilize resorbable membranes has not been studied and is not recommended by the manufacturer.

Adequate flap release must be accomplished in order to achieve a tension-free primary closure. A double layer closure with a deep layer of horizontal mattress sutures followed by a standard wound closure with interrupted sutures is recommended. Avoid overlapping or folding the barrier membrane during the procedure.



Incidence of surgical complications is related to the severity of the bone defect. Cases requiring sophisticated technique should only be undertaken by surgeons with appropriate training and experience.

Special considerations should be taken for patients including those with a medical history of smoking, diabetes, immune diseases, systemic diseases, need for prophylactic antibiotics, head/neck radiation therapy, and chemotherapy. Patients with a limited amount and width of keratinized mucosa or thin biotype are prone to soft tissue complications.

Re-entry

Cytoflex® Resorb® maintains barrier function for up to 2 months and resorbs within 6 months. After membrane placement, the treated area should remain covered for approximately 4 to 6 months. Remnants of the barrier matrix with a liquefied and/or granular appearance, usually within the soft tissue flap, may be present at the time of re-entry. These remnants will resorb and disappear. No special measures need to be taken.

Mitigation of Soft Tissue Complications

Soft tissue complications including membrane exposure, dehiscence, and acute infection/abscess, may adversely affect the bone regeneration outcome. According to the literature, the rate of developing soft tissue complications varies widely from 0% to 45% with a weighted complication rate of 16.8%. There are no significant differences in the complication rates among types of membranes. Complications were reported as early as 1 week and as late as months following the operation.

Soft tissue dehiscence refers to the phenomena of membrane or implant perforated oral mucosa during the follow-up period. This is considered a minor complication, since the site typically shows gradual improvement with chlorhexidine application. Membrane exposure occurs when a primarily closed membrane becomes unintentionally exposed. Minor exposure without infection may be treated with systemic antibiotic or with addition of chlorhexidine mouth rinse. Large exposure involving the exposure of underlying graft may necessitate complete removal of the graft and membrane and a repeat augmentation procedure.

Summary

Proper soft tissue management technique is reported as the main contributing factor to avoid complications. However, even among the most skilled surgeons, soft tissue complications may still occur, particularly in complex and challenging cases. A careful surgical treatment plan is critical in mitigating potential complications. Pre-surgery considerations should include a detailed review of the following: (A) patient's health history, patient's tissue type, defect size and shape, and any potential impediment to regeneration and wound healing, (B) implant materials, including, bone graft, suture, membrane, the materials' properties and potential impact to the surgical outcome, (C) soft tissue management, including flap thickness, flap design, and tension free primary closure, and (D) practitioner's skill set, and if needed, consultation with colleagues about the specific case.

References

1. Clinical and histological sequelae of surgical complications in horizontal guided bone regeneration: a systematic review and proposal for management. Tay JRH, et al. Int J Implant Dent. 2020 Nov 26;6(1):76.
2. Wound healing complications following guided bone regeneration for ridge augmentation: A systematic review and meta-analysis. Lim G, et al. Int J Oral Maxillofac Implants. 2018 January/February;33(1):41–50.
3. Complications in bone-grafting procedures: Classification and management. Sanz-Sánchez I, et al. Periodontol 2000. 2022 Feb;88(1):86-102
4. Clinical safety of a new synthetic resorbable dental membrane: a case series study. Hélène Martin-Thomé et al. J Oral Implantol 2018 Apr;44(2):138-145.
5. The effect of membrane exposure on lateral ridge augmentation: a case-controlled study. Mehmet A Eskan et al.Int J Implant Dent 2017 Dec;3(1):26.
6. Clinical study of guided bone regeneration with resorbable polylactide-co-glycolide membrane. Takako Kawasaki et al. Odontology 2018 Jul;106(3):334-339.
7. Alveolar bone ridge augmentation using polymeric membranes: a systematic review and meta-analysis. Toledano-Osorio M, et al. Polymers (Basel). 2021 Apr 6;13(7):1172
8. Healing complications and their detrimental effects on bone gain in vertical-guided bone regeneration: A systematic review and meta-analysis. Tay JRH, et al. Clin Implant Dent Relat Res. 2022 Feb;24(1):43-71.
9. Flap advancement: Practical techniques to attain tension-free primary closure. Greenstein, G. et al. J. Periodontol. 2009, 80, 4–15.